OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 890

RIN 3206–AO29

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[TD 9955]

RIN 1545–BQ05

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Parts 2510 and 2590

RIN 1210–AC00

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 147 and 149

[CMS–9908–IFC]

RIN 0938–AU62

Requirements Related to Surprise Billing; Part II

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

ACTION: Interim final rules with request for comments.

SUMMARY: This document sets forth interim final rules implementing certain provisions of the No Surprises Act, which was enacted as part of the Consolidated Appropriations Act, 2021. These interim final rules implement provisions of the No Surprises Act that provide for a Federal independent dispute resolution (IDR) (Federal IDR) process to permit group health plans and health insurance issuers offering group or individual health insurance coverage and nonparticipating providers, facilities, and providers of air ambulance services to determine the out-of-network rate for items and services that are emergency services, nonemergency services furnished by nonparticipating providers at participating facilities, and air ambulance services furnished by nonparticipating providers of air ambulance services, under certain circumstances. The Department of Health and Human Services (HHS), the Department of Labor (DOL), and the Department of the Treasury (collectively, the Departments) are issuing these interim final rules with largely parallel provisions that apply to group health plans and health insurance issuers offering group or individual health insurance coverage and certified IDR entities, providers, facilities, and providers of air ambulance services. In addition to the interim final rules issued jointly by the Departments, this document also includes interim final rules issued by the Office of Personnel Management (OPM) to clarify how certain No Surprises Act provisions apply to health benefits plans offered by carriers under the Federal Employees Health Benefits (FEHB) Act. In addition to the interim final rules issued jointly by the Departments and OPM, this document includes interim final rules issued by HHS that address good faith estimates of health care items and services for uninsured or self-pay individuals and the associated patient-provider dispute resolution process. The HHS-only interim final rules apply to selected dispute resolution (SDR) entities, providers, facilities, and providers of air ambulance services.

DATES:

Effective date: These regulations are effective on October 7, 2021.

Applicability date: Except as otherwise specified in this paragraph, the regulations issued jointly by the Departments of HHS, Labor, and the Treasury are generally applicable for plan or policy years beginning on or after January 1, 2022. The regulations regarding certification of IDR entities at 26 CFR 54.9816–8T(a) and (e), 29 CFR 2590.716–8(a) and (e), and 45 CFR 149.510(a) and (e) are applicable beginning on October 7, 2021. The OPM-only regulations that apply to health benefits plans are applicable to contract years beginning on or after January 1, 2022. The regulations issued by HHS alone that apply to health care providers, facilities, providers of air ambulance services, and SDR entities are applicable beginning on January 1, 2022, except that the regulations at 45 CFR 149.620(a) and (d) are applicable beginning on October 7, 2021.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on December 6, 2021.

ADDRESSES: Written comments may be submitted to the addresses specified below. Any comment that is submitted will be shared among the Departments. Please do not submit duplicates.

Comments will be made available to the public. Warning: Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. Comments are posted on the internet exactly as received and can be retrieved by most internet search engines. No deletions, modifications, or redactions will be made to the comments received, as they are public records. Comments may be submitted anonymously.

In commenting, refer to file code RIN 1210–AB00. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

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

2. *By mail.* You may mail written comments to the following address ONLY: Office of Health Plan Standards and Compliance Assistance, Employee Benefits Security Administration, U.S. Department of Labor, 200 Constitution Avenue NW, Room N–5653, Washington, DC 20210, Attention: RIN 1210–AB00.

You may mail written comments regarding the HHS-only regulations to the following address: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention CMS–9908–IFC, P.O. Box 8010, Baltimore, MD 21244–8010. Attention: RIN 0938–AU62.

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

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

FOR FURTHER INFORMATION CONTACT: Padma Babubhai Shah, Office of Personnel Management, at 202–606–4056; Kari DiCecco, Internal Revenue Service, Department of the Treasury, at 202–317–5500; Elizabeth Schumacher or David Sydlik, Employee Benefits Security Administration, Department of Labor, at 202–693–8335; Deborah Bryant, Centers for Medicare & Medicaid Services, Department of Health and Human Services, at 301–492–4293.

Customer Service Information: Information from OPM on health benefits plans offered under the FEHB

Program can be found on the OPM website (*www.opm.gov/healthcare-insurance/healthcare/*).

Individuals interested in obtaining information from the DOL concerning employment-based health coverage laws may call the Employee Benefits Security Administration (EBSA) Toll-Free Hotline at 1–866–444–EBSA (3272) or visit the DOL's website (*www.dol.gov/agencies/ebsa*).

In addition, information from HHS on private health insurance coverage, coverage provided by non-Federal governmental group health plans, and requirements that apply to health care providers, health care facilities, and providers of air ambulance services can be found on the Centers for Medicare & Medicaid Services (CMS) website (*www.cms.gov/cciio*), and information on health care reform can be found at *www.HealthCare.gov.*

SUPPLEMENTARY INFORMATION:

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

I. Background

A. Preventing Surprise Medical Bills Under the Consolidated Appropriations Act, 2021

On December 27, 2020, the Consolidated Appropriations Act, 2021 (CAA), which includes the No Surprises Act, was enacted.[1] 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. Surprise billing occurs when an individual receives an unexpected medical bill from a health care provider or facility after receiving medical services from a provider or facility that, usually unknown to the participant, beneficiary, or enrollee, is a nonparticipating provider or facility with respect to the individual's coverage.

The No Surprises Act added new provisions applicable to group health plans and health insurance issuers offering group or individual health insurance coverage in Subchapter B of chapter 100 of the Internal Revenue Code (Code), Part 7 of the Employee Retirement Income Security Act (ERISA), and Part D of title XXVII of the Public Health Service Act (PHS Act). Section 102 of the No Surprises Act added Code section 9816, ERISA section 716, and PHS Act section 2799A–1,[2] which contain limitations on cost sharing and requirements regarding the timing of initial payments for emergency services furnished by nonparticipating providers and emergency facilities, and for nonemergency services furnished by nonparticipating providers at certain participating health care facilities. Section 103 of the No Surprises Act amended Code section 9816, ERISA section 716, and PHS Act section 2799A–1 to establish a Federal IDR process that allows plans and issuers and nonparticipating providers and facilities to resolve disputes regarding out-of-network rates. 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 the timing of initial payments for nonparticipating providers of air ambulance services and allow plans and issuers and providers of air ambulance services to access the Federal IDR process described in Code section 9816, ERISA section 716, and PHS Act section 2799A–1. The No Surprises Act provisions that apply to health care providers and facilities and providers of air ambulance services, such as prohibitions on balance billing for certain items and services and requirements related to disclosures about balance billing protections, were added to title XXVII of the PHS Act in a new part E.

On July 13, 2021, the Departments of the Treasury, Labor, and Health and Human Services (Departments) and the Office of Personnel Management (OPM) published interim final rules with request for comments titled, *Requirements Related to Surprise Billing; Part I,* which generally apply to group health plans and health insurance issuers offering group or individual health insurance coverage (including grandfathered health plans) with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022; to carriers in the FEHB Program with respect to contract years beginning on or after January 1, 2022; and to health care providers and facilities, and providers of air ambulance services beginning on January 1, 2022 (July 2021 interim final rules).[3] The July 2021 interim final rules implement Code sections 9816(a)–(b) and 9817(a), ERISA sections 716(a)–(b) and 717(a), and PHS Act sections 2799A–1(a)–(b), 2799A–2(a), 2799A–7, 2799B–1, 2799B–2, 2799B–3, and 2799B–5 to protect consumers from surprise medical bills for emergency services, nonemergency services furnished by nonparticipating providers at participating facilities in certain circumstances, and air ambulance services furnished by nonparticipating providers of air ambulance services. Among other requirements, the July 2021 interim final rules require plans and issuers that provide or cover any benefits with respect to services in an emergency department of a hospital or with respect to emergency services in an independent freestanding emergency department to cover emergency services without any prior authorization; without regard to whether the health care provider furnishing the emergency services is a participating provider or the services are provided in a participating emergency facility; and without regard to any other term or condition of the plan or coverage other than the exclusion or coordination of benefits or a permitted affiliation or waiting period. With respect to emergency services furnished by nonparticipating providers or facilities, nonemergency services furnished by nonparticipating providers at certain participating facilities, and air ambulance services furnished by nonparticipating providers of air ambulance services, the July 2021 interim final rules generally limit cost sharing for out-of-network services to in-network levels, require such cost sharing to count toward any in-network deductibles and out-of-pocket maximums, and prohibit balance billing.

The July 2021 interim final rules also specify that consumer cost-sharing amounts for emergency services furnished by nonparticipating providers or facilities, and for nonemergency services furnished by nonparticipating providers at certain participating facilities, must be calculated based on one of the following amounts: (1) An amount determined by an applicable All-Payer Model Agreement under

[1] Public Law 116–260 (December 27, 2020).

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

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

Social Security Act section 1115A; (2) if there is no such applicable All-Payer Model Agreement, an amount determined by a specified state law; or (3) if there is no such applicable All-Payer Model Agreement or specified state law, the lesser of the billed charge or the plan's or issuer's median contracted rate, the latter referred to as the qualifying payment amount (QPA). Cost-sharing amounts for air ambulance services provided by nonparticipating providers of air ambulance services must meet the same standards as would apply if the services were provided by a participating provider of air ambulance services and must be calculated using the lesser of the billed charges or the QPA.

Under the July 2021 interim final rules, balance billing for services subject to the requirements in those interim final rules generally is prohibited.[4] In general, the protections in the July 2021 interim final rules that limit cost sharing and prohibit balance billing do not apply to certain post-stabilization services, or to certain nonemergency services performed by nonparticipating providers at participating health care facilities, if the provider makes certain disclosures to the participant, beneficiary, or enrollee, and obtains the individual's consent to waive balance billing protections. However, this exception to the prohibition on balance billing is narrow. In particular, it is not available in certain circumstances where surprise bills are likely to occur, such as for ancillary services provided by nonparticipating providers in connection with nonemergency care in a participating health care facility. The July 2021 interim final rules also include a number of other specific requirements regarding notice and consent that must be met in order for a provider or facility to be permitted to balance bill a participant, beneficiary, or enrollee for items and services that would otherwise be subject to the prohibition on balance billing.

The Departments are issuing regulations in several phases implementing provisions of title I (No Surprises Act) and title II (Transparency) of Division BB of the CAA. These interim final rules build upon the protections in the July 2021 interim final rules and implement the Federal IDR provisions under Code sections 9816(c) and 9817(b), ERISA sections 716(c) and 717(b), and PHS Act sections 2799A–1(c) and 2799A–2(b). OPM is also issuing regulations in phases to implement 5 U.S.C. 8902(p).

The Departments and OPM also published a notice of proposed rulemaking on September 16, 2021, titled *Requirements Related to Air Ambulance Services, Agent and Broker Disclosures, and Provider Enforcement.*[5] The proposed rule would, if finalized, implement reporting requirements for air ambulance claims data; requirements on health insurance issuers offering individual health insurance coverage or short term, limited-duration insurance to disclose and report information regarding direct or indirect compensation provided to agents and brokers (section 202(c) of title II of Division BB of the CAA); as well as provisions related to HHS enforcement of requirements on issuers, non-Federal governmental group health plans, providers, facilities, and providers of air ambulance services. Later this year, the Departments intend to undertake rulemaking to implement reporting requirements related to pharmacy benefits and prescription drug costs (section 204 of title II of Division BB of the CAA).

The provisions of the No Surprises Act that are applicable to group health plans and health insurance issuers offering group or individual health insurance coverage in the Code, ERISA, and the PHS Act apply to grandfathered health plans. Section 1251 of the Affordable Care Act provides that grandfathered health plans are not subject to certain provisions of the Code, ERISA, and the PHS Act, as added by the Affordable Care Act, for as long as they maintain their status as grandfathered health plans.[6] For example, grandfathered health plans are neither subject to the requirement to cover certain preventive services without cost sharing under PHS Act section 2713 nor to the annual limitation on cost sharing set forth under PHS Act section 2707(b). If a plan or coverage were to relinquish its grandfathered status, it would be required to comply with both provisions, in addition to several other requirements. However, the CAA does not include an exception for grandfathered health plans that is comparable to section 1251 of the Affordable Care Act. Furthermore, section 102(d)(2) of the No Surprises Act amended section 1251(a) of the Affordable Care Act to clarify that the new and recodified patient protections provisions of the No Surprises Act, including those related to choice of health care professional, apply to grandfathered health plans. Therefore, not only do the provisions of these interim final rules and the provisions of the July 2021 interim final rules that apply to group health plans and issuers of group or individual health insurance coverage apply to grandfathered plans, so do the other provisions applicable to group health plans and issuers of group or individual health insurance coverage in titles I and II of Division BB of the CAA.

B. PHS Act Section 2719 and Scope of Claims Eligible for External Review

PHS Act section 2719, as added by the Affordable Care Act, applies to group health plans that are not grandfathered health plans and health insurance issuers offering non-grandfathered coverage in the group and individual markets, and sets forth standards for plans and issuers regarding both internal claims and appeals and external review. With respect to external review, PHS Act section 2719 provides for both state external review processes and a Federal external review process that applies in the absence of an applicable state process that meets the requirements of section 2719. Non-grandfathered group health plans that are not self-insured plans (as self-insured plans are not subject to state insurance regulations) and health insurance issuers offering non-grandfathered group or individual health insurance coverage must comply with an applicable state external review process if that process includes, at a minimum, the consumer protections set forth in the Uniform Health Carrier External Review Model Act issued by the National Association of Insurance Commissioners (the NAIC Uniform Model Act). If a state's external review process does not meet the minimum consumer protection standards set forth in the NAIC Uniform Model Act (or if a plan is self-insured and not subject to state insurance regulation), group health plans and health insurance issuers in the group and individual markets in that state are required to implement an effective external review process that meets minimum standards established by the Departments through rulemaking.

The Departments issued interim final regulations to implement PHS Act section 2719, including the provisions related to external review, in 2010.[7] An

[4] 45 CFR 149.410(a), 149.420(a) and 149.440(a).

[5] 86 FR 51730 (Sept. 16, 2021).

[6] For a list of the market reform provisions applicable to grandfathered health plans under title XXVII of the PHS Act that the Affordable Care Act added or amended and that were incorporated into ERISA and the Code, visit *https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/affordable-care-act/for-employers-and-advisers/grandfathered-health-plans-provisions-summary-chart.pdf.*

[7] 75 FR 43329 (July 23, 2010).

amendment to the interim final rules was issued in 2011.[8] In 2015, the Departments issued final rules to finalize the interim final regulations.[9] Among other things, the 2015 final rules address the scope of claims eligible for external review.[10] State external review processes that meet the minimum standards must provide for the external review of adverse benefit determinations that are based on requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit. The Federal external review process must be available for any adverse benefit determination by a plan or issuer that involves medical judgment, as well as rescissions. Section 110 of the No Surprises Act directs the Departments, in applying section 2719(b) of the PHS Act, to require the external review process to apply with respect to any adverse determination by a plan or issuer under Code section 9816 or 9817, ERISA section 716 or 717, or PHS Act section 2799A–1 or 2799A–2.

C. Protecting Uninsured Individuals Through Transparency and Patient-Provider Dispute Resolution

On July 9, 2021, President Biden signed Executive Order 14036, Promoting Competition in the American Economy in order to promote the interests of American workers, businesses, and consumers.[11] The executive order acknowledges that robust competition is critical to providing consumers with more choices, better service, and lower prices and directs the Secretary of HHS to support existing price transparency initiatives for hospitals, other providers, and insurers along with any new price transparency initiatives or changes made necessary by the No Surprises Act or any other statues. Consistent with Executive Order 14036, these interim final rules implement provisions of the No Surprises Act that will provide individuals with more pricing information prior to seeking care, allowing them to shop for the care that is best for them and increase competition in the health care market.

The No Surprises Act also adds a new Part E of title XXVII of the PHS Act establishing requirements applicable to health care providers, providers of air ambulance services, and health care facilities. Section 112 of the No Surprises Act adds PHS Act sections 2799B–6 and 2799B–7. PHS Act section 2799B–6 requires providers and facilities to furnish a good faith estimate of expected charges upon request or upon scheduling an item or service. Providers and facilities are required to inquire if an individual is enrolled in a group health plan, group or individual health insurance coverage, an FEHB plan,[12] or a Federal health care program, and, if enrolled in a group health plan, or group or individual health insurance coverage, or a health benefits plan under chapter 89 of title 5,[13] whether the individual is seeking to have a claim for such item or service submitted to such plan or coverage. In the case that the individual is enrolled in such a plan or coverage (and is seeking to have a claim for such an item or services submitted to such plan or coverage), PHS Act section 2799B–6(2)(A) requires that the provider or facility furnish the good faith estimate to the individual's plan or issuer of such coverage to inform the advanced explanation of benefits that plans and issuers are required to provide a participant, beneficiary, enrollee, or FEHB covered individual under Code section 9816(f), ERISA section 716(f), PHS Act section 2799A–1(f), and 5 U.S.C. 8902(p). In the case that the individual requesting a good faith estimate for an item or service or seeking to schedule an item or service to be furnished who is not enrolled in a plan or coverage, or is not seeking to file a claim with such plan or coverage (self-pay), PHS Act section 2799B–6(2)(B) and these interim final rules at 45 CFR 149.610 require providers and facilities to furnish the good faith estimate to the individual.

These interim final rules do not include requirements regarding PHS Act section 2799B–6(2)(A), which require providers and facilities to furnish good faith estimates to plans or issuers. Under Code section 9816(f), ERISA section 716(f), and PHS Act section 2799A–1(f) and 5 U.S.C. 8902(p), plans and issuers are required to include the good faith estimates in an advanced explanation of benefits provided to participants, beneficiaries, enrollees, and FEHB covered individuals. As stated in the August 20, 2021, FAQs issued by the Departments, the Departments have received feedback from the public about the challenges of developing the technical infrastructure necessary for providers and facilities to transmit to plans and issuers starting January 1, 2022, the good faith estimates required under PHS Act section 2799B–6, which plans and issuers must then include in the advanced explanation of benefits. Accordingly, until rulemaking to fully implement this requirement to provide such a good faith estimate to an individual's plan or coverage is adopted and applicable, HHS will defer enforcement of the requirement that providers and facilities provide good faith estimate information for individuals enrolled in a health plan or coverage and seeking to submit a claim for scheduled items or services to their plan or coverage. Additionally, stakeholders have requested that the Departments delay the applicability date of Code section 9816(f), ERISA section 716(f), and PHS Act section 2799A–1(f) until the Departments have established standards for the data transfer between providers and facilities and plans and issuers and have given enough time for plans and issuers and providers and facilities to build the infrastructure necessary to support the transfers. The Departments agree that compliance with this section is likely not possible by January 1, 2022, and therefore intend to undertake notice and comment rulemaking in the future to implement this provision, including establishing appropriate data transfer standards. Until such time, the Departments will defer enforcement of the requirement that plans and issuers must provide an advanced explanation of benefits. HHS will consider whether additional interim solutions for insured consumers are feasible. The Departments note that any rulemaking to fully implement Code section 9816(f), ERISA section 716(f), and PHS Act sections 2799A–1(f) and 2799B–6(2)(A) will include a prospective applicability date that provides plans, issuers, providers, and facilities with a reasonable amount of time to comply with new requirements. HHS encourages states that are primary enforcers of these requirements with regard to providers and issuers to take a similar enforcement approach, and

[8] 76 FR 37207 (June 10, 2011).

[9] 80 FR 72191 (Nov. 18, 2015).

[10] 26 CFR 54.9815–2719(d)(1); 29 CFR 2590.715–2719(d)(1); 45 CFR 147.136(d)(1).

[11] 86 FR 36987 (Jul 9, 2021).

[12] HHS interprets the requirements described in PHS Act section 2799B–6 to apply with respect to FEHB covered individuals as they would to other individuals enrolled in a group health plan, group or individual health insurance coverage offered by a health insurance issuer. Although PHS Act section 2799B–6 does not reference health benefits plans under chapter 89 of title 5, the definition of ''uninsured individual'' at PHS Act section 2799B–7 does include individuals who do not have benefits under these health benefits plans, and these sections work together to provide protections for the uninsured (or self-pay) population. Moreover, the requirement for the provision of an advance explanation of benefits required by Code section 9816(f), ERISA section 716(f), and PHS Act section 2799A–(1)(f), as well as 5 U.S.C. 8902(p) cannot be accomplished by a FEHB carrier unless it receives a good faith estimate from a provider in accordance with PHS Act section 2799B–6(2)(A).

[13] A health benefits plan offered under chapter 89 of title 5, United States Code is also known as an FEHB plan.

will not determine that a state is failing to substantially enforce these requirements if it takes such an approach.

Nonetheless, providers and facilities will be subject to enforcement action for failure to provide a good faith estimate to individuals not enrolled in a plan or coverage, or not seeking to have a claim for such item or services submitted to such plan or issuer of such coverage, as specified under these interim final rules. HHS seeks comment on this approach.

On November 12, 2020, the Departments issued the Transparency in Coverage final rules,[14] which require group health plans and health insurance issuers of group or individual health insurance coverage to make price comparison information available to participants, beneficiaries, and enrollees through an internet-based self-service tool and in paper form, upon request. This information must be available for plan years—or in the individual market, for policy years—beginning on or after January 1, 2023 with respect to 500 specified items and services, and with respect to all covered items and services, for plan or policy years beginning on or after January 1, 2024. The Departments are of the view that the disclosure requirements to participants, beneficiaries, and enrollees under the Transparency in Coverage final rules, and those required under Code section 9816(f), ERISA section 716(f), and PHS Act section 2799A–1(f), are substantially similar and therefore the Departments seek comment on whether there are ways to leverage the Transparency in Coverage requirements, including whether there are ways for plans and issuers to provide the information required in the Transparency in Coverage final rules to participants, beneficiaries, and enrollees during plan or policy years beginning in 2022. The Departments also seek comment on whether it would be feasible for providers and facilities to provide an estimate or range of estimated costs for insured consumers upon request for 2022.

Section 112 of the No Surprises Act also adds PHS Act section 2799B–7, which directs the Secretary of HHS to establish a process under which uninsured (or self-pay) individuals can avail themselves of a patient-provider dispute resolution process if their billed charges after receiving an item or service are substantially in excess of the expected charges listed in the good faith estimate furnished by the provider or facility, pursuant to PHS Act section 2799B–6. Under PHS Act section 2799B–7, an uninsured (or self-pay) individual means, with respect to an item or service, an individual who does not have benefits for such item or service under a group health plan, group or individual health insurance coverage offered by a health insurance issuer, Federal health care program (as defined in section 1128B(f) of the Social Security Act), or a health benefits plan under chapter 89 of title 5, United States Code (or an individual who has benefits for such item or service under a group health plan or individual or group health insurance coverage offered by a health insurance issuer, but does not seek to have a claim for such item or service submitted to such plan or coverage).

II. Executive Summary

A. Departments of the Treasury, Labor, and HHS: Federal IDR Process and External Review

In order to implement the Federal IDR provisions under Code sections 9816(c) and 9817(b), ERISA sections 716(c) and 717(b), and PHS Act sections 2799A–1(c) and 2799A–2(b), as added by sections 103 and 105 of the No Surprises Act, these interim final rules establish a Federal IDR process that nonparticipating providers or facilities, nonparticipating providers of air ambulance services, 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, and air ambulance services furnished by nonparticipating providers of air ambulance services where an All-Payer Model Agreement or specified state law does not apply.

Under Code sections 9816(c)(1)(A) and 9817(b)(1)(A), ERISA sections 716(c)(1)(A) and 717(b)(1)(A), PHS Act sections 2799A–1(c)(1)(A) and 2799A–2(b)(1)(A), and these interim final rules, upon receiving an initial payment or notice of denial of payment from a plan or issuer with respect to such items or services, such provider or facility or provider of air ambulance services (as applicable) or plan or issuer (as applicable) may initiate an open negotiation period within 30 business days beginning on the date the provider or facility receives the initial payment or notice of denial of payment. The open negotiation period may continue for up to 30 business days beginning on the date that either party first initiates the open negotiation period. The parties may discontinue the negotiation if they agree on an out-of-network rate before the last day of the 30-business-day open negotiation period. If the parties cannot agree on an out-of-network rate, they must exhaust the 30-business-day open negotiation period before initiating the Federal IDR process. Either party may initiate the Federal IDR process during the 4-business-day period beginning on the 31st business day after the start of the open negotiation period. The parties may select a certified IDR entity, or if the parties do not select a certified IDR entity, the Departments will do so. The No Surprises Act and these interim final rules specify that the certified IDR entity selected cannot be a party to the determination or an employee or agent of such a party, or have a material familial, financial, or professional relationship with such party.

In resolving the disputes through the Federal IDR process, the No Surprises Act and these interim final rules provide that each party must submit to the certified IDR entity an offer for a payment amount for the qualified IDR item or service in dispute and other information related to the offer as requested by the certified IDR entity within 10 business days of selection of the certified IDR entity and may submit additional information for the certified IDR entity to consider. In making a determination of which payment offer to select, these interim final rules specify that the certified IDR entity must begin with the presumption that the QPA is the appropriate out-of-network rate for the qualified IDR item or service under consideration. These interim final rules further provide that the certified IDR entity must select the offer closest to the QPA unless the certified IDR entity determines that credible information submitted by either party clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate, based on the additional factors set forth in Code sections 9816(c)(5)(C)(ii) and 9817(b)(5)(C)(ii), ERISA sections 716(c)(5)(C)(ii) and 717(b)(5)(C)(ii), and PHS Act sections 2799A–1(c)(5)(C)(ii) and 2799A–2(b)(5)(C)(ii). The certified IDR entity may not consider usual and customary charges, the amount that would have been billed (including billed charges that are directed to the plan or issuer) if the protections of 45 CFR 149.410,

[14] 26 CFR 54.9815–2715A2(b), 29 CFR 2590.715–2715A2(b), and 45 CFR 147.211(b).

149.420, or 149.440 [15] (as applicable) had not applied, or any public payor payment or reimbursement rates.[16] As discussed more fully in section III.D.4.ii. of this preamble, this approach is consistent with the No Surprises Act's emphasis on the QPA, both as the basis of the surprise billing protections also included in the statute and implemented by the July 2021 interim final rules and as the sole factor identified without any qualification by the statute.[17] The Departments are of the view that implementing the Federal IDR process in this manner encourages predictable outcomes, which will reduce the use of the Federal IDR process over time and the associated administrative fees born by the parties, while providing equitable and clear standards for when payment amounts may deviate from the QPA, as appropriate.

The No Surprises Act and these interim final rules also set forth requirements for certification of IDR entities by the Departments. To become certified IDR entities, IDR entities must provide written documentation demonstrating that they meet the eligibility criteria, including having sufficient expertise and staffing to conduct determinations on a timely basis, being free of conflicts of interest, being accredited by a nationally recognized and relevant accrediting body (such as URAC) or otherwise ensuring that IDR entity personnel possess the requisite training to conduct payment determinations (for example, providing documentation that personnel employed by the IDR entity have completed arbitration training by the American Arbitration Association (AAA), the American Health Law Association (AHLA), or a similar organization), ensuring policies and procedures are in place to maintain confidentiality of individually identifiable health information, providing a fixed fee for single determinations and a separate fee for batched determinations, having a procedure in place to retain certified IDR entity fees and retain and remit administrative fees, meeting appropriate indicators of fiscal integrity and stability, evidencing its ability to collect and transmit the information required to be reported to the Departments, and properly carrying out the requirements of the Federal IDR process in accordance with the law. These interim final rules also establish a process whereby members of the public, providers, facilities, providers of air ambulance services, plans, or issuers may petition for the denial or revocation of certification of an IDR entity. Finally, these interim final rules require the collection of information related to the Federal IDR process from certified IDR entities in order to allow the Departments to quarterly publish information on IDR payment determinations.

The Departments are also establishing a Federal IDR portal to administer the Federal IDR process. The Departments' Federal IDR portal will be available at *https://www.nsa-idr.cms.gov* and will be used throughout the Federal IDR process to maximize efficiency and reduce burden. As discussed throughout this preamble, the Federal IDR portal may be used to satisfy various requirements under these interim final rules, including provision of notices, Federal IDR initiation, submission of an application to be a certified IDR entity, as well as satisfying reporting requirements.

These interim final rules also amend final regulations issued by the Departments in 2015 related to external review in order to implement section 110 of the No Surprises Act. Section 110 requires that ''[i]n applying the provisions of section 2719(b) of the [PHS Act] to group health plans and health insurance issuers offering group or individual health insurance coverage, the Secretary of [HHS], Secretary of Labor, and Secretary of the Treasury, shall require, beginning not later than January 1, 2022, the external review process described in paragraph (1) of such section to apply with respect to any adverse determination by such a plan or issuer under Code section 9816 or 9817, ERISA section 716 or 717, or PHS Act section 2799A–1 or 2799A–2, including with respect to whether an item or service that is the subject to such a determination is an item or service to which such respective section applies.'' Accordingly, these interim final rules amend the final regulations regarding external review in two ways. First, the scope of adverse benefit determinations eligible for external review is amended to ensure that issues related to compliance with the specified provisions of the No Surprises Act fall within that scope. Several examples are also added to provide greater clarity to stakeholders regarding the expanded scope. Second, applicability provisions are amended to require that grandfathered health plans, which generally are exempt from requirements related to external review, must nonetheless provide for external review of adverse benefit determinations for claims subject to the cost-sharing and surprise billing protections in the No Surprises Act. The Departments seek comment on all aspects of these interim final rules.

B. Office of Personnel Management: Federal IDR Process for FEHB Carriers

The OPM interim final rules amend existing 5 CFR 890.114(a) to include references to the Treasury, DOL, and 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 FEHB 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 FEHB 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 FEHB carrier notice to the OPM Director (herein, the Director) of an FEHB carrier's notice of initiation, or receipt of a provider's notice of initiation, of the Federal IDR process. The Director will coordinate with the Departments in matters regarding FEHB

[15] The July 2021 interim final rules prohibit nonparticipating emergency facilities and nonparticipating providers furnishing emergency services from billing participants, beneficiaries, or enrollees for payment amounts that exceed the cost-sharing requirement for those items or services. The July 2021 interim final rules also generally prohibit nonparticipating providers furnishing nonemergency items and services at participating facilities from balance billing participants, beneficiaries, or enrollees for those items or services. In addition, the July 2021 interim final rules prohibit nonparticipating providers of air ambulance services furnishing air ambulance services for which benefits are available under a group health plan or group or individual health insurance coverage from balance billing participants, beneficiaries, or enrollees for those items or services.

[16] Public payor payment and reimbursement rates include reimbursement rates under the Medicare program under title XVIII of the Social Security Act, under the Medicaid program under title XIX of such Act, under the Children's Health Insurance Program under title XXI of such Act, under the TRICARE program under chapter 55 of title 10, United States Code, and under chapter 17 of title 38, United States Code.

[17] The No Surprises Act limits the certified IDR entity's consideration of additional factors by prohibiting the certified IDR entity from considering certain other factors, such as usual and customary charges and billed charges, in making a payment determination.

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 rules, 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.

C. Department of HHS: Protections for the Uninsured

To ensure that uninsured (or self-pay) individuals are also afforded protections against surprise health care costs, the No Surprises Act includes provisions that require providers and facilities to furnish good faith estimates to uninsured (or self-pay) individuals upon their request and at the time of scheduling the item or service. In order to implement these provisions under PHS Act sections 2799B–6(1) and 2799B–6(2)(B), HHS is adding 45 CFR 149.610 to establish requirements for providers and facilities to specifically inquire about an individual's health coverage status and requirements for providing a good faith estimate to uninsured (or self-pay) individuals. These interim final rules define uninsured (or self-pay) individuals to include those who do not have benefits for an item or service under a group health plan, group or individual health insurance coverage offered by a health insurance issuer, a Federal health care program (as defined in section 1128B(f) of the Social Security Act), or a health benefits plan under chapter 89 of title 5, United States Code, or an individual who has benefits for such item or service under a group health plan or individual or group health insurance coverage offered by a health insurance issuer, but who does not seek to have a claim for such item or service submitted to such plan or coverage. PHS Act section 2799B–6, added by section 112 of the No Surprises Act, does not specifically define a Federal health care program and also does not reference health benefits plans under chapter 89 of title 5. However, PHS Act section 2799B–7, which was also added by section 112 of the No Surprises Act, and which provides protections related to the good faith estimate required under PHS Act section 2799B–6, defines an uninsured individual to include individuals not enrolled in a Federal health care program (as defined in section 1128B(f) of the Social Security Act) and individuals not enrolled in health benefits plans under chapter 89 of title 5. To align these two related sections, HHS is adopting the definition of an uninsured (or self-pay) individual at PHS Act section 2799B–7 for the purposes of the interim final rules at 45 CFR 149.610 which implements PHS Act section 2799B–6(1) and 2799B–6(2)(B) and 45 CFR 149.620 which implements PHS Act section 2799B–7.

The definition of uninsured (or self-pay) individuals in these interim final rules includes individuals enrolled in individual or group health insurance coverage offered by a health insurance issuer, or a health benefits plan under chapter 89 of title 5, but not seeking to have a claim for such item or service submitted to such plan or coverage. These individuals are often referred to as self-pay individuals, therefore these interim final rules include the term self-pay when discussing uninsured individuals.

Under PHS Act section 2791(b)(5), short-term, limited-duration insurance is excluded from the definition of individual health insurance coverage. Therefore, for purposes of 45 CFR 149.610 and 45 CFR 149.620, uninsured (or self-pay) individuals include individuals who are enrolled in short-term, limited-duration insurance and not also enrolled in a group health plan, group or individual health insurance coverage offered by a health insurance issuer, Federal health care program (as defined in section 1128B(f) of the Social Security Act), or a health benefits plan under chapter 89 of title 5, United States Code. Thus, providers and facilities will be required to provide to such individuals a good faith estimate and such individuals will be able to avail themselves of the patient-provider dispute resolution process, where applicable.

PHS Act section 2799B–6(2) and these interim final rules specify that a provider or facility must provide a notification (in clear and understandable language) of the good faith estimate of the expected charges for furnishing the items or services listed on the good faith estimate (including any items or services that are reasonably expected to be provided in conjunction with such scheduled or requested items or services and such items or services reasonably expected to be so provided by another health care provider or health care facility), with the expected billing and diagnostic codes for any such items or services.

As discussed in section I.C. of this preamble, requirements to implement PHS Act section 2799B–6(2)(A) are not included in these interim final rules given the challenges of developing the technical infrastructure necessary to transmit such data from providers and facilities to plans and issuers. The requirements in these interim final rules apply only to good faith estimate notifications for uninsured (or self-pay) individuals as described in PHS Act section 2799B–6(2)(B) and in these interim final rules. HHS acknowledges that PHS Act section 2799B–6 also requires providers and facilities to make certain disclosures to an individual's plan or coverage if the individual is enrolled in such a plan or coverage and is seeking to have a claim for such items or services submitted to such plan or coverage. Specifically, section 2799B–6(2)(A) requires a provider or facility to provide such a plan or issuer notification of the good faith estimate of expected charges for furnishing an item or service on the same terms as provided to individuals.

Health care providers and health care facilities are required under PHS Act section 2799B–6 to furnish a notification of the good faith estimate of expected charges to an uninsured (or self-pay) individual who schedules an item or service, and to an individual who has not yet scheduled an item or service, but requests a good faith estimate. PHS Act section 2799B–6 requires providers and facilities to furnish a good faith estimate to an uninsured (or self-pay) individual who schedules an item or service at least 3 business days before the date such item or service is to be so furnished, not later than 1 business day after the date of such scheduling (or, in the case of such an item or service scheduled at least 10 business days before the date such item or service is to be so furnished (or if requested by the uninsured (or self-pay) individual), not later than 3 business days after the date of such scheduling or such request). As further discussed in section VI of this preamble, in instances where an uninsured (or self-pay) individual requests a good faith estimate of expected charges, but the item or service has not been scheduled, these interim final rules require that the treating provider furnish a good faith estimate to the uninsured (or self-pay) individual, within 3 business days of such request. For example, if an uninsured (or self-pay) individual schedules an item or service on Monday, January 3 to be provided on Thursday, January 6, the provider and facility must furnish a good faith estimate no later than Tuesday, January 4. If scheduling occurs on Monday, January 3 for items or services to be

provided on Thursday, January 13, the provider and facility must furnish a good faith estimate no later than Thursday, January 6. If an uninsured (or self-pay) individual requests a good faith estimate on Monday, January 3 for items or services not yet scheduled, the provider and facility must furnish the good faith estimate no later than Thursday, January 6.

These interim final rules include definitions relating to good faith estimates of expected charges for uninsured (or self-pay) individuals for scheduled items or services and upon request. These interim final rules also include requirements for providers and facilities regarding the contents of the good faith estimates and the manner in which good faith estimates must be provided.

PHS Act section 2799B–7 provides further protections for the uninsured (or self-pay) individual by requiring the Secretary of HHS to establish a process (in this section referred to as patient-provider dispute resolution) under which an uninsured (or self-pay) individual who received from a provider or facility a good faith estimate of the expected charges, and who, after being furnished the item or service, is billed an amount that is substantially in excess of the expected charges in the good faith estimate, may seek a determination from a certified dispute resolution entity of the amount to be paid to the provider or facility.

HHS is adding new 45 CFR 149.620 to implement this patient-provider dispute resolution process, including specific definitions related to the process. HHS is also codifying provisions related to eligibility for the patient-provider dispute resolution process, and selection of an SDR entity. HHS clarifies that while SDR entities provide a similar function and must meet similar requirements as certified IDR entities, SDR entities are specific to the patient-provider dispute resolution process. These interim final rules also codify requirements related to the determination of payment amounts by SDR entities, fees associated with the patient-provider dispute resolution process, certification of SDR entities, and deferral to state-established patient-provider dispute resolution processes that meet certain minimum Federal standards.

III. Overview of the Interim Final Rules Regarding the Federal Independent Dispute Resolution Process for Plans, Issuers, Providers, Facilities, and Providers of Air Ambulance Services—Departments of the Treasury, Labor, and HHS

A. Definitions

Code section 9816, ERISA section 716, and PHS Act sections 2799A–1 and 2799A–2 include defined terms that are specific to the law's requirements and implementation.[18] The definitions in 26 CFR 54.9816–3T, 29 CFR 2590.716–3, and 45 CFR 149.30 apply to these interim final rules; these interim final rules also define additional terms specific to the Federal IDR process. Under these interim final rules, ''batched items and services'' means multiple qualified IDR items or services that are considered jointly as part of one payment determination by a certified IDR entity for purposes of the Federal IDR process. For a qualified IDR item or service to be included as a batched item or service, the qualified IDR item or service must satisfy the criteria for batching set forth in 26 CFR 54.9816–8T(c)(3), 29 CFR 2590.716–8(c)(3), and 45 CFR 149.510(c)(3). ''Certified IDR entity'' means an entity responsible for conducting determinations under 26 CFR 54.9816–8T(c), 29 CFR 2590.716–8(c), and 45 CFR 149.510(c) that meets the certification criteria specified in 26 CFR 54.9816–8T(e), 29 CFR 2590.716–8(e), and 45 CFR 149.510(e) and that has been certified by the Departments. Separately, ''IDR entity'' means an entity that may apply or has applied for certification to conduct determinations under 26 CFR 54.9816–8T(c), 29 CFR 2590.716–8(c), and 45 CFR 149.510(c) and currently is not certified by the Departments pursuant to 26 CFR 54.9816–8T(e), 29 CFR 2590.716–8(e), and 45 CFR 149.510(e). If a certified IDR entity's certification has expired or has been revoked as a result of the process described in 26 CFR 54.9816–8T(e)(6), 29 CFR 2590.716–8(e)(6), and 45 CFR 149.510(e)(6), upon the date of the expiration or revocation, the formerly-certified IDR entity will be referred to as an IDR entity.

These interim final rules also define certain terms related to conflict-of-interest standards applicable to certified IDR entities. Stakeholders have emphasized the importance of ensuring a broad conflict-of-interest standard in order to avoid the risk of biased IDR payment determinations (or the appearance of biased IDR payment determinations). In general, a ''conflict of interest'' means, with respect to a party to a payment determination, a certified IDR entity, a material relationship, status, or condition of the party, or certified IDR entity that impacts the ability of a certified IDR entity to make an unbiased and impartial payment determination. For purposes of these interim final rules, a conflict of interest exists when a certified IDR entity is a group health plan; a health insurance issuer offering group health insurance coverage, individual health insurance coverage or short-term, limited-duration insurance; an FEHB carrier; or a provider, a facility,[19] or a provider of air ambulance services. While the statute does not specify that the IDR entity must not be a health insurance issuer offering short-term, limited-duration insurance, the Departments have determined that such entities should not be eligible for certification, due to their similarity to health insurance issuers offering group and individual health insurance coverage and their inherent interest as issuers in keeping reimbursement rates for providers, facilities, and providers of air ambulance services low. A conflict of interest also exists when a certified IDR entity is an affiliate or a subsidiary of a group health plan; a health insurance issuer offering group health insurance coverage, individual health insurance coverage or short-term, limited-duration insurance; an FEHB carrier; or provider, facility, or provider of air ambulance services. A conflict of interest also exists when a certified IDR

[18] To implement these interim final rules regarding the Federal IDR process under the PHS Act, HHS is amending 45 part CFR 149 by adding new Subparts F and G. Additionally, the Departments are amending 26 CFR 54.9816–1T and 54.9816–2T, 29 CFR 2590.716–1 and 2590.716–2 and 45 CFR 149.10 and 149.20 to expand the scope and applicability of this part to include IDR entities and the Federal IDR process. HHS is also amending 45 CFR 149.10 and 149.20 to expand the scope and applicability of this part to include SDR entities, the good faith estimate requirements, and patient-provider dispute resolution process.

[19] Similar to the July 2021 interim final rules, the term ''facility'' indicates a facility that furnishes health care services that is subject to the surprise billing protections of the No Surprises Act, such as a hospital (including a hospital's emergency department), urgent care center, or ambulatory surgical center. For purposes of good faith estimates under 45 CFR 149.610 and the Patient-Provider dispute resolution process in 45 CFR 149.620 ''facility'' includes an institution (such as a hospital or hospital outpatient department, critical access hospital, ambulatory surgical center, rural health center, federally qualified health center, laboratory, or imaging center) in any state in which state or applicable local law provides for the licensing of such an institution, that is licensed as such an institution pursuant to such law or is approved by the agency of such state or locality responsible for licensing such institution as meeting the standards established for such licensing.

entity is an affiliate or subsidiary of a professional or trade association representing group health plans; health insurance issuers offering group health insurance coverage, individual health insurance coverage or short-term, limited-duration insurance; FEHB carriers; or providers, facilities, or providers of air ambulance services. Additionally, a conflict of interest exists when a certified IDR entity has, or any personnel assigned to a determination have a material familial, financial, or professional relationship with a party to the payment determination being disputed, or with any officer, director, or management employee of the plan, issuer or carrier offering a health benefits plan under 5 U.S.C. 8902; the plan administrator, plan fiduciaries, or plan, issuer, or carrier's employees; the health care provider, the health care provider's group or practice association; the provider of air ambulance services, the provider of air ambulance services' group or practice association, or the facility that is a party to the dispute. The Departments are of the view that an officer, director, or management employee of the plan issuer, or carrier offering a health benefits plan under 5 U.S.C. 8902; the plan administrator, plan fiduciaries, or plan, issuer or carrier employees; the health care provider, the health care provider's group or practice association; the provider of air ambulance services, the provider of air ambulance services' group or practice association, or the facility that is a party to the dispute are individuals who could have significant involvement with the dispute. Relationships with these individuals could therefore improperly affect the certified IDR entities' ability to be impartial.

These interim final rules also define what constitutes a material familial relationship, a material financial relationship, or material professional relationship with a party to the payment determination. In developing these definitions, the Departments looked to states' conflict-of-interest standards for external review and arbitrations of surprise billing claims. These state standards typically use terms that are similar to those used in Code section 9816(c)(4)(F)(i)(II), ERISA section 716(c)(4)(F)(i)(II), and PHS Act section 2799A–1(c)(4)(F)(i)(II).[20] By adopting definitions that largely mirror these state standards, the Departments seek to ensure that the definitions are workable and increase the likelihood that IDR entities may be familiar with these standards, if they have performed services in these states. Accordingly, these interim final rules provide that the term ''material familial relationship'' means any relationship as a spouse, domestic partner, child, parent, sibling, spouse's or domestic partner's parent, spouse's or domestic partner's sibling, spouse's or domestic partner's child, child's parent, child's spouse or domestic partner, or sibling's spouse or domestic partner. ''Material financial relationship'' means any financial interest of more than five percent of total annual revenue or total annual income of a certified IDR entity or an officer, director, or manager thereof, or of a reviewer or reviewing physician employed or engaged by a certified IDR entity to conduct or participate in any payment determination under the Federal IDR process. Under the definition of ''material financial relationship,'' annual revenue and annual income do not include mediation fees received by mediators who are also arbitrators, provided that the mediator acts in the capacity of a mediator and does not represent a party in the mediation. Finally, with respect to terms related to the conflict-of-interest standards, ''material professional relationship'' means any physician-patient relationship, any partnership or employment relationship or affiliation, any shareholder or similar ownership interest in a professional corporation, partnership, or other similar entity, or any independent contractor arrangement that constitutes a material financial relationship with any expert used by the certified IDR entity or any officer or director of the certified IDR entity. The Departments solicit comment on whether the defined terms related to the conflict-of-interest standards should include threshold requirements to further define the level of relationship that would rise to the level of a conflict of interest.

Additionally, under these interim final rules, the Departments define certain terms related to confidentiality, information security, and privacy requirements that apply to an IDR entity seeking certification under these interim final rules. Code section 9816(c)(4)(A)(v), ERISA section 716(c)(4)(A)(v), and PHS Act section 2799A–1(c)(4)(A)(v) require certified IDR entities to maintain the confidentiality of individually identifiable health information (IIHI) obtained while making payment determinations and engaging in other activities related to the Federal IDR process. In establishing definitions for these terms, the Departments looked to existing Federal standards, particularly the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the Health Information Technology for Economic and Clinical Health (HITECH) Act, and the privacy, security, and breach notification standards under 45 CFR part 160 A and subparts A, C, D, and E of part 164, because the Departments are of the view that these provisions are industry standards. The Departments have modified these standards in some cases to fit the circumstances of IDR entities.

These interim final rules define ''Individually identifiable health information (IIHI)'' to mean any information, including demographic data, that relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and that identifies the individual; or with respect to which there is a reasonable basis to believe the information can be used to identify the individual.[21] Finally, these interim final rules define ''Unsecured IIHI'' to mean IIHI that is not rendered unusable, unreadable, or indecipherable to unauthorized persons through the use of a technology or methodology specified by the Departments. For technologies and methodologies approved for this purpose, certified IDR entities should refer to the HHS Guidance to Render Unsecured Protected Health Information Unusable, Unreadable, or Indecipherable to Unauthorized Individuals.[22]

These interim final rules provide that the term ''breach'' means the acquisition, access, use, or disclosure of IIHI in a manner not permitted under 26 CFR 54.9816–8T(e)(2)(v), 29 CFR 2590.716–8(e)(2)(v), and 45 CFR 149.510(e)(2)(v) that compromises the security or privacy of the IIHI. Under these interim final rules, a breach excludes any unintentional acquisition, access, or use of IIHI by personnel, including a contractor or subcontractor, acting under the authority of a certified IDR entity, if the acquisition, access, or use was made in good faith and within the scope of authority and does not result in further use or disclosure in a

[20] *See e.g.,* WAC 284–43A–010; N.Y. Comp. Codes R. & Regs. tit. 11 section 410.2.

[21] Note that this definition is broader than the definition of IIHI set forth in the Health Insurance Portability and Accountability Act (HIPAA) Rules at 45 CFR 160.103.

[22] HHS Office for Civil Rights, ''Guidance to Render Unsecured Protected Health Information Unusable, Unreadable, or Indecipherable to Unauthorized Individuals,'' available at *https://www.hhs.gov/guidance/document/guidance-render-unsecured-protected-health-information-unusable-unreadable-or.*

manner not permitted under 26 CFR 54.9816–8T(e)(2)(v), 29 CFR 2590.716–8(e)(2)(v), and 45 CFR 149.510(e)(2)(v). Also excluded is any inadvertent disclosure by a person who is authorized to access IIHI as personnel of a certified IDR entity to another person authorized to access IIHI as personnel of the same certified IDR entity (including a contractor or subcontractor of the certified IDR entity), and the information received as a result of such disclosure is not further used or disclosed in a manner not permitted under 26 CFR 54.9816–8T(e)(2)(v), 29 CFR 2590.716–8(e)(2)(v), and 45 CFR 149.510(e)(2)(v). Finally, also excluded is a disclosure of IIHI when a certified IDR entity has a good faith belief that an unauthorized person to whom the disclosure was made would not reasonably have been able to retain such information. For example, if, while conducting an IDR payment determination, a certified IDR entity sends paperwork containing IIHI to the wrong address and the paperwork is returned by the post office, unopened, as undeliverable, the certified IDR entity can conclude that the entity at the improper address could not reasonably have retained the information. The definition of breach additionally provides that an acquisition, access, use, or disclosure of IIHI in a manner not permitted under 26 CFR 54.9816–8T(e)(2)(v), 29 CFR 2590.716–8(e)(2)(v), and 45 CFR 149.510(e)(2)(v) is presumed to be a breach unless the certified IDR entity demonstrates that there is a low probability that the security or privacy of the IIHI has been compromised based on a risk assessment of at least the following factors: (1) The nature and extent of the IIHI involved, including the types of identifiers and the likelihood of re-identification; (2) the unauthorized person who used the IIHI or to whom the disclosure was made; (3) whether the IIHI was actually acquired or viewed; and (4) the extent to which the risk to the IIHI has been mitigated.

Additionally, ''qualified IDR item or service'' means an item or service that is either an emergency service furnished by a nonparticipating provider or nonparticipating emergency facility subject to the protections of 26 CFR 54.9816–4T, 29 CFR 2590.716–4, or 45 CFR 149.110, for which the conditions of 45 CFR 149.410(b) (regarding receipt of notice of surprise billing protections and providing consent to waive them) are not met. The term also means an item or service furnished by a nonparticipating provider at a participating health care facility subject to the requirements of 26 CFR 54.9816–5T, 29 CFR 2590.716–5, and 45 CFR 149.120, for which the conditions of 149.420(c)–(i) (regarding receipt of notice of surprise billing protections and providing consent to waive them) are not met, for which the provider or facility (as applicable) or plan or issuer submits a valid Notice of IDR Initiation initiating the Federal IDR process. For the Notice of IDR Initiation to be valid, the open negotiation period under 26 CFR 54.9816–8T(b)(1), 29 CFR 2590.716–8(b)(1), and 45 CFR 149.510(b)(1) must have lapsed, and an agreement on the payment amount must not have been reached. The term qualified IDR item or service includes air ambulance services provided by nonparticipating providers of air ambulance services subject to the protections of 26 CFR 54.9817–1T, 29 CFR 2590.717–1, and 45 CFR 149.130, as these services are defined in 26 CFR 54.9816–3T, 29 CFR 2590.716–3, and 45 CFR 149.30, for which the open negotiation period under 26 CFR 54.9816–8T(b)(1), 29 CFR 2590.716–8(b)(1), and 45 CFR 149.510(b)(1) has lapsed, and no agreement on the payment amount has been reached.

The term ''qualified IDR item or service'' does not include items and services for which the out-of-network rate is determined by an All-Payer Model Agreement under section 1115A of the Social Security Act, or by reference to a specified state law. Additionally, this term does not include items or services submitted by the initiating party that are subject to the 90-calendar-day suspension period under 26 CFR 54.9816–8T(c)(4)(vii)(B), 29 CFR 2590.716–8(c)(4)(vii)(B), and 45 CFR 149.510(c)(4)(vii)(B). However, the term may include items or services that are subject to the 90-calendar-day suspension period if they are submitted during the subsequent 30-business-day period, as allowed under these interim final rules. The Departments solicit comment on these definitions, including whether other terms should be defined.

B. The Term ''Days''

The No Surprises Act specifies a number of time periods that providers, facilities, providers of air ambulance services, plans, issuers, certified IDR entities, and the Departments must abide by throughout the course of the Federal IDR process, including time periods for initiation of the Federal IDR process, selection of a certified IDR entity, submission of documents, and payment determinations. The statute is largely silent on whether the term ''days'' used in these provisions means business days or calendar days. However, in certain provisions, the No Surprises Act specifies the use of calendar days or business days, indicating that where the statute is silent the Departments may choose either meaning. The Departments received feedback from stakeholders that meeting various deadlines under the Federal IDR process may be challenging (for example, depending on a certified IDR entity's case load or the number of claims that a provider or facility batches together) and that, if possible, additional time should be provided for the parties and the certified IDR entity to meet these deadlines. The Departments are of the view that in order to provide parties with the most time permitted under the statute to meet the various deadlines under the Federal IDR process as set forth in the No Surprises Act, business days should be used, unless there is a reason to use calendar days. For example, these interim final rules provide that calendar days are used for the timing requirement for the non-prevailing party to make payment after the certified IDR entity issues a written determination, as well as the requirement barring the initiation of the Federal IDR process for a payment dispute that concerns the same or similar qualified IDR item or service that was the subject of the initial notification during the 90-calendar-day period following the initial determination discussed later in this preamble. In these instances, the Departments are of the view that once a decision has been rendered, these interim final rules should not unduly delay the payment entitled under that decision. Moreover, in terms of the 90-day suspension period, the Departments are of the view that using a business day standard here has the potential to create an unnecessary barrier to accessing the Federal IDR process.

Furthermore, the Departments are of the view that using business days will avoid issues that may arise if deadlines were to fall on weekends or Federal holidays. Therefore, business days (Monday through Friday, not including Federal holidays) instead of calendar days are used throughout these interim final rules for the Federal IDR process unless otherwise indicated, regardless of whether a nonparticipating provider or facility, or a plan or issuer's business typically operates on weekend days.

C. Open Negotiation and Initiation of the Federal IDR Process

Code section 9816(c)(1)(A), ERISA section 716(c)(1)(A), PHS Act section 2799A–1(c)(1)(A), and these interim final rules provide that with respect to an emergency service, a nonemergency

item or service furnished by a nonparticipating provider at a participating facility subject to the surprise billing protections for which the notice and consent exceptions do not apply, and for which the out-of-network rate is not determined by reference to an All-Payer Model Agreement under section 1115A of the Social Security Act or specified state law as defined in 26 CFR 54.9816–3T, 29 CFR 2590.716–3, and 45 CFR 149.30, the provider or facility, or plan or issuer, may engage in open negotiations to determine the total out-of-network rate (including any cost sharing). If the parties fail to reach an agreement through open negotiation, they may initiate the Federal IDR process. Code section 9817(b), ERISA section 717(b), and PHS Act section 2799A–2(b) provide that out-of-network rates for air ambulance services may be determined through open negotiation or an IDR process that is largely identical to the process provided for in Code section 9816(c), ERISA section 716(c), and PHS Act section 2799A–1(c), provided the out-of-network rate is not determined by reference to an All-Payer Model Agreement under section 1115A of the Social Security Act or specified state law as defined in 26 CFR 54.9816–3T, 29 CFR 2590.716–3, and 45 CFR 149.30. Therefore, where applicable, providers of air ambulance services are included in the preamble and regulatory language text describing open negotiations and the Federal IDR process. The primary distinctions between air ambulance services and other health care services apply in how the certified IDR entity should select an offer and in the obligations on the certified IDR entity regarding reporting of information relating to the Federal IDR process.

1. Open Negotiation

The open negotiation period may be initiated by any party during the 30-business-day period beginning on the day the nonparticipating provider, facility, or nonparticipating provider of air ambulance services receives either an initial payment or a notice of denial of payment for an item or service.[23] If the provider, facility, or provider of air ambulance services accepts such initial payment as the total payment, that initial payment combined with the cost-sharing amount for the item or service is the out-of-network rate, as defined in 26 CFR 54.9816–3T, 29 CFR 2590.716–3, and 45 CFR 149.30. Under the July 2021 interim final rules, the plan or issuer must provide in writing, with each initial payment or notice of denial of payment, certain information, including a statement that if the provider, facility, or provider of air ambulance services, as applicable, wishes to initiate a 30-business-day open negotiation period for purposes of determining the out-of-network rate, the provider, facility, or provider of air ambulance services may contact the appropriate person or office to initiate open negotiation, and that if the 30-business-day open negotiation period does not result in an agreement on the out-of-network rate, generally, the provider, facility, or provider of air ambulance services may initiate the Federal IDR process. The plan or issuer must also provide contact information, including a telephone number and email address, for the appropriate person or office to initiate open negotiations for purposes of determining an amount of payment (including cost sharing) for the item or service.

In order for a plan, issuer, provider, facility, or provider of air ambulance services to know when it is a party to an open negotiation period and which items or services are subject to negotiation, these interim final rules require that the party initiating the open negotiation must provide written notice to the other party of its intent to negotiate, referred to as an open negotiation notice. 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. The open negotiation notice must be sent within 30 business days of the initial payment or notice of denial of payment from the plan or issuer regarding such item or service and must be provided in writing. The party sending the open negotiation notice may satisfy this requirement by providing the notice to the opposing party electronically (such as by email) if the following two conditions are satisfied: (1) The party sending the open negotiation notice has a good faith belief that the electronic method is readily accessible to the other party; and (2) the notice is provided in paper form free of charge upon request. For example, if a provider sends an open negotiation notice to the email address identified by the group health plan or issuer in the notice of denial or initial payment, such electronic delivery would satisfy this requirement (as long as the provider also sends the notice in paper form free of charge upon request). Similarly, if a provider, facility, or provider of air ambulance services submits a claim electronically, this could provide the plan or issuer with a good faith belief that the electronic method is readily accessible to the other party.

The 30-business-day open negotiation period begins on the day on which the open negotiation notice is first sent by a party. The Departments expect that most open negotiation notices will be sent electronically, and that, in general, the date the notice is sent will also be the date the notice is received. Furthermore, given that the parties have already made initial contact (namely that the provider or facility has transmitted a bill to the plan or issuer, and the plan or issuer has sent a notice of denial or initial payment to the provider or facility), the Departments anticipate that the parties should be able to provide effective notice without problems, and encourage the parties to take reasonable measures to ensure that actual notice is provided, such as confirming that the email address is accurate. The Departments caution that if the open negotiation notice is not properly provided to the other party (and no reasonable measures have been taken to ensure actual notice has been provided), the Departments may determine that the 30-business-day open negotiation period has not begun. In such case, any subsequent payment determination from a certified IDR entity may be unenforceable due to the failure of the party sending the open negotiation notice to meet the open negotiation requirement of these interim final rules. Therefore, the Departments encourage parties submitting open negotiation notices to take steps to confirm the other party's contact information and confirm receipt by the other party, through approaches such as read receipts, especially where a party does not initially respond to an open negotiation notice. The Departments solicit comment on whether there are any challenges or additional clarifications needed to ensure the parties are afforded the full open negotiation period, including whether there are any challenges regarding designating the date the notice is sent as the commencement date of the open negotiation period.

To facilitate communication between parties and compliance with this notice requirement, the Departments are concurrently issuing a standard notice

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

that the parties must use to satisfy the open negotiation notice requirement.

Negotiation during the open negotiation period will occur without the involvement of the Departments or a certified IDR entity. The Departments note that this requirement for a 30-business-day open negotiation period prior to initiating the Federal IDR process does not preclude the parties from reaching an agreement in fewer than 30 business days. However, in the event the parties do not reach an agreement, the parties must still exhaust the 30-business-day open negotiation period before either party may initiate the Federal IDR process. The Departments encourage parties to negotiate in good faith during this time period to reach an agreement on the out-of-network rate. To the extent parties reach agreement during this period, they can avoid the administrative costs associated with the Federal IDR process.

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

Code section 9816(c)(1)(B), ERISA section 716(c)(1)(B), PHS Act section 2799A–1(c)(1)(B), and these interim final rules provide that with respect to items or services that were subject to open negotiation, if the parties have not reached 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 during the 4-business-day period beginning on the 31st business day after the start of the open negotiation period. A party may not initiate the Federal IDR process if, with respect to an item or service, the party knows or reasonably should have known that the provider or facility provided notice and obtained consent from a participant, beneficiary, or enrollee to waive surprise billing protections consistent with PHS Act sections 2799B–1(a) and 2799B–2(a) and the implementing regulations at 45 CFR 149.410(b) and 149.420(c)–(i).

To initiate the Federal IDR process, the initiating party must submit a notice to the other party and to the Departments (Notice of IDR Initiation) through the Federal IDR portal. 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 initiating party's preferred certified IDR entity; (6) an attestation that the items or services are qualified IDR items and services within the scope of the Federal IDR process; (7) the QPA; (8) information about the QPA as described in 26 CFR 54.9816–6T(d), 29 CFR 2590.716–6(d), and 45 CFR 149.140(d); and (9) general information describing the Federal IDR process. This general information will help ensure that the non-initiating party is informed about the process and is familiar with the next steps. Such general information should include a description of the scope of the Federal IDR process and key deadlines in the Federal IDR process, including the dates to initiate the Federal IDR process, how to select a certified IDR entity, and the process for selecting an offer. The Departments have developed a form that parties must use to satisfy this requirement to provide general information describing the Federal IDR process.

As with the open negotiation notice, the initiating party may provide the Notice of IDR Initiation to the opposing party electronically (such as by email) if the following two conditions are satisfied: (1) The initiating party has a good faith belief that the electronic method is readily accessible by the other party; and (2) the notice is provided in paper form free of charge upon request.

In addition to furnishing notice to the non-initiating party, the initiating party must also furnish the Notice of IDR Initiation to the Departments on the same day the notice is furnished to the non-initiating party. The initiating party must provide its Notice of IDR Initiation through the Departments' Federal IDR portal. Moreover, IDR entities, certified IDR entities and disputing parties will be required to use the Federal IDR portal to perform certain functions related to the Federal IDR process. The Federal IDR portal will be used to facilitate and support IDR entity certification, the initiation of the Federal IDR process, the selection of certified IDR entities, the submission of supporting documentation to certified IDR entities, and the submission of certified IDR entity reporting metrics, as required by these interim final rules.

Under Code section 9816(c)(1)(B), ERISA section 716(c)(1)(B), and PHS Act section 2799A–1(c)(1)(B), the date of initiation of the Federal IDR process will be the date of the submission or such other date specified by the Departments that is not later than the date of receipt of the Notice of IDR Initiation by both the other party and the Departments. Consistent with the flexibility provided by the statute to specify an alternate date of initiation, these interim final rules specify that the initiation date of the Federal IDR process is the date of receipt of the Notice of IDR Initiation by the Departments. As noted, since the Departments will monitor the Federal IDR portal, submitting the Notice of IDR Initiation through the Federal IDR portal will provide a clear date on which the Notice of IDR Initiation has been received by the Departments. This approach will better enable the Departments to meet the statutory requirement to select a certified IDR entity within 6 business days of the initiation of the IDR process in instances in which the parties have not jointly selected a certified IDR entity. The Departments will acknowledge and confirm the initiation date with both parties upon receipt of the Notice of IDR Initiation. Given that the Departments expect most of these notices to be provided electronically, and that the parties will have been in continuous contact by this point in the process (through the submission of the initial bill, the remittance of the initial payment of the claim or notice of denial of payment, the submission of the open negotiation notice, and negotiations during the open negotiation period), the Departments expect minimal delay between when the Departments are notified through the portal and when the opposing party is notified (either by the initiating party or the Departments). The Departments solicit comment on both the content of the Notice of IDR Initiation as well as the manner for providing the notices as set forth under these interim final rules.

D. Federal IDR Process Following Initiation

1. Selection of Certified IDR Entity

Under Code section 9816(c)(4)(F), ERISA section 716(c)(4)(F), and PHS Act section 2799A–1(c)(4)(F), the plan or issuer and the nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services (as applicable) that are parties to the Federal IDR process may jointly select a certified IDR entity no later than 3 business days

following the date of the IDR initiation. As stated above, in initiating the Federal IDR process, the initiating party will indicate its preferred certified IDR entity in the Notice of IDR Initiation. Under these interim final rules, the party in receipt of the Notice of IDR Initiation may agree or object to the selection of the preferred certified IDR entity identified in the Notice of IDR Initiation. If the non-initiating party in receipt of the Notice of IDR Initiation fails to object within 3 business days of the date of initiation of the Federal IDR process, the preferred certified IDR entity identified in the Notice of IDR Initiation will be the selected certified IDR entity, provided that the certified IDR entity does not have a conflict of interest. If the party in receipt of the Notice of IDR Initiation timely objects, that party must timely notify the initiating party of the objection, including an explanation of the reason for objecting, and propose an alternative certified IDR entity. The initiating party must then agree or object to the alternative certified IDR entity. In order to jointly select a certified IDR entity, the plan or issuer and the nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services must agree on a certified IDR entity not later than 3 business days after the date of initiation of the Federal IDR process. Due to the short timeframe for this selection, the Departments anticipate that communication between the parties regarding certified IDR entity selection will typically be conducted through electronic mail to the email addresses used to send and receive the Notice of IDR Initiation. The Departments anticipate that most users of the Federal IDR process will be providers, facilities, providers of air ambulance services, plans, and issuers, which are likely to use electronic communications regularly. If both parties agree on and select a certified IDR entity, or fail to agree upon a certified IDR entity within the specified timeframe, the initiating party must notify the Departments by electronically submitting the notice of the certified IDR entity selection or failure to select (as applicable), no later than 1 business day after the end of the 3-business-day period (or in other words, 4 business days after the date of initiation of the Federal IDR process) through the Federal IDR portal. In addition, in instances where the non-initiating party believes that the Federal IDR process is not applicable, the non-initiating party must notify the Departments through the Federal IDR portal within the same timeframe that the notice of selection (or failure to select) is required and provide information regarding the lack of applicability. Based upon this information and any additional information requested by the selected certified IDR entity, the selected certified IDR entity will determine whether the Federal IDR process is applicable. The Departments seek comment on this approach and whether any challenges exist in relying solely upon electronic notifications.

The Departments will make available on the Federal IDR portal a list of certified IDR entities among which parties to the Federal IDR process may select, including basic information about the certified IDR entities, such as contact information, certified IDR entity numbers (unique identification numbers assigned to each certified IDR entity by the Departments), websites, and service areas. The Departments seek comment on this approach, including whether additional information about the certified IDR entities should be made public, and whether any challenges exist in relying solely upon electronic notifications.

Under these interim final rules, the selected certified IDR entity must not have a conflict of interest as defined in 26 CFR 54.9816–8T(a)(2), 29 CFR 2590.716–8(a)(2), and 45 CFR 149.510(a)(2). The selected certified IDR entity must also ensure that assignment of personnel to the dispute and decisions regarding hiring, compensation, termination, promotion, or other similar matters related to personnel assigned to the dispute are not made based upon the likelihood that the assigned personnel will support a particular party or type of party (that is, provider, facility, provider of air ambulance services, plan, or issuer) to the determination being disputed other than as outlined under 26 CFR 54.9816–8T(c)(4)(iii), 29 CFR 2590.716–8(c)(4)(iii), and 45 CFR 149.510(c)(4)(iii). Also, as agents of the certified IDR entity, personnel responsible for handling individual payment determinations must comply with the certification requirements of these interim final rules as set forth by their principal, the certified IDR entity, in its procedures. Therefore, the personnel assigned to disputes by the certified IDR entity must not have a conflict of interest, as defined by 26 CFR 54.9816–8T(a)(2), 29 CFR 2590.716–8(a)(2), and 45 CFR 149.510(a)(2). In addition, any personnel assigned to the matter must not have been a party to the determination being disputed or an employee or agent of such a party within the 1 year immediately preceding the dispute resolution assignment, similar to the ''revolving door'' laws [24] laid out in 18 U.S.C. 207(b), 207(c), and 207(e). Under 18 U.S.C. 207(b), 207(c), and 207(e), former officers or employees of the executive branch, including independent agencies, are prohibited from aiding or advising on matters with which they were involved while in the executive branch for 1 year. These interim final rules adopt the same 1-year timeframe by prohibiting former employees' or agents' involvement in dispute resolution processes involving former employers for 1 year. The Departments are of the view that this approach provides a reasonable and appropriate standard for preventing conflicts of interest. Although 18 U.S.C. 207(b), 207(c), and 207(e) are typically used in reference to trade or treaty negotiations, the 1-year prohibition is also a standard applied generally to employees of the executive and legislative branches and independent agencies. These statutes represent conflict-of-interest standards that the Departments view as reasonable and appropriate for developing standards for preventing conflicts of interest involving certified IDR entities that are resolving disputes in the Federal IDR process. Certified IDR entities are expected to ensure staff compliance with the standards of these interim final rules, and as such, attestations of no conflict of interest at the organization level are intended also to represent the absence of conflicts of interest among the employees and agents of the certified IDR entity.

The Departments anticipate that certified IDR entities will likely be limited to organizations with sufficient staff who have arbitration and health care claims experience, including entities currently providing services for external review or state IDR determinations. To further ensure that personnel assigned to any determination in the Federal IDR process do not have a conflict of interest, the Departments have included additional safeguards for personnel, as well as an additional requirement that the certified IDR entity have procedures in place to ensure adherence by personnel with these additional safeguards. Accordingly, at the time of application for certification, the IDR entity must attest that it has procedures in place to ensure that no conflicts of interest exist or will exist, as set forth in the discussion of

[24] Maskell, J., Post-Employment, ''Revolving Door,'' Laws for Federal Personnel. Congressional Research Service. 2014. *https://fas.org/sgp/crs/misc/R42728.pdf.*

certification requirements later in this preamble. As an additional requirement, certified IDR entities will have had to submit, as part of their application to be certified IDR entities, policies and procedures for conducting ongoing audits for conflicts of interest, to ensure that should any arise, the certified IDR entity procedures in place to inform the Departments of the conflict of interest and mitigate the risk by reassigning the dispute to other personnel in the event that any personnel previously assigned have a conflict of interest.

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 has not responded) that the selected certified IDR entity does not have a conflict of interest. The attestation must be submitted based on conducting a conflicts of interest check using information available (or accessible using reasonable means) to the parties (or the initiating party if the other party has not responded) at the time of the selection.

As stated earlier in this preamble, upon receipt of notification that the parties failed to agree on a certified IDR entity, the Departments will select a certified IDR entity. In such instances, the Departments will randomly select a certified IDR entity that charges a fee within the allowed range provided for in guidance and defined further in section III.D.4.viii of this preamble. If there are insufficient certified IDR entities that charge a fee within the allowed range available to adjudicate the payment determination, the Departments will randomly select a certified IDR entity that has received approval to charge a fee outside of the allowed range. The Departments will make the random selection not later than 6 business days after the date of initiation of the Federal IDR process, and will notify the parties of the selection. The Departments considered alternative approaches to randomly selecting a certified IDR entity, including whether the Departments should consider the specific fee of the certified IDR entity or look to other factors, such as how often the certified IDR entity chooses the amount closest to the QPA. Following consideration of various approaches, the Departments have chosen to utilize a random selection method to select a certified IDR entity that charges a fee within the allowed range (or has received approval from the Departments to charge a fee outside of the allowed range, if there are insufficient certified IDR entities that charge a fee within the allowed range available) and that does not have a conflict of interest with either party. The Departments are of the view that this approach will help ensure that requests for IDR and workload associated with making determinations for such requests are appropriately distributed across the certified IDR entities, will result in an efficient and timely assignment of a certified IDR entity to payment determinations, and will protect against bias in the types of cases a certified IDR entity reviews while encouraging certified IDR entities to charge reasonable fees for their services. Additionally, the Departments are of the view that this approach will provide predictability to the parties regarding the fees they will be expected to pay if they do not select the certified IDR entity. The Departments seek comment on this approach, including whether the random selection method should be limited only to certified IDR entities that charge a fee within the allowed range. The Departments may issue future guidance regarding whether entities that have received approval from the Departments to charge a fee outside of the allowed range may be selected by the Departments under the random selection method.

After selection by the parties (including when the initiating party selects a certified IDR entity and the other party does not object), or by the Departments, the certified IDR entity must also review its selection to ensure that it meets the requirements of 26 CFR 54.9816–8T(c)(1)(ii), 29 CFR 2590.716–8(c)(1)(ii), and 45 CFR 149.510(c)(1)(ii) related to potential conflicts of interest. If the selected certified IDR entity meets these requirements, the certified IDR entity must attest to meeting these requirements. If the certified IDR entity is unable to attest that it meets these requirements, the certified IDR entity must notify the Departments through the Federal IDR portal within 3 business days, after which the Departments will notify the parties. Upon notification, the parties will have 3 business days to select another certified IDR entity under the process described in 26 CFR 54.9816–8T(c)(1), 29 CFR 2590.716–8(c)(1), or 45 CFR 149.510(c)(1). If the parties notify the Departments that they have not agreed on a certified IDR entity, the Departments may randomly select another certified IDR entity.

The certified IDR entity must also review the information submitted by the parties to determine whether the Federal IDR process applies, including whether an All-Payer Model Agreement or specified state law applies. If the Federal IDR process does not apply, the certified IDR entity must notify the Departments and the parties within 3 business days of making this determination.

2. Authority To Continue Negotiation

Code sections 9816(c)(2)(B) and 9817(b)(2)(B), ERISA sections 716(c)(2)(B) and 717(b)(2)(B), PHS Act sections 2799A–1(c)(2)(B) and 2799A–2(b)(2)(B), and these interim final rules provide that, in instances in which the parties agree on an amount for a qualified IDR item or service after the Federal IDR process is initiated but prior to a determination by a certified IDR entity, the agreed-upon amount will be treated as the out-of-network rate and will be treated as resolving the dispute. If the parties to the Federal IDR process agree on an out-of-network rate for a qualified IDR item or service after providing to the Departments the Notice of IDR Initiation, but before the certified IDR entity has made its payment determination, the initiating party must notify the Departments and the certified IDR entity (if selected) by electronically submitting notification of such agreement through the Federal IDR portal as soon as possible but no later than 3 business days after the date of the agreement. As is the case in instances where the parties do not come to an agreement before the certified IDR entity selects the amount submitted by one of the parties, the amount by which this agreed-upon out-of-network rate exceeds the cost-sharing amount for the qualified IDR item or service is the total plan or coverage payment.[25] The plan or issuer must pay the balance of the total plan or coverage amount of the agreed-upon out-of-network rate (with any initial payment made counted towards the total plan or coverage payment) to the nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services not later than 30 business days after the agreement is reached. As noted in section III.D.4.viii of this preamble regarding costs of the Federal IDR process, when there is an agreement after initiation and a certified IDR entity is selected but prior to a determination by the certified IDR entity, each party must pay half of the certified IDR entity fee, unless the parties agree otherwise on a method for allocating the applicable fee. In no instance may either party seek

[25] *See* 26 CFR 54.9816–4T, 54.9816–5T, and 54.9817–1T; 29 CFR 2590.716–4, 2590.716–5, and 2590.717–1; and 45 CFR 149.110, 149.120, and 149.130.

additional payment from the participant or beneficiary, including in instances in which the out-of-network rate exceeds the QPA. When an agreement is reached, either before or after a certified IDR entity is selected, notification to the Departments 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.

3. Treatment of Batched Items and Services

Code section 9816(c)(3), ERISA section 716(c)(3), and PHS Act section 2799A–1(c)(3) direct the Departments to specify criteria under which multiple qualified IDR items and services may be considered jointly as part of one payment determination (batching). Under these interim final rules, multiple claims for qualified IDR items and services may be submitted and considered jointly as part of one payment determination by a certified IDR entity (batched items and services) only if certain conditions are met. Batched items and services submitted and considered jointly as part of one payment determination under 26 CFR 54.9816–8T(c)(3)(i), 29 CFR 2590.716–8(c)(3)(i), 45 CFR 149.510(c)(3)(i) are subject to the fee for batched determinations under these interim final rules.

First, the qualified IDR items and services must be billed by the same provider or group of providers or facility or same provider of air ambulance services. Items and services are billed by the same provider or group of providers or facility or same provider of air ambulance services if the items or services are billed with the same National Provider Identifier (NPI) or Taxpayer Identification Number (TIN).

Second, the payment for the items and services would be made by the same group health plan or health insurance issuer.

Third, the qualified IDR items and services must be the same or similar items or services. The definition of a same or similar item or service in these interim final rules is consistent with the definition under the July 2021 interim final rules. The Departments defined a same or similar item or service in 26 CFR 54.9816–6T(a)(13), 29 CFR 2590.716–6(a)(13), and 45 CFR 149.140(a)(13) as those items and services that are billed under the same service code, or a comparable code under a different procedural code system, and the Departments defined the service codes as the code that describes an item or service using Current Procedural Terminology (CPT), Healthcare Common Procedure Coding System (HCPCS), or Diagnosis-Related Group (DRG) codes.

Finally, all the qualified IDR items and services must have been furnished within the same 30-business-day period, or the 90-calendar-day suspension period described later in this preamble. Therefore, if items or services are furnished within the 90-calendar-day suspension period and meet the other applicable requirements, they may be submitted and considered jointly as part of one payment determination by a certified IDR entity, once the suspension period has ended. Under Code section 9816(c)(9), ERISA section 716(c)(9), and PHS Act section 2799A–1(c)(9), the Departments may provide an alternative period to the aforementioned 30-business-day period as determined by the Departments for certain circumstances, such as low-volume items and services. The Departments are using this authority to ensure that items and services delivered during the 90-calendar-day suspension period are eligible for the Federal IDR process and may be included in the same batch.

The Departments are of the view that the approach set forth to allow for batching of multiple qualified IDR items and services will avoid combinations of unrelated claims, providers, facilities, providers of air ambulance services and plans and issuers in a single dispute that could unnecessarily complicate an IDR payment determination and create inefficiencies in the Federal IDR process. The Departments solicit comment on this approach and whether there is a need to prescribe an alternative period for other qualified IDR items and services different from the 30-business-day period discussed earlier in the discussion of the batching requirements and what circumstances should be considered in defining any alternative period.

Additionally, in some cases, a plan or issuer may pay a provider, facility, or provider of air ambulance services a single payment for multiple services an individual received during an episode of care (bundling). In the case of qualified IDR items or services that are billed by a provider, facility, or provider of air ambulance services as part of a bundled arrangement, or where a plan or issuer makes an initial payment as a bundled payment (or specifies that a denial of payment is made on a bundled payment basis), these interim final rules provide that those qualified items or services may be submitted and considered as part of one payment determination by a certified IDR entity (and is subject to the fee for single determinations under 26 CFR 54.9816–8T(c)(3)(ii), 29 CFR 2590.716–8(c)(3)(ii), 45 CFR 149.510(c)(3)(ii)).

The Departments recognize that certain batched items and services may have different QPAs. For example, if a determination includes multiple batched claims for Service A furnished by Provider B to individuals covered by Issuer C, with some individuals covered by plans in the individual market and others covered by plans in the large group market, there likely would be two different QPAs for the certified IDR entity to consider—one QPA for the services furnished to individuals enrolled in individual market coverage, and one QPA for individuals with large group market coverage. As discussed elsewhere in this preamble, when this is the case, the parties must provide the relevant information for each QPA, and the certified IDR entity must consider each QPA for each item or service separately. However, since batched items and services involve the same or similar medical procedure, batching is likely to reduce redundant IDR proceedings as well as streamline the certified IDR entity's decision-making, as some of the considerations relate to factors not specific to the individual encounter.

The Departments seek comment on all aspects of the criteria for batching claims and bundling, including whether additional conditions should be added to limit batching or whether the conditions should be amended to facilitate broader batching of qualified IDR items and services. The Departments also seek comment on how frequently nonparticipating providers, nonparticipating emergency facilities, or nonparticipating providers of air ambulance services will be reimbursed through a bundled payment and whether allowing items or services included in a bundled payment by a provider or facility to be treated as one payment determination could be used to circumvent the batching requirements by not requiring precise consideration of what specific claims within the batch should be arbitrated and which claims should not, thereby resulting in potential overuse of the Federal IDR process in a manner that creates inefficiencies.

4. Payment Determination

i. Submission of Offers

Code section 9816(c)(5)(B), ERISA section 716(c)(5)(B), and PHS Act section 2799A–1(c)(5)(B) provide that, not later than 10 days after the date of selection of the certified IDR entity with respect to a determination for a

qualified IDR item or service, the plan or issuer and the nonparticipating provider, nonparticipating emergency facility, or provider of air ambulance services must each submit to the certified IDR entity an offer for a payment amount for such qualified IDR item or service. Under these interim final rules, the offer must be submitted not later than 10 business days after the selection of the certified IDR entity and must be expressed as both a dollar amount and the corresponding percentage of the QPA represented by that dollar amount, to facilitate the certified IDR entity reporting the offer as a percentage of the QPA to the Departments. Where batched items and services have different QPAs, the parties should provide these different QPAs and may provide different offers for these batched items and services, provided that the same offer should apply for all items and services with the same QPA.

Parties to the Federal IDR process must also submit information requested by the certified IDR entity relating to the offer. 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. Providers and facilities must also indicate the size of their practices and facilities at the time the information is submitted. This will enable certified IDR entities to report on the size of the provider practices and facilities, as required under 26 CFR 54.9816–8T(f)(1)(ii), 29 CFR 2590.716–8(f)(1)(ii), and 45 CFR 149.510(f)(1)(ii). Specifically, 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). Similarly, 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.[26] FEHB carriers must identify if a particular item or service relates to FEHB plans. The information such as practice or facility size, coverage area, geographic region, and whether a plan is fully-insured or partially or fully self-insured is required to be submitted as part of an offer so that the certified IDR entities can report this information to the Departments. This information will inform the reports required from the Departments under Code section 9816(c)(7), ERISA section 716(c)(7), and PHS Act section 2799A–1(c)(7). Both parties must submit any other information requested by the certified IDR entity relating to such offer. In addition, parties may submit any information relating to the offer, except that the information may not include information that relates to usual and customary charges, billed amounts, and public payor rates as discussed later in this preamble.

With regard to the number of employees of a provider or facility, the Departments understand that hospitals and facilities may use a variety of methods for staffing, such as through contracting with physicians' practices or foundations whose physicians or medical staff are not considered employees of the hospital or facility. The Departments seek comment on whether additional guidance is needed to account for these situations in the reporting of provider and facility size.

ii. Selection of Offer for Qualified IDR Items or Services That Are Not Air Ambulance Services

These interim final rules provide that, not later than 30 business days after the selection of the certified IDR entity, the certified IDR entity must select one of the offers submitted by the plan or issuer and the provider or facility to be the out-of-network rate for the qualified IDR item or service. For each qualified IDR item or service, the amount by which this out-of-network rate exceeds the cost-sharing amount for the qualified IDR item or service is the total plan or coverage payment (with any initial payment made counted towards the total plan or coverage payment). In selecting the offer, the certified IDR entity must presume that the QPA is an appropriate payment amount but must also consider the additional circumstances, following the requirements of 26 CFR 54.9816–8T(c)(4)(iii)(B) through (D), 29 CFR 2590.716–8(c)(4)(iii)(B) through (D), and 45 CFR 149.510(c)(4)(iii)(B) through (D), only if the information is submitted by the parties. However, to be considered by the certified IDR entity, information submitted by the parties must be credible and relate to the offer submitted by either party, and must not include information on the prohibited factors described in 26 CFR 54.9816–8T(c)(4)(v), 29 CFR 2590.716–8(c)(4)(v), or 45 CFR 149.510(c)(4)(v). After considering the QPA, additional information requested by the certified IDR entity from the parties, and all of the credible information that the parties submit that is consistent with the requirements in 26 CFR 54.9816–8T(c)(4)(i)(A), 29 CFR 2590.716–8(c)(4)(i)(A), or 45 CFR 149.510(c)(4)(i)(A), the certified IDR entity must select the offer closest to the QPA, unless the credible information submitted by the parties clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate, based on the additional circumstances allowed under 26 CFR 54.9816–8T(c)(4)(iii)(B) through (D), 29 CFR 2590.716–8(c)(4)(iii)(B) through (D), or 45 CFR 149.510(c)(4)(iii)(B) through (D) with respect to the qualified IDR item or service. In these cases, or when the offers are equally distant from the QPA but in opposing directions, the certified IDR entity must select the offer that the certified IDR entity determines best represents the value of the items or services, which could be either party's offer.

These interim final rules define information as credible if upon critical analysis the information is worthy of belief and is trustworthy. These interim final rules also specify that a material difference exists where there is substantial likelihood that a reasonable person with the training and qualifications of a certified IDR entity making a payment determination would consider the information important in determining the out of network rate and view the information as showing that the QPA is not the appropriate out-of-network rate under such additional circumstances.

If the certified IDR entity determines that credible information about additional circumstances clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate, the certified IDR entity must select the offer that the certified IDR entity determines best represents the appropriate out-of-network rate for the qualified IDR items or services, which could be either party's offer. Not later than 30 business days after the selection of the certified IDR entity, the certified IDR entity must also notify the plan or issuer and the provider or facility of the selection of the offer, and provide the written decision required under 26 CFR 54.9816–8T(c)(4)(vi), 29 CFR 2590.716–8(c)(4)(vi), and 45 CFR 149.510(c)(4)(vi).

[26] Pursuant to OPM contracts with FEHB carriers under 5 U.S.C. Ch. 89, all FEHB carriers offer fully insured health benefits plans in consideration of premium payments pursuant to contract terms, and no health benefits plan is self-insured by OPM or the federal government.

The Departments are of the view that the best interpretation of Code section 9816, ERISA section 716, and PHS Act section 2799A–1 is that when selecting an offer, a certified IDR entity must look first to the QPA, as it represents a reasonable market-based payment for relevant items and services, and then to other considerations. This presumption that the QPA is the appropriate out-of-network rate can be rebutted by presentation of credible information about additional circumstances, following the requirements of 26 CFR 54.9816–8T(c)(4)(iii)(B) through (D), 29 CFR 2590.716–8(c)(4)(iii)(B) through (D), and 45 CFR 149.510(c)(4)(iii)(B) through (D), that clearly demonstrate that the QPA is materially different from the appropriate out-of-network rate. The statutory text lists the QPA as the first factor that the certified IDR entity must consider in determining which offer to select. The ''additional circumstances'' that the certified IDR entity must consider if relevant, credible information is provided are described in a separate paragraph, and the certified IDR entity's consideration of additional circumstances is subject to a prohibition on considering certain factors. Additionally, whereas the statute provides relatively limited guidance on how to consider or define these additional circumstances, the statute sets out detailed rules for calculating the QPA, suggesting that an accurate and clear calculation of the QPA is integral to the application of consumer cost sharing and to the certified IDR entity's determination of the out-of-network rate. For example, the statute includes a requirement that when plans and issuers do not have sufficient information to calculate their own median contracted rates, they utilize a database free of conflicts of interest.[27] Plans and issuers must also provide specific information on how the QPA is calculated to nonparticipating providers and facilities, ensuring that they are aware of how this amount is calculated.[28] Plans and issuers are also subject to audit requirements that will be enforced by the Departments to ensure that they follow these rules.[29] Cost sharing for participants, beneficiaries, and enrollees for items and services will be based on the recognized amount, which will generally be the QPA for services eligible for the Federal IDR process, indicating that the QPA is a reasonable out-of-network rate. The Departments are also required to report how payment determinations compare to the corresponding QPA, reflecting that the QPA is a benchmark for determining the appropriate out-of-network rate.[30] Taken together, these statutory elements reflect the importance the No Surprises Act assigns to the QPA in the Federal IDR process, and show that the statute contemplates that typically the QPA will be a reasonable out-of-network rate.

The Departments are also of the view that policy considerations support the approach taken under these interim final rules regarding which offer a certified IDR entity must select. Generally, the QPA should reflect standard market rates arrived at through typical contract negotiations and should therefore be a reasonable out-of-network rate under most circumstances. The QPA is generally based on the median of contracted rates, and these contracted rates are established through arms-length negotiations between providers and facilities and plans and issuers (or their service providers). Anchoring the determination of the out-of-network rate to the QPA will increase the predictability of IDR outcomes, which may encourage parties to reach an agreement outside of the Federal IDR process to avoid the administrative costs, and will aid in reducing prices that may have been inflated due to the practice of surprise billing prior to the No Surprises Act. Finally, anchoring the determination to the QPA will help limit the indirect impact on participants, beneficiaries, and enrollees that would occur from higher out-of-network rates if plans and issuers were to pass higher costs on to individuals in the form of increases in premiums.

Accordingly, the certified IDR entity must begin with the presumption that the QPA is the appropriate out-of-network rate for the qualified IDR item or service under consideration. Therefore, in determining which offer to select, these interim final rules provide that the certified IDR entity must select the offer closest to the QPA, unless credible information presented by the parties rebuts that presumption and clearly demonstrates the QPA is materially different from the appropriate out-of-network rate, as discussed earlier in this section of the preamble.

The Departments clarify that it is not the role of the certified IDR entity to determine whether the QPA has been calculated by the plan or issuer correctly, to make determinations of medical necessity, or review denials of coverage.[31] Rather, the certified IDR entity is responsible for considering only the information presented by the parties to determine whether either party has presented credible information regarding additional circumstances, following the requirements set forth in paragraphs 26 CFR 54.9816–8T(c)(4)(iii)(B) through (D), 29 CFR 2590.716–8(c)(4)(iii)(B) through (D), and 45 CFR 149.510(c)(4)(iii)(B) through (D), demonstrating that the QPA is materially different from the appropriate out-of-network rate, in order to rebut the presumption that the QPA is the appropriate out-of-network rate. For batched items and services, the certified IDR entity may select different offers, from either or both parties, when the QPAs for the qualified IDR items or services within the batch are different. The certified IDR entity may do so even if it does not select the offer closest to the QPA for a particular qualified IDR item or service due to the factors listed later in this section of the preamble, and instead selects the offer closest to the QPA for other qualified IDR items and services within the batch.

In the Departments' view, the requirements set forth in these interim final rules regarding which offer a certified IDR entity must select, based on the presumption that the QPA is the appropriate payment amount and on the parties' ability to rebut that presumption, will help promote efficiency and predictability in the Federal IDR process, and will increase the likelihood that a certified IDR entity will generally select the offer closest to the QPA. While the QPA is the presumptive factor, the Departments are of the view that a clear standard indicating how a certified IDR entity may select an offer that is not closest to the QPA is necessary to help ensure consistency in how different certified IDR entities evaluate offers, which will help ensure that the Federal IDR process yields predictable outcomes and reduces administrative costs. Establishing a standard framework for certified IDR entities to evaluate factors furthers the intent of these interim final

[27] Code section 9816(a)(2), (3)(E); ERISA section 716(a)(2), (3)(E), and PHS Act section 2799A–1(a)(2), (3)(E); 26 CFR 54.9816–6T, 29 CFR 2590.716–6, and 45 CFR 149.140.

[28] *Id.*

[29] 86 FR 36872, 36899 (July 13, 2021).

[30] Code section 9816(c)(7)(A)(v), (B)(iii) and (iv); ERISA section 716(c)(7)(A)(v), (B)(iii) and (iv); and PHS Act section 2799A–1(c)(7)(A)(v), (B)(iii) and (iv).

[31] However, if either the certified IDR entity or one of the parties believes the QPA has not been calculated in accordance with the requirements in 26 CFR 54.9816–6T, 29 CFR 2590.716–6, or 45 CFR 149.140, the Departments encourage the certified IDR entity or the provider or facility to notify the applicable state or federal authority, or submit a complaint against the plan or issuer as set forth in 26 CFR 54.9816–7T, 29 CFR 2590.716–7, or 45 CFR 149.150, as applicable.

rules to create equity and consistency in the Federal IDR process and aligns with other policies set forth in these interim final rules, such as the conflict-of-interest standards and the certification standards for IDR entities. Ensuring that all certified IDR entities apply the same standards will help ensure that the Federal IDR process is appropriately predictable, fair, and equitable.

Although these interim final rules establish the QPA as the presumptive factor, these interim final rules and the underlying statute also specify additional circumstances that certified IDR entities must consider in selecting an offer, if a party submits information about the additional circumstance that the certified IDR entity determines is credible. These interim final rules also require that the parties provide certain information to the certified IDR entity, described previously in this preamble, regarding practice size, practice specialty or type; information about the plan or issuer's coverage area; information about the QPA; and, if applicable, information showing that the Federal IDR process is inapplicable to the dispute. In addition, the certified IDR entity may request additional information relating to the parties' offers and must consider credible information submitted to determine if it demonstrates that the QPA is materially different from the appropriate out-of-network rate (unless the information relates to a factor that the certified IDR entity is prohibited from considering).

Regarding those factors, first, to the extent credible information is submitted by a party, the certified IDR entity must consider whether the credible information about the level of training, experience, and quality and outcome measurements (such as those endorsed by the consensus-based entity authorized under section 1890 of the Social Security Act) of the provider or facility that furnished the qualified IDR item or service clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate for the qualified IDR item or service. In order for a certified IDR entity to consider this additional information submitted by a party, the credible information must clearly demonstrate that the QPA failed to take into account that the experience or level of training of a provider was necessary for providing the qualified IDR item or service to the patient or that the experience or training made an impact on the care that was provided. The Departments are of the view that qualified IDR items or services should not necessitate an out-of-network rate higher than the offer closest to the QPA, simply based on the level of experience or training of a provider, as this would lead to an increase in prices without a valid reason and does not align with the goals of the No Surprises Act. For instance, the out-of-network payment amount for the simple repair of a superficial wound (CPT codes 12001–12007) in most cases would not necessitate a rate higher than the QPA just because a provider has 30 years of experience versus 10 years of experience. Alternatively, if the plan's or issuer's contracted rates included risk-sharing, bonus, penalty, or other incentive-based or retrospective payments that were excluded for purposes of calculating the QPA for the items and services as required by the July 2021 interim final rules, a party may provide evidence as to why the provider's or facility's quality or outcome measures support an out-of-network rate that is different from the QPA and the certified IDR entity should consider whether this requires selecting an out-of-network rate that is higher (in the case of a bonus) or lower (in the case of a penalty) than the offer closest to the QPA.

Second, to the extent credible information is submitted by a party, the certified IDR entity must consider whether the credible information about the market share held by the nonparticipating provider or facility or the plan (including, for self-insured plans, the market share of their third-party administrator (TPA) in instances where the self-insured plan relies on the TPA's networks) or issuer in the geographic region in which the qualified IDR item or service was provided, clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate for the qualified IDR item or service. Research suggests that the market dominance of a provider or facility, or that of a plan or issuer, can drive reimbursement rates up or down in a given region.[32] For instance, a plan or issuer having the majority of the market share in a geographic region may signal a QPA that is unreasonably low, as plans and issuers with a large market share may drive down rates,[33] in which case an out-of-network rate higher than the offer closest to the QPA may be appropriate. Alternatively, a provider having the majority of the market share in a geographic region may signal a QPA that is unreasonably high, as providers with a large market share may drive up rates, in which case an out-of-network rate lower than the offer closest to the QPA may be appropriate.

Third, to the extent credible information is submitted by a party, the certified IDR entity must consider whether the credible information about patient acuity or the complexity of furnishing the qualified IDR item or service to the participant, beneficiary, or enrollee clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate for the qualified IDR item or service. In many cases, because the plan or issuer is required to calculate the QPA using median contracted rates for service codes, as well as modifiers, if applicable, and because service codes and modifiers reflect patient acuity and the complexity of the service provided,[34] these factors will already be reflected in the QPA. Therefore, the Departments anticipate that there would only be rare instances in which the QPA would not adequately account for the acuity of the patient or complexity of the service. For example, if the complexity of a case is an outlier such that the time or intensity of care exceeds what is typical for a service code, the certified IDR entity may conclude that the QPA does not adequately take the factor into account. Similarly, the QPA for a qualified IDR item or service may be considered too high for items or services that become less complex or are furnished more frequently over time, such as items for which the QPA reflects reimbursement for a product with a patent that expires after 2019, in instances where the QPA is based off the median of the contracted rates from 2019. A certified IDR entity may also conclude that the QPA does not adequately account for patient acuity, or the complexity of furnishing the qualified IDR item or service in instances where the parties disagree on what service code or modifier accurately describes the qualified IDR item or service. For instance, the Departments are aware that some plans and issuers review claims and alter the service code or modifier submitted by the provider or facility to another service code or modifier that the plan or issuer determines to be more appropriate (a practice commonly referred to as ''downcoding'' when the adjustment

[32] Schwartz, K., Lopez, E., Rae, M., Neuman, T. What We Know About Provider Consolidation. Kaiser Family Foundation. September 2020. *https://www.kff.org/health-costs/issue-brief/what-we-know-about-provider-consolidation/.*

[33] See Richard M. Scheffler and Daniel R. Arnold. ''Insurer Market Power Lowers Prices in Numerous Concentrated Provider Markets.'' Health Affairs. 2017 36:9, 1539–1546; Glenn Melnick, Yu-Chu Shen and Vivian Wu. ''The Increased Concentration Of Health Plan Markets Can Benefit Consumers Through Lower Hospital Prices.'' Health Affairs 30, no. 9.

[34] *https://www.medicalbillingandcoding.org/cpt-modifiers/.*

results in lower reimbursement).[35] If a plan or issuer has altered the service code or modifier(s) for a submitted claim and applies a QPA that uses a different service code or modifier(s) than the service code or modifier(s) submitted by the provider or facility, the provider or facility could submit credible information to the certified IDR entity demonstrating that the QPA applied by the plan or issuer to the claim is based on a service code or modifier that did not properly encompass patient acuity, the complexity of furnishing the qualified IDR item or service. If the certified IDR entity agrees that either of the parties have presented credible information that clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate, and adequately takes into account the considerations allowed under 26 CFR 54.9816–8T(c)(4)(iii)(B) through (D), 29 CFR 2590.716–8(c)(4)(iii)(B) through (D), and 45 CFR 149.510(c)(4)(iii)(B) through (D), then it could select either offer, but must select the offer that the certified IDR entity determines best represents the value of the qualified IDR item or service.[36]

Fourth, to the extent credible information is submitted by a party, the certified IDR entity must also consider whether the credible information about the teaching status, case mix, and scope of services of the nonparticipating facility, clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate for the qualified IDR item or service. Similar to the other factors, it is the view of the Departments that the QPA, which is intended to reflect the market-driven rate, should be considered the prevailing rate unless a party provides credible information that the characteristic of the teaching status, case mix, or scope of services of the nonparticipating facility was in some way critical to the delivery of the qualified IDR item or service, and not adequately accounted for in the QPA, thereby rebutting the presumption that the QPA is the appropriate out-of-network rate. For example, a certified IDR entity could consider the trauma level of a hospital when the dispute involves trauma care or qualified IDR items or services that could not be performed at a lower-level hospital, but only to the extent the QPA does not otherwise reflect this factor. The Departments seek comment on whether additional requirements should be considered to address any potentially abusive scenarios, including scenarios in which parties could potentially distort information that informs the enumerated considerations, such as overestimating the teaching experience of providers at the facility or upcoding the costs for items or services, and seek comment on the potential for gaming of the Federal IDR process.

Fifth, to the extent credible information is submitted by a party, the certified IDR entity must also consider whether the credible information about any demonstrations of good faith efforts (or lack thereof) made by the nonparticipating provider, nonparticipating facility, or nonparticipating provider of air ambulance services or the plan or issuer, as applicable, to enter into network agreements and, if applicable, contracted rates between the provider or facility and the plan or issuer, as applicable during the previous 4 plan years, clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate for the qualified IDR item or service. For example, a certified IDR entity must consider what the contracted rate might have been had the good faith negotiations resulted in the nonparticipating provider, facility, or provider of air ambulance services being in-network, if a party is able to provide related credible information of good faith efforts or the lack thereof.

Beyond these enumerated factors, the certified IDR entity must also generally consider additional information submitted by a party, provided the information is credible and relates to the offer submitted by either party. The certified IDR entity is not permitted to consider that information if it includes information on factors described in 26 CFR 54.9816–8T(c)(4)(v), 29 CFR 2590.716–8(c)(4)(v), and 45 CFR 149.510(c)(4)(v). This prohibition is discussed further in the next section of this preamble.

The Departments intend to provide additional guidance to certified IDR entities as necessary to clarify how the allowable factors should be considered and seek comment on this approach, including the appropriateness and scope of the factors previously discussed.

iii. Selection of Offer for Qualified IDR Services That Are Air Ambulance Services

The process for a certified IDR entity to select an offer in a dispute related to qualified IDR services that are air ambulance services is essentially the same as the process applicable to disputes related to qualified IDR items or services that are not air ambulance services. As with disputes related to qualified IDR items or services that are not air ambulance services, in determining which offer to select, these interim final rules provide that the certified IDR entity must consider the QPA for the applicable year for the qualified IDR services that are air ambulance services. However, Code section 9817(b)(5)(C), ERISA section 717(b)(5)(C), PHS Act section 2799A–2(b)(5)(C), and these interim final rules specify additional circumstances, in addition to the QPA, that the certified IDR entity must also consider in making the determination for air ambulance services, to the extent the parties provide credible information on such criteria. As with qualified IDR items or services, the certified IDR entity should only consider this information to the extent the certified IDR entity determines that either party submitted credible information that clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate. If a party presents credible information clearly demonstrating that the QPA is materially different from the appropriate out-of-network rate, the certified IDR entity must consider the additional circumstances.

To the extent credible information is submitted by a party, the certified IDR entity must consider whether credible information about the quality and outcomes measurements of the provider of air ambulance services that furnished the services clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate. Additionally, to the extent credible

[35] The Departments clarify that the July 2021 interim final rules do not require the plan or issuer to calculate the participant's, beneficiary's, or enrollee's cost sharing using a QPA for the service code submitted by the provider or facility. The plan or issuer could instead calculate the participant's, beneficiary's, or enrollee's cost sharing using a QPA for the service code that the plan or issuer determined was more appropriate. However, the QPA methodology under 26 CFR 54.9816–6T, 29 CFR 2590.716–6, and 45 CFR 149.140 requires plans and issuers to calculate the median contracted rate for an item or service using contracted rates for the same or similar item or service. A plan or issuer would be considered out of compliance with these requirements if the plan or issuer calculated a QPA using a service code that does not reasonably reflect the furnished item or service.

[36] The Departments note that in instances in which the certified IDR entity selects an offer based on a determination that a service code other than the one upon which the QPA was based more accurately describes the qualified IDR item or service, neither the plan or issuer nor provider or facility is permitted to adjust the participant's, beneficiary's, or enrollee's cost-sharing amount. The cost-sharing amount remains the same as originally calculated in accordance with 26 CFR 54.9816–4T(b)(3)(ii) and (iii), 29 CFR 2590.716–4(b)(3)(ii) and (iii), and 45 CFR 149.110(b)(3)(ii) and (iii); 26 CFR 54.9816–5T(c)(1) and (2), 29 CFR 2590.717–1(c)(1) and (2), and 45 CFR 149.120(c)(1) and (2); or 26 CFR 54.9817–1T(b)(1) and (2), 29 CFR 2590.717–1(b)(1) and (2), and 45 CFR 149.130(b)(1) and (2).

information is submitted by a party, the certified IDR entity must consider whether credible information about the acuity of the condition of the participant, beneficiary, or enrollee receiving the services, or the complexity of providing the services to the participant, beneficiary, or enrollee, clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate. Further, to the extent credible information is submitted by a party, the certified IDR entity must consider credible information submitted by a party about whether the level of training, experience, and quality of medical personnel that furnished the air ambulance services clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate for the air ambulance services. To the extent a party submits any such credible information, the certified IDR entity must also consider whether credible information about the ambulance vehicle type, including the clinical capability level of the vehicle, clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate for the air ambulance services. In considering the ambulance vehicle type, the certified IDR entity may not consider whether the air ambulance is fixed wing or rotary wing, because the QPA will reflect this difference, as different service codes are used to bill for air ambulance services depending on whether fixed wing or rotary wing vehicles are used. Instead, the certified IDR entity should consider air ambulance vehicle type only to the extent that it is not already taken into account by the QPA.

To the extent a party submits any such credible information, the certified IDR entity must also consider whether credible information about the population density of the point of pick-up (as defined in 42 CFR 414.605) for the air ambulance (such as urban, suburban, rural, or frontier [37]), clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate for a particular air ambulance service. Under the July 2021 interim final rules, the QPA is calculated by reference to the geographic region, which for air ambulance services distinguishes between one region containing all metropolitan statistical areas (as described by the U.S. Office of Management and Budget (OMB) and published by the U.S. Census Bureau) in a state and one region consisting of all other portions of the state, determined based on the point of pick-up (as defined in 42 CFR 414.605). If these geographic regions do not provide sufficient information, the QPA is calculated in reference to Census divisions, with one region consisting of all metropolitan statistical areas in each Census division, and one region consisting of all other portions of the Census division, determined at the point of pick-up. Therefore, the QPA for these geographic regions may already reflect the population density of the pick-up location. Nevertheless, in certain circumstances, the QPA for air ambulance services may not adequately capture the population density, due to additional distinctions, such as between metropolitan areas within a state, or between rural and frontier areas. To the extent that there is credible information about additional circumstances clearly demonstrating that the QPA is materially different from the appropriate out-of-network rate for a particular air ambulance service, the certified IDR entity must consider these distinctions.

Finally, to the extent credible information is submitted by a party, the certified IDR entity must consider whether credible information about demonstrations of good faith efforts (or lack thereof) made by the nonparticipating provider of air ambulance services or the plan or issuer to enter into network agreements, as well as contracted rates between the provider and the plan or issuer, as applicable, during the previous 4 plan years, clearly demonstrate that the QPA is materially different from the appropriate out-of-network rate for such air ambulance services.

As with qualified IDR items or services that are not air ambulance services, the certified IDR entity must begin with the presumption that the amount closest to the QPA is the appropriate out-of-network rate for the air ambulance service under consideration and select the offer closest to the QPA, unless credible information submitted by the parties clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate, or unless the offers are equally distant from the QPA but in opposing directions. In those cases, the certified IDR entity must select the offer that the certified IDR entity determines best represents the value of the qualified IDR items or services, which could be either party's offer.

iv. Prohibition on Consideration of Certain Factors

Code section 9816(c)(5)(D), ERISA section 716(c)(5)(D), PHS Act section 2799A–1(c)(5)(D), and these interim final rules provide that the certified IDR entity may not consider certain factors in determining which offer is the out-of-network rate. First, the certified IDR entity may not consider usual and customary charges. This term, also known as usual, customary and reasonable charges, refers to the amount providers in a geographic area usually charge for the same or similar medical service.[38] This provision also prohibits consideration of payment or reimbursement rates expressed as a proportion of usual and customary charges. Second, certified IDR entities cannot consider the amount that would have been billed to either a plan or issuer, or a participant, beneficiary, or enrollee by a provider, facility, or provider of air ambulance services if the provider, facility, or provider of air ambulance services were not subject to a prohibition on balance billing. The Departments recognize that 45 CFR 149.410, 149.420, and 149.440 prohibit providers, facilities, and providers of air ambulance services from billing participants, beneficiaries, or enrollees for the full charge for items and services to which these provisions apply, but do not limit the amount that may be billed to the plan or issuer. However, the Departments are of the view that the intent of Code section 9816(c)(5)(D), ERISA section 716(c)(5)(D), and PHS Act section 2799A–1(c)(5)(D) is to prohibit the certified IDR entity from considering the billed charge for a qualified IDR item or service. Therefore, the Departments interpret this prohibition to include consideration of billed charges to the plan or issuer for the qualified IDR item or service. Finally, certified IDR entities must not consider payment or reimbursement rates payable by a public payor, in whole or in part, for items and services furnished by the providers, facilities, or providers of air ambulance services. This prohibition includes payments or reimbursement rates under the Medicare program under title XVIII of the Social Security Act, the Medicaid program under title XIX of the Social Security Act, the Children's Health Insurance Program under title XXI of the Social

[37] For these purposes, the term ''frontier'' should be understood as including those ZIP codes where the point of pick-up is in a rural area determined to be in the lowest 25 percent of rural population arrayed by population density (also known as super rural ZIP codes for purposes of determining ground ambulance base rates). *See* 42 CFR 414.610(c)(5)(ii) and 42 CFR 414.626(c)(1)(ii).

[38] See Uniform Glossary of Coverage and Medical Terms, available at *https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/affordable-care-act/for-employers-and-advisers/sbc-uniform-glossary-of-coverage-and-medical-terms-new.pdf* and *https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/Uniform-Glossary-01-2020.pdf.*

Security Act, and the TRICARE program under chapter 55 of title 10, United States Code, chapter 17 of title 38, United States Code. This prohibition also applies to payment rates for demonstration projects under section 1115 of the Social Security Act, as these are payment or reimbursement rates payable by a public payor. This provision prohibits consideration of payment or reimbursement rates expressed as a proportion of rates payable by public payors. Thus, the certified IDR entity must not consider, for example, which offer is closest to 150 percent of the Medicare reimbursement rate for a certain item or service.[39] The Departments solicit comment regarding whether any additional guidance or clarification is needed on these prohibited factors.

v. Written Decision

Once the certified IDR entity has made a determination, the certified IDR entity must provide the underlying rationale for its determination in a written decision submitted to the parties and the Departments. The certified IDR entity must submit the decision and the underlying rationale through the Federal IDR portal in a form and manner specified by the Departments in guidance. This rationale will inform the reports required from the Departments under Code section 9816(c)(7), ERISA section 716(c)(7), and PHS Act section 2799A–1(c)(7), and will assist in ensuring that the certified IDR entities comply with the requirements of this process, including the requirements of 26 CFR 54.9816–8T(c)(4)(iii), 29 CFR 2590.716–8(c)(4)(iii), and 45 CFR 149.510(c)(4)(iii). If a certified IDR entity does not choose the offer closest to the QPA, the written decision's rationale must include a detailed explanation of the additional considerations relied upon, whether the information about those considerations submitted by the parties was credible, and the basis upon which the certified IDR entity determined that the credible information demonstrated that the QPA is materially different from the appropriate out-of-network rate.

v. Effect of Determination

Code section 9816(c)(5)(E), ERISA section 716(c)(5)(E), PHS Act section 2799A–1(c)(5)(E), and these interim final rules provide that a determination made by a certified IDR entity is binding upon all parties involved, in the absence of fraud or evidence of intentional misrepresentation of material facts to the certified IDR entity by any party regarding the claim. A certified IDR entity's determination is not subject to judicial review, except as set forth in 9 U.S.C. 10(a)(1)–(4).[40]

Under Code section 9816(c)(5)(E)(ii), ERISA section 716(c)(5)(E)(ii), PHS Act section 2799A–1(c)(5)(E)(ii), and these interim final rules, when a certified IDR entity makes a determination, the party that submitted the initial Notice of IDR Initiation may not submit a subsequent Notice of IDR Initiation involving the same other party with respect to a claim that is the same as or similar to a qualified IDR item or service that was the subject of the initial determination during the 90-calendar-day period following the initial determination. The Departments interpret the 90-day period in the statute to refer to 90 calendar days. The Departments are of the view that this interpretation balances the statutory intent to provide for a ''cooling-off'' period between disputes that relate to the same or similar items or services while ensuring that the initiating party is able to resolve outstanding payment disputes through the Federal IDR process as soon as permitted under the statute. The Departments interpret the statutory phrase of ''such item or service'' in this context to refer to the same or similar item or service, in order to maintain consistency with the statutory provisions related to the QPA and the provisions allowing batching of items and services. Additionally, such an interpretation clarifies the meaning of the statutory provisions at Code section 9816(c)(5)(E)(iii), ERISA section 716(c)(5)(E)(iii), and PHS Act section 2799A–1(c)(5)(E)(iii), which allow subsequent submission of such an item or service only if the open negotiation period ended during such a 90-day period (as the open negotiation period for the particular item or service under dispute would have already ended). For claims for the same or similar item or service for which the end of the open negotiation period occurs during the 90-calendar-day suspension period, after the end of the 90-calendar-day suspension period, either party may initiate the Federal IDR process for the items and services affected by the suspension. For these items or services, the initiating party must submit the Notice of IDR Initiation within 30 business days following the end of the 90-calendar-day suspension period, as opposed to the standard 4-business-day period following the end of the open negotiation period. The 30-business-day period begins on the day after the last day of the 90-calendar-day period.

The plan or issuer must make any additional payment, if applicable, of the amount of the offer selected by the certified IDR entity directly to the provider, facility, or provider of air ambulance services not later than 30 calendar days after the determination by the certified IDR entity. This amount will be the offer selected, reduced by the sum of any initial payment the plan or issuer has paid to the provider, facility, or provider of air ambulance services and any cost sharing paid or owed by the participant, beneficiary, or enrollee to the provider, facility, or provider of air ambulance services. If the offer selected by the certified IDR entity is less than the sum of the initial payment and any cost sharing paid by the participant, beneficiary, or enrollee, the provider, facility, or provider of air ambulance services will be liable to the plan or issuer for the difference. This difference must be paid directly to the plan or issuer not later than 30 calendar days after the determination by the certified IDR entity. The Departments note that this determination of the out-of-network rate does not change the participant's, beneficiary's, or enrollee's cost sharing, which is based on the recognized amount. The cost-sharing amount remains the same as originally calculated in accordance with 26 CFR 54.9816–4T(b)(3)(ii) and (iii), 29 CFR 2590.716–4(b)(3)(ii) and (iii), and 45 CFR 149.110(b)(3)(ii) and (iii); 26 CFR 54.9816–5T(c)(1) and (2), 29 CFR 2590.716–5(c)(1) and (2), and 45 CFR 149.120(c)(1) and (2); or 26 CFR 54.9817–1T(b)(1) and (2), 29 CFR 2590.717–1(b)(1) and (2), and 45 CFR 149.130(b)(1) and (2).

vi. Recordkeeping Requirement

These interim final rules require that the certified IDR entity must maintain records of relevant documentation associated with any Federal IDR process determination for 6 years. The 6-year

[39] The Departments recognize that contracted rates are frequently based off a percentage of the Medicare payment rate. The Departments clarify that even in instances where the QPA is calculated using contracted rates that are expressed as a proportion of rates payable by a public payor (or other prohibited considerations), the certified IDR entity is required to consider the QPA. In the Departments' view, this does not constitute consideration of the payment or reimbursement rate payable by a public payor.

[40] Subparagraphs (1) through (4) of 9 U.S.C. 10(a) provide that courts may vacate an arbitration: where the award was procured by corruption, fraud, or undue means; where there was evident partiality or corruption in the arbitrators; where the arbitrators were guilty of misconduct in refusing to postpone the hearing, in refusing to hear evidence pertinent and material to the controversy; or of any other misbehavior prejudicing the rights of the parties; or where the arbitrators exceeded their powers, or so imperfectly executed them that a mutual, final, and definite award was not made.

recordkeeping requirement is similar to other recordkeeping requirements under the Code, ERISA, and the PHS Act. For example, independent review organizations involved in the Federal external review process under 26 CFR 54.9815–2719, 29 CFR 2590.715–2719, and 45 CFR 147.136 must retain records 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.

vii. Costs of the Federal IDR Process and Payment

At the time that a certified IDR entity is selected by both of the parties or by the Departments, each party to a determination must pay to the certified IDR entity the administrative fee due to the Departments for participating in the Federal IDR process. At the time of submission of the offer by each party to a determination, the certified IDR entity fee must be paid to the certified IDR entity. Each party will be able to view the certified IDR entity fees and administrative fees in the Federal IDR portal when engaging in the certified IDR entity selection process. As discussed later in this preamble, certified IDR entities must set the certified IDR entity fee within a pre-determined range (or as otherwise approved by the Departments) specified by the Departments through guidance. The Departments anticipate issuing this guidance annually. For a discussion of the considerations the Departments will review when setting the certified IDR entity fee range, see section III.D.5 of this preamble.

These interim final rules require each party to pay the entire certified IDR entity fee at the time the parties provide their offer under 26 CFR 54.9816–8T(c)(4)(i), 29 CFR 2590.716–8(c)(4)(i), and 45 CFR 149.510(c)(4)(i). Certified IDR entities are required to hold these funds in a trust or escrow account until the certified IDR entity makes a determination of the out-of-network rate, or in instances in which the parties agree on an out-of-network rate, until the Departments notify the certified IDR entity that it may remit the funds as specified in these interim final rules. The certified IDR entity may (but is not required to) accrue interest on the funds. The certified IDR entity is not required to remit any accrued interest to any other party. Within 30 business days of making the determination, the certified IDR entity must refund to the prevailing party the amount the party submitted for the certified IDR entity fee. The certified IDR entity will retain the certified IDR entity fee submitted by the non-prevailing party, as the non-prevailing party is required to pay the certified IDR entity fee. In the case of batched determinations, the certified IDR entity may make different payment determinations for each qualified IDR item or service under dispute. In these cases, the party with fewest determinations in its favor is considered the non-prevailing party and is responsible for paying the certified IDR entity fee. In the event that each party prevails in an equal number of determinations, the certified IDR entity fee will be split evenly between the parties. The Departments are of the view that this approach reduces the administrative burden of fee collections and ensures payment of certified IDR entities. This approach also eliminates any concerns that certified IDR entities will make determinations based on which party is more likely to pay the certified IDR entity fee. The Departments may issue additional guidance if abusive situations or other issues related to the payment of the administrative fee or the certified IDR entity fee arise. The Departments also solicit comment on whether additional requirements, including procedures to offset against or make adjustments to amounts owed under a payment determination, are necessary to ensure payment or collection of the administrative fee and the certified IDR entity fee.

If the parties negotiate an out-of-network rate before the certified IDR entity makes a determination, the certified IDR entity is required to return half of each party's payment for the certified IDR entity fee, unless directed otherwise by both parties to distribute the total amount of that refund in different shares.

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 determination must pay an administrative fee for participating in the Federal IDR process. The statute further indicates that the administrative fee must be paid to the Departments at the time and in the manner specified by the Departments. These 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. Having the certified IDR entity collect both the administrative fee and the certified IDR entity fee will help ensure efficiency by streamlining the process and will facilitate administrative convenience for the parties and the Departments. These interim final rules also specify that the administrative fee is non-refundable, even in instances where the parties negotiate an out-of-network rate before the certified IDR entity makes a determination or where the certified IDR entity determines that the case does not qualify for the Federal IDR process. Code section 9816(c)(8)(B), ERISA section 716(c)(8)(B), and PHS Act section 2799A–1(c)(8)(B) specify that the administrative fee is established such that the total amount of fees is approximately equal to the amount of expenditures estimated by the Departments in carrying out the Federal IDR process. Because the Departments expect that a large part of the expenditures in carrying out the Federal IDR process will come from the initiation of the Federal IDR process, the Departments will have incurred expenditures in instances in which the parties reach an agreement before the certified IDR entity makes a determination or in which the certified IDR entity determines that the case does not qualify for the Federal IDR process, and thus, it is appropriate that the parties should still be expected to pay the fee.

As explained in the following section on certification, the certified IDR entity must remit the administrative fee to the Departments at the time and in the manner specified in guidance. The administrative fee amount will be established in guidance published by the Departments in a manner so that the total administrative fees collected by the certified IDR entities and remitted to the Departments during a calendar year are approximately equal to the estimated amount of expenditures by the Departments for that calendar year in carrying out the Federal IDR process. In setting the administrative fee, the Departments will consider the estimated costs for the Departments to administer the Federal IDR process for the following calendar year, including the staffing and contracting costs related to certifying and providing oversight to certified IDR entities; the costs of developing and publishing reports as required under Code sections 9816 and 9817, ERISA sections 716 and 717, and PHS Act sections 2799A–1 and 2799A–2; the costs of collecting the administrative fees from certified IDR

entities; and the cost of maintaining the Federal IDR portal. In future years, such projected costs will be informed by the actual costs incurred by the Departments to date to administer the Federal IDR process. The Departments expect that certain resources related to the Federal IDR process will also be used for the patient-provider dispute resolution process, such as the Federal IDR portal, certain staffing, and contracts. In setting the administrative fee, the Departments will consider the expected volume for the Federal IDR process and the patient-provider dispute resolution process and apportion the IDR administrative fee such that it reflects the appropriate usage of the Federal IDR process by providers, facilities, providers of air ambulance services, plans, and issuers.

5. Certification of IDR Entities

Under Code section 9816(c)(4), ERISA section 716(c)(4), and PHS Act section 2799A–1(c)(4), an IDR entity must meet certain standards and be certified by the Departments to be selected for the Federal IDR process. Consistent with these provisions, these interim final rules provide that an IDR entity must provide through the Federal IDR portal written documentation to the Departments that demonstrates the entity satisfies certain standards and procedures outlined in these interim final rules and set forth in guidance issued by the Departments. Specifically, the Departments will indicate through guidance 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. 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, subject to the petition and revocation process, discussed later in this preamble.[41] Once certified, the certified IDR entity must continue to satisfy these requirements.

IDR entities will be expected, as part of their application for certification, to submit general information about their organization, including contact information, Taxpayer Identification Number (TIN), and website information, as well as the service area in which the IDR entity intends to conduct payment determinations under the Federal IDR process. IDR entities may choose to apply to operate in all states or self-limit to a particular subset of states. Further, anyone submitting the application for certification must have the legal and financial authority to bind the IDR entity. An IDR entity that the Departments certify must enter into an agreement with the Departments. That agreement will include specified provisions encompassed by these interim final rules, including, but not limited to, the requirements applicable to certified IDR entities when making payment determinations as well as the requirements regarding certification and revocation (such as specifications for wind down activities and reallocation of certified IDR entity fees, where warranted).

In order to be certified, an IDR entity must possess (directly or through contracts or other arrangements) and demonstrate sufficient arbitration and claims administration of health care services, managed care, billing, coding, medical, and legal expertise. With regard to medical expertise, where the payment determination depends on the patient acuity or the complexity of furnishing the qualified IDR item or service, or the level of training, experience, and quality and outcome measurements of the provider or facility that furnished the qualified IDR item or service, the IDR entity should have available medical expertise with the appropriate training and experience in the field of medicine involved in the qualified IDR item or service. Additionally, the IDR entity must employ (directly or through contracts or other arrangements) sufficient personnel to make determinations within the 30 business days allowed for such determinations. To satisfy this standard, the written documentation the IDR entity submits must include a description of its organizational structure and capabilities, including an organizational chart and the credentials, responsibilities, and number of personnel employed to make determinations. The Departments considered requiring IDR entities to have personnel (either hired directly or through a contract) with air space law knowledge for making determinations related to air ambulance cases, but are concerned that such a requirement may limit the number of eligible entities and increase the likelihood of conflicts of interests in air ambulance cases. The Departments seek comment on whether IDR entities should be required to have air space law knowledge for IDR entity certification to make determinations for air ambulance cases.

Next, an IDR entity must also maintain a current accreditation from a nationally recognized and relevant accreditation organization, such as URAC, or ensure that its personnel otherwise possess the requisite training to conduct payment determinations (for example, providing documentation that personnel employed by the IDR entity have completed arbitration training by the AAA, the AHLA, or a similar organization). This requirement will ensure the IDR entity has the operational ability to perform its primary functions as set forth in the No Surprises Act and these interim final rules. States have imposed similar requirements on independent review organizations for external review processes under PHS Act section 2719 (which is incorporated by reference into Code section 9815 and ERISA section 715), or for their state IDR processes. Similar to independent review organizations, certified IDR entity personnel should have the skills and training necessary to conduct unbiased and impartial determinations between plans or issuers and providers, facilities, or providers of air ambulance services, and similar billing, coding, and medical expertise. The Departments expect that many of the organizations with current experience in arbitration or dispute resolution will already have such accreditation and will employ personnel with relevant experience. The Departments seek comment on whether any additional accreditation or training standards would meet this requirement, including whether additional flexibility is needed to help encourage innovation in the provision of IDR services and new entrants as IDR entities that may be certified for the Federal IDR process.

Additionally, as a condition of certification, the IDR entity must have a process to ensure that no conflicts of interest exist between the parties and the personnel the certified IDR entity assigns to each dispute, and to screen for any material relationships between the parties and the personnel assigned to each dispute. This process will allow certified IDR entities to comply with the requirements of 26 CFR 54.9816–8T(c)(1)(ii), 29 CFR 2590.716–8(c)(1)(ii), and 45 CFR 149.510(c)(1)(ii).

While conducting the Federal IDR process, a certified IDR entity will be entrusted with IIHI. Code section 9816(c)(4)(A)(v), ERISA section 716(c)(4)(A)(v), and PHS Act section 2799A–1(c)(4)(A)(v) require a certified IDR entity to maintain the confidentiality of IIHI obtained in the course of conducting payment determinations. This IIHI is often protected under Federal and state law, but certain laws, such as the privacy and security regulations promulgated

[41] As discussed in the section on Economic Impact and Paperwork Burden, the Departments estimate there will be 50 IDR entities that will seek certification by the Departments.

under HIPAA, as amended, may not apply to IIHI when it is held by a certified IDR entity.

Therefore, these interim final rules specify that a certified IDR entity must provide written documentation to the Departments that demonstrates that the certified IDR entity satisfies, among other things, the confidentiality standards set forth in 26 CFR 54.9816–8T(e)(2)(v), 29 CFR 2590.716–8(e)(2)(v), and 45 CFR 149.510(e)(2)(v). These provisions include standards for certified IDR entities to maintain the confidentiality of IIHI obtained in the course of conducting the Federal IDR process. Because IIHI is sensitive, private information about consumers and their health, including information that is identifiable to a particular individual, IIHI warrants strong protection by the parties that will be handling this information. Therefore, the Departments are of the view that certified IDR entities must have procedures in place to protect consumers from improper storage, use, handling, or transmission of this information. The confidentiality standards in these interim final rules are informed by the privacy, security, and breach notification regulations issued under HIPAA and the HITECH Act, because the Departments are of the view that these provisions are industry standards.[42] Drawing from those standards for these interim final rules promotes continuity in the way consumer information is protected and secured throughout systems involved in health care. The Departments have drawn mainly from relevant HIPAA standards because these are the predominant federal standards that apply to identifiable consumer health information, when possessed by some of the parties to the Federal IDR process. Therefore the Departments are of the view that these standards are the most appropriate privacy standards for certified IDR entities. The Departments have tailored these requirements to the particular functions of certified IDR entities to ensure that they have clear, workable, and appropriate standards to implement.

These interim final rules set forth the confidentiality requirements applicable to certified IDR entities and include provisions regarding privacy, security, and breach notification. The Departments begin by discussing the general privacy requirement in 26 CFR 54.9816–8T(e)(2)(v)(A), 29 CFR 2590.716–8(e)(2)(v)(A), and 45 CFR 149.510(e)(2)(v)(A) that specify that a certified IDR entity may create, collect, handle, disclose, transmit, access, maintain, store, and/or use IIHI only to perform two categories of activities, described in 26 CFR 54.9816–8T(e)(2)(v)(A)(*1*) through (*2*), 29 CFR 2590.716–8(e)(2)(v)(A)(*1*) through (*2*), and 45 CFR 149.510(e)(2)(v)(A)(*1*) through (*2*): (1) To perform the certified IDR entity's required duties under these sections of the interim final rules; and (2) to perform functions related to carrying out additional obligations as may be required under applicable Federal or state laws or regulations.

Additionally, certified IDR entities are required to maintain the security of the IIHI they obtain by ensuring the confidentiality of all IIHI they create, obtain, maintain, store, and transmit; protecting against any reasonably anticipated threats or hazards to the security of this information; protecting against any reasonably anticipated unauthorized uses or disclosures of this information; and by ensuring compliance by any of their personnel, including their contractors and subcontractors (as applicable), assigned to a payment determination. To satisfy this requirement, certified IDR entities are required to have policies and procedures in place to properly use and disclose IIHI, identify when IIHI should be destroyed or disposed of, properly store and maintain confidentiality of IIHI that is accessed or stored electronically, and identify the steps the certified IDR entities will take in the event of a breach regarding IIHI. The Departments based these requirements on the similar rule applicable to HIPAA covered entities under 45 CFR 164.306(a)(1), but because the rule for HIPAA covered entities applies specifically with regard to electronic protected health information (PHI), the requirements in these interim final rules specify that certified IDR entities must ensure the confidentiality of all IIHI they create, obtain, maintain, store, or transmit in accordance with Code section 9816(c)(4)(A)(v), ERISA section 716(c)(4)(A)(v), and PHS Act section 2799A–1(c)(4)(A)(v). A certified IDR entity's responsibility to comply with these confidentiality requirements shall survive revocation of the IDR entity's certification for any reason, and IDR entities must comply with the record retention and disposal requirements described in these interim final rules.

The Departments also require certified IDR entities to securely destroy or dispose of IIHI in an appropriate and reasonable manner 6 years from either the date of its creation or the first date on which the certified IDR entity had access to it, whichever is earlier. In determining what is appropriate and reasonable, certified IDR entities should assess potential risks to participant, beneficiary, or enrollee privacy, as well as consider such issues as the form, type, and amount of IIHI to be disposed. The Departments are of the view that 6 years is a reasonable timeframe for destruction of such information since relevant business procedures should be complete well before this deadline, including IDR payment determinations and certified IDR entity compliance with the Departments' audits as applicable. Furthermore, the 6-year timeframe matches the record retention requirements for certified IDR entities under these interim final rules as well as other record retention requirements under ERISA. These standards are also similar to HIPAA Security Rule requirements[43] under 45 CFR 164.310(d)(2)(i) and (ii), except that the Departments have tailored the requirements in section 26 CFR 54.9816–8T(e)(2)(v)(B)(*4*), 29 CFR 2590.716–8(e)(2)(v)(B)(*4*), and 45 CFR 149.510(e)(2)(v)(B)(*4*) to apply to IIHI.

Next, the Departments require certified IDR entities to develop and utilize secure electronic interfaces when transmitting IIHI electronically, including through data transmission with the Federal IDR portal, and between disputing parties during the Federal IDR process and the certified IDR entity. In addition, the Departments are of the view that certified IDR entities must have in place requirements for their personnel, including their contractors and subcontractors (as applicable), similar to those required under HIPAA Rules to make sure IIHI is only handled by appropriate staff who are trained to handle IIHI, and that proper protocol is followed if a breach of IIHI occurs.

Finally, 26 CFR 54.9816–8T(e)(2)(v)(D), 29 CFR 2590.716–8(e)(2)(v)(D), and 45 CFR 14.510(e)(2)(v)(D) require that all confidentiality requirements applicable to certified IDR entities also apply to certified IDR entities' contractors and subcontractors with access to IIHI performing any duties related to the Federal IDR process. For example, if a breach rises to the level of requiring a breach notification, the contractor or subcontractors must notify the certified IDR entity to inform it of the risk assessment results, and the certified IDR entity must notify the provider, facility,

[42] 45 CFR part 160 subpart A and subparts A, C, D, and E of part 164.

[43] U.S. Dept. of Health and Human Servs., Office for Civil Rights, ''The HIPAA Privacy and Security Rules: Frequently Asked Questions About the Disposal of Protected Health Information,'' available at *https://www.hhs.gov/sites/default/files/disposalfaqs.pdf.*

or provider of air ambulance services; plan and issuer; the Departments; and each individual whose unsecured IIHI has been, or is reasonably believed to have been, subject to the breach, to the extent possible, as required by these interim final rules.

In addition to the privacy and security requirements discussed in this section of this preamble, these interim final rules contain breach notification requirements, similar to the HIPAA breach notification standards (the ''HIPAA Notification Rule'') at 45 CFR 164.402 and 164.404, to address steps that a certified IDR entity must take following the discovery of a breach of unsecured IIHI as defined in these interim final rules. The Departments are of the view that adopting breach notification standards similar to the HIPAA breach notification standards for certified IDR entities provides important protections for IIHI. For purposes of these interim final rules, the Departments made changes from the HIPAA breach notification standards to account for IIHI and certified IDR entities, as opposed to PHI and covered entities, in accordance with Code section 9816(c)(4)(C), ERISA section 716(c)(4)(C), and PHS Act section 2799A–1(c)(4)(C). The Departments require a certified IDR entity, upon discovery of a potential breach of unsecured IIHI, to conduct a risk assessment to determine the probability that the security or privacy of IIHI has been compromised based on at least the nature and extent of the IIHI involved, including the types of identifiers and the likelihood of re-identification; the unauthorized person who used the IIHI or to whom the disclosure was made; whether the IIHI was actually acquired or viewed; and the extent to which the risk to the IIHI has been mitigated. The Departments also require a breach to be treated as discovered by the certified IDR entity as of the first day on which such breach is known to the certified IDR entity or, by exercising reasonable diligence, should have been known to the certified IDR entity. A certified IDR entity shall be deemed to have knowledge of a breach if the breach is known, or by exercising reasonable diligence should have been known, to any person, other than the person committing the breach, who is an employee, officer, or other agent of the certified IDR entity.

The Departments are also including requirements for timing, content, and method of providing the breach notification in these interim final rules. Under these provisions, a certified IDR entity must provide notification without unreasonable delay and in no case later than 60 calendar days after the discovery of the breach. The Departments are of the view that 60 calendar days provides sufficient time for a certified IDR entity to discover a potential breach, conduct a risk assessment, and send notification as required in these interim final rules, in line with the requirements in 45 CFR 164.404 that allow up to 60 calendar days for such a notification to be sent. Since a condition for IDR entity certification involves submission of policies and procedures to: Properly create, obtain, maintain, store, or transmit IIHI in accordance with Code section 9816(c)(4)(A)(v), ERISA section 716(c)(4)(A)(v), and PHS Act section 2799A–1(c)(4)(A)(v); monitor, periodically assess, and update the security controls and related system risks to ensure the continued effectiveness of these controls; and guard against, detect, and report malicious software, the Departments are of the view that 60 calendar days are sufficient for proper identification, risk assessment, and notification of a breach.

When a certified IDR entity sends a breach notification, the content must include similar information as that required under 45 CFR 164.404, but focused on IIHI. Certified IDR entities 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 the breach, including the date of the breach and the date of the discovery of the breach, if 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 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. The Departments are of the view that this level of detail is necessary for full transparency for those who are potentially affected by such a breach.

Finally, a certified IDR entity must submit such notification in written form (in clear and understandable language) either on paper, electronically through the Federal IDR portal, or by email to the Departments; the plan, issuer or FEHB carrier; the provider, facility, or provider of air ambulance services; and, when possible, each individual whose unsecured protected IIHI has been, or is reasonably believed by the certified IDR entity to have been, subject to the breach. The Departments understand that a certified IDR entity may not have access to contact information for each individual whose unsecured protected IIHI has been, or is reasonably believed by the certified IDR entity to have been, subject to a breach. In these cases, IDR entities must work with issuers, plans, providers, and facilities to ensure that these individuals are appropriately notified.

The Departments seek comment on the confidentiality requirements enumerated in 26 CFR 54.9816–8T(e)(2)(v), 29 CFR 2590.716–8(e)(2)(v), and 45 CFR 149.510(e)(2)(v), which are based on certain provisions of the HIPAA Rules, and whether any additional or different protections are warranted.

Additionally, the certified IDR entity must ensure the fiscal integrity and stability of its organization. In order to meet this standard, the IDR entity must demonstrate that it has a system of safeguards and controls in place to prevent and detect improper financial activities by its employees and agents and to assure fiscal integrity and accountability for all fees received and held. To demonstrate financial stability, IDR entities must also submit 3 years of financial statements, or other documentation that demonstrates fiscal stability as directed by the Departments if 3 years of financial statements are unavailable. This financial disclosure requirement is informed by similar requirements under the Sarbanes-Oxley Act.[44] The Departments are of the view that, because the Sarbanes-Oxley Act represents the primary standard for corporate disclosure of financial information, it is appropriate to mirror its standard as a means of ensuring certified IDR entity compliance with the statutory requirements related to fiscal integrity. The Departments are also of the view that the disclosure of these financial statements will enable the Departments to assess whether the IDR entity is financially viable and capable of maintaining its operations, independent of any future revenue earned under the Federal IDR process as a certified IDR entity.

As a condition of certification, an IDR entity must indicate to the Departments the fees it intends to charge for payment determinations, which are limited to a fixed fee amount for single

[44] Public Law 107–204, available at *https://www.govinfo.gov/content/pkg/PLAW-107publ204/html/PLAW-107publ204.htm.*

determinations (including determinations for bundled arrangements) and a separate fixed fee amount for batched determinations under paragraph (c)(3)(i) of these interim final rules. These fixed fees must be within a range set forth in guidance by the Departments, unless the IDR entity receives written approval from the Departments for a fee outside that range. The Departments are of the view that setting a range of permitted flat amounts, including a lower and upper limit, will permit certified IDR entities to charge a reasonable certified IDR entity fee for IDR payment determinations, while also making IDR costs clear to parties in advance of the Federal IDR process. Setting a minimum and a maximum rate will mitigate potential concerns regarding overuse of the Federal IDR process due to low fees and potential concerns regarding overcharging by certified IDR entities. For batched items and services, setting a separate range that is higher to account for the potential for a larger number of claims and increased complexity will help ensure that certified IDR entities are compensated adequately for their services. The certified IDR entity may update its fees and seek approval from the Departments to charge a flat rate beyond the upper or lower limits for fees annually, as provided in guidance.

The Departments considered whether to allow certified IDR entities to set their fees without limitations and also considered imposing anti-abuse provisions to prevent certified IDR entities from charging unreasonable amounts, while also taking into account the statutory intent to discourage the overuse of the Federal IDR process and incentivize IDR entity participation in the process. The Departments are of the view, however, that requiring certified IDR entities to set fees within fixed ranges will reduce the potential for excessive certified IDR entity fees that could result in inflated health care and insurance costs that could ultimately be passed on to consumers. The Departments are also setting a lower bound for certified IDR entity fees to ensure that certified IDR entity fees do not lead to the overuse of the Federal IDR process, thereby encouraging parties to exhaust other paths to agreement, such as open negotiation, before entering the Federal IDR process.

In setting the allowable certified IDR entity fee range, the Departments will consider current IDR entity fees for state-managed IDR processes that are similar to the Federal IDR process. Based on the Departments' research on existing IDR processes in states that have implemented similar surprise billing legislation, IDR entity fees generally range from $300–$600 per payment determination.[45] The Departments acknowledge that in some states, individual arbitrators charge as little as $270 and as much as $6,000 per arbitration.[46] However, the Departments are of the view that such drastic ranges of IDR entity fees risk inflating costs of care that could ultimately be passed on to consumers.

The Departments will also consider the anticipated time and resources needed for certified IDR entities to meet the requirements of these interim final rules, such as the time and resources needed to obtain certification, making payment determinations (including determining whether the dispute belongs in the Federal IDR process), data reporting, and audits. The Departments will also consider factors such as the anticipated volume of payment determinations under the Federal IDR process and adequacy of the Federal IDR process capacity to efficiently handle the volume of IDR initiations and payment determinations. The Departments will review and update the allowable fee range annually based on these factors and the impact of inflation and other cost increases. The Departments seek comment on these factors and any additional factors that should be considered when determining the range for allowable certified IDR entity fees.

The certified IDR entity may not charge a fee that is beyond the upper or lower limits for fees set forth in annual guidance published by the Departments as approved fixed fees, unless the IDR entity or certified IDR entity requests and can provide justification for the higher or lower fee, and the Departments provide written approval for the certified IDR entity to charge a fee beyond the upper or lower limits for fees set forth in guidance. For example, if the IDR entity or certified IDR entity is able to show that, due to matters the Department has not considered, the cost of making determinations under 26 CFR 54.9816–8T(c)(4), 29 CFR 2590.716–8(c)(4), and 45 CFR 149.510(c)(4) will be higher than the upper limit for fees set forth in guidance, the certified IDR entity may charge a higher fee for determinations in that calendar year with the Departments' written approval in accordance with 26 CFR 54.9816–8T(e)(2)(vii), 29 CFR 2590.716–8(e)(2)(vii), 45 CFR 149.510(e)(2)(vii). Certified IDR entities will not be permitted to vary their fees from any approved higher fees during the year for which such higher fees were approved.

Specifically, in order for the certified IDR entity to receive the Departments' written approval to charge a fee beyond the upper or lower bounds for fees as set forth in guidance, the IDR entity or certified IDR entity must submit a written proposal that includes: (1) The alternative flat fee the IDR entity or certified IDR entity believes is appropriate; (2) a description of the circumstances that require the alternative flat fee; and (3) a description of how the alternative flat fee will be used to mitigate such circumstances. A fee other than the higher (or lower) fee previously approved, including one outside the allowable range, will be permitted only upon the Departments' written approval to charge the fee documented in the IDR entity's or certified IDR entity's written proposal. The Federal IDR portal will provide the functionality for IDR entities and certified IDR entities to request a fixed fee beyond the lower and upper limits set forth in guidance. As discussed earlier in this preamble, in instances where the disputing parties do not select a certified IDR entity, the Departments will select a certified IDR entity that charges a fee within the allowed range as provided for in guidance by the Departments. Only if there are insufficient certified IDR entities that charge a fee within the allowed range available to make the payment determination will the Departments select a certified IDR entity that charges a fee that has been approved by the Department but that is outside the allowed range.

A certified IDR entity must also have procedures in place to retain the certified IDR entity fees paid by both parties at the initiation of the Federal IDR process in a trust or escrow account separate from other funds and to return the certified IDR entity fees paid by the prevailing party of an IDR payment determination, or a portion of the fees paid by both parties should they agree on an out-of-network rate through ongoing open negotiations, within 30 business days of the determination, as specified in these interim final rules. The certified IDR entity may (but is not required to) accrue interest on the funds held in a trust or escrow account and is not required to include accrued interest with the returned fee. Additionally, the IDR entity must also have a procedure in place to retain the administrative fee

[45] Hoadley, J., and Maanasa, K. ''How States are Using Independent Dispute Resolution to Resolve Out-of-Network Payment in Surprise Billing,'' To the Point 9blog), Commonwealth Funds, Feb. 27, 2020. *https://doi.org/10.26099/pqt4-vy24.*

[46] *https://www.kff.org/private-insurance/fact-sheet/surprise-medical-bills-new-protections-for-consumers-take-effect-in-2022/amp/.*

required under 26 CFR 54.9816–8T(e)(2)(ix), 29 CFR 2590.716–8(e)(2)(ix), and 45 CFR 149.510(e)(2)(ix), and to remit it to the Departments in accordance with the timeframe and procedures set forth in guidance.

As a condition of certification, the IDR entity must show that it is able to conduct the Federal IDR process as required under these interim final rules. As part of this requirement, the IDR entity must have processes and procedures in place to ensure that it will not make a determination under the Federal IDR process with respect to which the certified IDR entity would not be eligible for selection due to a conflict of interest.

Therefore, in order to be certified, an IDR entity must provide written documentation that shows the IDR entity satisfies certain standards related to conflicts of interest. Under 26 CFR 54.9816–8T(e)(3)(i), 29 CFR 2590.716–8(e)(3)(i), and 45 CFR 149.510(e)(3)(i) the IDR entity must attest that it does not have a conflict of interest as defined in 26 CFR 54.9816–8T(a)(2)(iv), 29 CFR 2590.716–8(a)(2)(iv), and 45 CFR 149.510(a)(2)(iv). Additionally, to be certified, an IDR entity must demonstrate that it has procedures in place to ensure that the specific personnel assigned to a payment determination do not have conflicts of interest regarding any party to the dispute within the 1 year immediately preceding an assignment of dispute determination. This requirement is similar to the requirements set forth in 18 U.S.C. 207(b) and, as discussed earlier in this section of the preamble, provides a reasonable and appropriate standard for preventing conflicts of interest.[47]

Finally, to preserve the integrity of the Federal IDR process, following certification, if a certified IDR entity, at any time acquires control of, becomes controlled by, or comes under common control with any entity described in paragraphs 26 CFR 54.9816–8T(e)(3)(i), 29 CFR 2590.716–8(e)(3)(i), and 45 CFR 149.510(e)(3)(i), the certified IDR entity must notify the Departments in writing no later than 3 business days after the acquisition or exercise of control. As the certified IDR entity would no longer meet the certification criteria, it will have its certification revoked under the processes set forth in 26 CFR 54.9816–8T(e)(6), 29 CFR 2590.716–8(e)(6), and 45 CFR 149.510(e)(6) (including the prohibition on accepting new payment determinations). The Departments seek comment on whether any additional protections are necessary.

Certified IDR entities must also adhere to audit standards set forth in these interim final rules and by the Departments in guidance to ensure that certified IDR entities are adhering to the requirements of these interim final rules, including those regarding certification as a certified IDR entity and those outlining how entities must conduct payment determinations as defined in Code section 9816(c), ERISA section 716(c), and PHS Act section 2799A–1(c). To ensure adherence, the Departments intend to perform audits on a select number of certified IDR entities. Certified IDR entities may be randomly selected by the Departments for an audit or selected based upon stakeholder complaints (including those received in connection with a petition for revocation of certification) received by the Departments. Resulting findings may be used for revocation of certification or in re-certification decisions made by the Departments.

Finally, the IDR entity must collect and provide the information required to be reported to the Departments under 26 CFR 54.9816–8T(f), 29 CFR 2590.716–8(f), and 45 CFR 149.510(f) and report such information about the Federal IDR process on a timely basis to the Departments in the form and manner provided by the Departments in guidance.

6. Petition for Denial or Revocation of IDR Entity Certification

An individual, provider, facility, provider of air ambulance services, plan, or issuer 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 these interim final rules, through the Federal IDR portal in the form and manner set forth in guidance to be issued by the Departments. 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. Petitioners submitting a petition for denial of a certification will have 5 business days from the announcement that an IDR entity is seeking certification to submit the written petition. This 5-business-day period is applicable until the Departments issue guidance outlining a different period for petitions for a denial of certification.

The Departments will acknowledge receipt of the petition within 10 business days of receipt. If, after review, the Departments find that the petition adequately shows a failure to comply with the requirements of Code section 9816(c), ERISA section 716(c), PHS Act section 2799A–1(c), or these interim final rules, the Departments shall notify the IDR entity seeking certification or the certified IDR entity by providing a de-identified copy of the petition. Following this notification, the IDR entity seeking certification or the certified IDR entity will have 10 business days to provide a response. After the time period for providing the response has passed, the Departments will review the response (if any) and determine whether a denial or a revocation of certification is warranted. The decision will be subject to the appeal requirements of 26 CFR 54.9816–8T(e)(6)(v), 29 CFR 2590.716–8(e)(6)(v), and 45 CFR 149.510(e)(6)(v). If the Departments, after reviewing a certified IDR entity's response, find that the petition shows a failure to comply with the requirements of Code section 9816(c), ERISA section 716(c), or PHS Act section 2799A–1(c) but have not yet made a final decision pending appeal, a certified IDR entity may continue to work on previously assigned determinations. However, the certified IDR entity will not be permitted to accept new requests for IDR payment determinations unless and until the Departments issue a notice of the decision to the certified IDR entity finding that a revocation of certification is not warranted. If the entity is seeking certification, and the Departments find that denying certification is warranted, then the Departments will deny certification.

The IDR entity certification requirements included in these final rules are developed to ensure the integrity of the Federal IDR process. Failure to meet these standards puts at risk the Departments' ability to ensure providers, facilities, providers of air ambulance services, plans, and issuers can avail themselves of an equitable and efficient process. Therefore, the Departments may deny an IDR entity

[47] 18 U.S.C. 207 provides for certain restrictions on former officers, employees, and elected officials of the executive and legislative branches of the federal government.

certification if, during the process of certification, including as a result of a petition, the Departments determine the IDR entity fails to meet the applicable standards required for certification. Additionally, these interim final rules set forth other reasons that certification may be denied. For example, if the IDR entity has knowingly committed or participated in fraudulent or abusive activities such as by submitting to the Departments fraudulent data or information during the certification process or submitting data or information that the IDR entity knows to be false, certification may be denied. Another situation in which an IDR entity's application for certification might be denied for knowingly committing or participating in fraudulent or abusive activities would be when an IDR entity has engaged in fraudulent practices related to activities conducted outside the Federal IDR process. Additionally, if the IDR entity submits information as part of the certification process that demonstrates that the IDR entity cannot fulfill the responsibilities required of certified IDR entities, certification will be denied.

Also, to the extent the IDR entity has failed to comply with requests for information from the Departments as part of the certification process, certification may be denied. The Departments expect that as part of the certification process, the Departments may need to contact the IDR entities and request clarifying information.

Moreover, if in conducting payment determinations, including those conducted outside the Federal IDR process, the IDR entity has failed to meet the standards that applied to those determinations or reviews, including standards of independence and impartiality, certification may be denied. With respect to certified IDR entities applying for recertification, the Departments will also consider whether, in conducting payment determinations under the Federal IDR process, the certified IDR entity has met the standards applicable to those payment determinations. It is the Departments' view that, although certain conduct (for example, unethical conduct regarding payment determinations conducted outside the Federal IDR process) may not constitute a violation of the Federal IDR process, this conduct could indicate that the IDR entity may be unable to comply with the requirements of the Federal IDR process. Additionally, to the extent it is otherwise determined that the IDR entity is not fit or qualified to make determinations, certification may be denied.

If the Departments find, after review of the evidence, that a certified IDR entity is no longer qualified to make determinations due to an audit, a petition, or otherwise, the certification of the IDR entity may be revoked. A certified IDR entity's certification may be revoked prior to the end of the 5-year term for the following reasons.

First, a certified IDR entity's certification may be revoked prior to the end of the 5-year term if the Departments determine that the certified IDR entity has a pattern or practice of noncompliance with any of the requirements applicable to certified IDR entities under the Federal IDR process.

Second, if the certified IDR entity is operating in a manner that hinders the efficient and effective administration of the Federal IDR process, its certification may be revoked prior to the end of the 5-year term. For example, if a certified IDR entity consistently fails to meet the deadline for rendering its decisions as set forth in these interim final rules, its certification may be revoked. Also, if a certified IDR entity repeatedly fails to check for a conflict of interest between itself, its personnel, and third parties with which the certified IDR entity contracts, and the disputing parties, its certification may be revoked prior to the end of the 5-year term.

Third, if the certified IDR entity no longer meets the applicable certification standards set forth in these interim final rules under 26 CFR 54.9816–8T(e)(1), 29 CFR 2590.716–8(e)(1), and 45 CFR 149.510(e)(1), its certification may be revoked prior to the end of the 5-year term.

Fourth, if the certified IDR entity has committed or knowingly participated in fraudulent or abusive activities, including submission of false or fraudulent data to the Departments, its certification may be revoked prior to the end of the 5-year term. A situation in which an IDR entity's application for certification might be revoked for knowingly committing or participating in fraudulent or abusive activities would be where a certified IDR entity has engaged in fraudulent practices related to activities conducted outside the Federal IDR process.

Fifth, if the certified IDR entity no longer possesses the financial viability to provide dispute resolution under the Federal IDR process, its certification may be revoked prior to the end of the 5-year term. The Departments are of the view that a certified IDR entity must possess the requisite level of fiscal stability that demonstrates the entity is a viable entity able to continue to carry out the Federal IDR process in a timely and efficient manner as set forth in the No Surprises Act and these interim final rules.

Sixth, if the certified IDR entity has failed to comply with requests from the Departments made as part of an audit, including submission of records, its certification may be revoked prior to the end of the 5-year term. The audit process plays an important part in helping to ensure that certified IDR entities are abiding by the requirements set forth in these interim final rules. In order to ensure that the Federal IDR process is fair, equitable, and does not have an inflationary effect on health care costs due to certified IDR entities failing to properly apply the factors as set forth in these interim final rules, the Departments are of the view that it will be prudent to review certified IDR entities' processes and procedures. Therefore, failure to comply with such audits will be a basis for revocation of certification.

Seventh, if it is otherwise determined that the certified IDR entity is no longer fit or qualified to make payment determinations, its certification may be revoked prior to the end of the 5-year term. For example, the Departments may determine that an IDR entity is unfit to participate in the Federal IDR process if the IDR entity is engaged in actions that risk the integrity of the Federal IDR process.

If the Departments make a preliminary determination that an IDR entity's certification should be denied or that a certified IDR entity's certification should be revoked, the Departments will issue a notice of proposed denial to the IDR entity seeking certification or a notice of proposed revocation to the certified IDR entity within 10 business days of the preliminary determination. The notice will include the proposed effective date of denial or revocation, explain the reasons for denial or revocation, and provide an opportunity to request an appeal of the proposed denial or revocation. The Departments seek comment on whether final rules should include additional bases for revocation. The Departments also seek comment on whether certain facts and circumstances should result in immediate revocation of certification of the certified IDR entity and reassignment of any pending payment determinations prior to completion by that certified IDR entity.

In order for an IDR entity that has received a notice of proposed denial or certified IDR entity that has received a notice of proposed revocation to request an appeal of its proposed denial or revocation, as applicable, it must submit its request for an appeal to the Departments within 30 business days of

the date of the notice and in the manner prescribed by the notice. During the period when the IDR entity or certified IDR entity may appeal the denial or revocation, the Departments will not issue a notice of final denial or revocation. Furthermore, until a final decision on the appeal is rendered by the Departments, the certified IDR entity may complete any open IDR payment determinations assigned to it at the time of notification, but may not receive new assignments until a final decision regarding revocation has been made. Relevant information to support a request for appeal may include a statement of the facts, law, and arguments that negate or mitigate the evidence provided in support of the IDR entity's certification denial or the revocation of a certified IDR entity's certification, including a description of the actions the certified IDR entity or IDR entity has taken, is taking, or intends to take to cure the failures identified in the notice (if possible) and to prevent the failures from reoccurring.

In the event the IDR entity or certified IDR entity does not timely submit a request for appeal of the proposed denial or revocation, the Departments will issue a final notice of denial or revocation as described under 26 CFR 54.9816–8T(e)(6)(ii), 29 CFR 2590.716–8(e)(6)(iii), and 45 CFR 149.510(e)(6)(iii). Similarly, if the Departments reach a final determination upon appeal that the IDR entity's certification is denied or the certified IDR entity's certification is revoked, the Departments will issue a final notice of denial or revocation including an explanation of the reasons for final denial or revocation and consequences of such denial or revocation of certification to the IDR entity and the petitioner. Upon final notice of denial or revocation, the IDR entity shall not be considered a certified IDR entity and therefore shall not be eligible to accept payment determinations under the Federal IDR process. If, following a final decision denying or revoking a certification, the IDR entity comes into compliance with the requirements of 26 CFR 54.9816–8T(e), 29 CFR 2590.716–8(e), and 45 CFR 149.510(e), the IDR entity may again apply for certification beginning on the 181st calendar day after the date of the final notice of denial or revocation. The Departments are of the view that providing a 180-calendar-day cooling-off period provides adequate time for an IDR entity to correct and improve its processes to comply with the standards of these interim final rules, ensuring that IDR entities are afforded an opportunity to come into compliance and re-apply for certification. The Departments are using calendar days for this standard rather than business days for consistency with other, similar suspension periods, such as those in the guaranteed availability provisions under PHS Act section 2702(d)(2), as implemented at 45 CFR 147.104(c)(2).

The Departments will monitor the implementation of the Federal IDR process, as well as the petition process, to determine whether certified IDR entities are abiding by the applicable requirements. The Departments seek comment on any additional requirements regarding denial and revocation, and whether other steps may be required to prevent patterns and practices of noncompliance.

7. Reporting of Information Relating to the Federal IDR Process for Qualified IDR Items and Services That Are Not Air Ambulance Services

Code section 9816(c)(7), ERISA section 716(c)(7), and PHS Act section 2799A–1(c)(7) direct the Departments to make certain information related to the Federal IDR process available on a public website for each calendar quarter in 2022 and each calendar quarter in subsequent years. Code section 9816(c)(7)(C), ERISA section 716(c)(7)(C), and PHS Act section 2799A–1(c)(7)(C) specifically require the certified IDR entities to provide information to the Departments as determined necessary to carry out the requirements regarding publication of information related to the Federal IDR process. To ensure the Departments have the information needed to satisfy this requirement, these interim final rules provide that, within 30 business days of the close of each month, each certified IDR entity must report certain data and information in a form and manner specified by the Departments for qualified IDR items and services furnished on or after January 1, 2022 that were subject to payment determinations. Such reporting will be required as an ongoing condition of certification. The Departments anticipate that much of this information will be captured by the certified IDR entities during the normal course of the Federal IDR process. As discussed elsewhere in this preamble, the Departments expect that many of these reporting requirements will be captured as information submitted through the Federal IDR portal. To the extent the necessary information is captured directly through the portal, the Departments do not intend for certified IDR entities to report duplicative information. The Departments will provide additional guidance to certified IDR entities on their reporting obligations.

Under these interim final rules, the certified IDR entity must report the number of Notices of IDR Initiation submitted to the certified IDR entity during the immediately preceding month. In instances where the provider or facility submits the initial Notice of IDR Initiation, the certified IDR entity must submit to the Departments information on the size of the provider practice and the size of the facilities submitting Notices of IDR Initiation. Specifically, the certified IDR entity must specify whether the provider practice has fewer than 20 employees, 20 to 50 employees, 51 to 100 employees, 101–500 employees or more than 500 employees. For facilities, the certified IDR entity must specify whether the facility has 50 or fewer employees, 51 to 100 employees, 101–500 employees, or more than 500 employees. This information will allow the Departments to determine whether smaller providers and facilities have the resources necessary to make use of the Federal IDR process and will assist the Departments in determining whether larger organizations may have an unfair advantage in the process. It also will assist the Departments in determining the effect of the Federal IDR process on horizontal and vertical integration of providers and facilities, and in reporting on this effect to Congress, as required by statute in Code section 9816(c), ERISA section 716(c), PHS Act section 2799A–1(c), and section 109 of the No Surprises Act.

Additionally, with respect to Notices of IDR Initiation submitted during the immediately preceding month, certified IDR entities must report the number of Notices of IDR Initiation for which a final determination was made by the certified IDR entity under these interim final rules. The certified IDR entity also must report a description of the qualified IDR items and services for each Notice of IDR Initiation submitted during the immediately preceding month for which a payment determination was made. This information should include the relevant billing and service codes, such as the CPT, HCPCS, DRG codes, or National Drug Codes (if applicable). The certified IDR entity must also report the relevant geographic region for purposes of the QPA for the qualified IDR items and services with respect to which the Notice of IDR Initiation was provided.

These interim final rules also require that for each determination issued in relation to a Notice of IDR Initiation submitted during the immediately

preceding month, the certified IDR entity must report the offers submitted by each party 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. For example, if one batch of services included services to which two different QPAs applied, and the parties each submitted the same offer for all batched services, then the certified IDR entity must report each offer as a dollar amount and as a percentage of both QPAs. However, if instead each party submitted two offers—one that applied to the services for which one QPA applied and one that applied to the services for which the other QPA applied—then the certified IDR entity is required to report each offer separately and must express each offer as a dollar amount and as a percentage of the applicable QPA. As discussed earlier in this preamble, in making the determination, the certified IDR entity must provide a rationale for its decision, including the extent to which a decision relied on criteria other than the QPA. The certified IDR entity must also report the number of times the out-of-network rate determined exceeded the QPA. Where the QPA differs within a group of batched items and services, the certified IDR entity also must include whether the out-of-network rate (or various out-of-network rates, when more than one out-of-network rate is selected) exceeded the applicable QPA.

For each determination issued in relation to a Notice of IDR Initiation submitted during the immediately preceding month, the certified IDR entity must also report certain additional information on the parties involved. Specifically, the certified IDR entity must report the practice specialty or type of each provider or facility involved in furnishing the qualified IDR items or services at issue with respect to the determination. Additionally, the certified IDR entity must provide each party's name and address.

The certified IDR entity also must report the number of business days taken between the selection of the certified IDR entity and the selection of the payment amount by the certified IDR entity for each determination issued in relation to a Notice of IDR Initiation submitted during the immediately preceding month. Finally, the certified IDR entity must report the total amount of certified IDR entity fees paid to the certified IDR entity during the immediately 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.

8. Reporting of Information Relating to the Federal IDR Process for Qualified IDR Items or Services That Are Air Ambulance Services

Under Code section 9817, ERISA section 717, and PHS Act section 2799A–2, the Departments must publish on a public website for each calendar quarter in 2022 and each calendar quarter in a subsequent year certain information regarding disputes about air ambulance services that differs from the information required under Code section 9816, ERISA section 716, and PHS Act section 2799A–1 regarding disputes for other items and services to which the protections of the No Surprises Act apply. Therefore, 26 CFR 54.9817–2T(b)(3), 29 CFR 2590.717–2(b)(3) and 45 CFR 149.520(b)(3) specify that in applying the requirements of 26 CFR 54.9816–8T(f), 29 CFR 2590.716–8(f), and 45 CFR 149.510(f) to air ambulance services, the information that the certified IDR entity must report within 30 business days of the close of each month, for services furnished on or after January 1, 2022, in a form and manner specified by the Departments, is as follows.

The certified IDR entity must report the number of Notices of IDR Initiation submitted to the certified IDR entity that pertain to air ambulance services during the immediately preceding month. Additionally, with respect to Notices of IDR Initiation submitted during the immediately preceding month, the certified IDR entity must report the number of Notices of IDR Initiation for which there was a determination under 26 CFR 54.9816–8T(c)(4)(ii), 29 CFR 2590.716–8(c)(4)(ii), and 45 CFR 149.510(c)(4)(ii), as applied by 26 CFR 54.9817–2T(b)(1), 29 CFR 2590.717–2(b)(1), and 45 CFR 149.520(b)(1) for air ambulance services. The certified IDR entity must also report the number of times the out-of-network rate determined (or agreed to) exceeded the QPA for air ambulance services.

With respect to each Notice of IDR Initiation submitted during the immediately preceding month, 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 Notice of IDR Initiation. For each Notice of IDR Initiation, the certified IDR entity must also provide the amount of the offer submitted by a plan or issuer (as applicable) and by the nonparticipating provider of air ambulance services, expressed as both a dollar amount and the corresponding percentage of the QPA represented by that dollar amount. Of these amounts, the certified IDR entity must also indicate 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 both a dollar amount and a percentage of the QPA. The certified IDR entity must also 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 the vehicle (if the parties have provided such information). The certified IDR entity must also report the identity of each plan or issuer, and provider of air ambulance services, with respect to the Notice of IDR Initiation submitted during the immediately preceding month. Specifically, each certified IDR entity must provide each party's name and address, as applicable. The certified IDR entity must report the number of business days taken between the selection of the certified IDR entity and the certified IDR entity's selection of the payment amount. Finally, the certified IDR entity must also report the total amount of certified IDR entity fees paid to the certified IDR entity for the immediately preceding month. This total amount of certified IDR entity fees should not include amounts refunded by the certified IDR entity to prevailing parties or the administrative fees that are collected on behalf of the Departments.

9. Extension of Time Periods for Extenuating Circumstances

Under Code section 9816(c)(9), ERISA section 716(c)(9), PHS Act section 2799A–1(c)(9), and these interim final rules, the time periods specified in these interim final rules (other than the timing of the payments, including, if applicable, payments to the provider, facility or provider of air ambulance services) may be extended in the case of

extenuating circumstances at the Departments' discretion. The Departments may extend time periods on a case-by-case basis if the extension is necessary to address delays due to matters beyond the control of the parties or for good cause. Such extension may be necessary if, for example, a natural disaster impedes efforts by plans, issuers, providers, facilities, and providers of air ambulance services to comply with the terms of these interim final rules. Additionally, for the extension to be granted, the parties must attest that prompt action will be taken to ensure that the payment determination under this section is made as soon as administratively practicable. 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.

E. Applicability of the Rules Regarding the Federal IDR Process

The applicability of these interim final rules with respect to the items and services, plans and issuers, and providers, facilities, and providers of air ambulance services subject to these interim final rules, parallels that of the July 2021 interim final rules to ensure that the surprise billing protections of the No Surprises Act are implemented in a consistent manner. Finally, these interim final rules provide standards for certifying IDR entities, and standards for certified IDR entities. Accordingly, these interim final rules amend 26 CFR 54.9816–2T, 29 CFR 2590.716–2, and 45 CFR 149.20 to include references to 26 CFR 54.9816–8T and 54.9817–2T; 29 CFR 2590.716–8 and 2590.717–2; and 45 CFR 149.510 and 149.520 to ensure that the items and services, as well as entities subject to the balance billing protections under the July 2021 interim final rules, are eligible for the Federal IDR process under these interim final rules. The Departments solicit comment on whether any differences or departures from the approach taken in the July 2021 interim final rules are warranted.

These interim final rules implementing the Federal IDR process generally apply to group health plans and health insurance issuers offering group or individual health insurance coverage (including grandfathered health plans) with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022 and to certified IDR entities, health care providers and facilities, and providers of air ambulance services beginning on January 1, 2022. The interim final rules regarding IDR entity certification at 26 CFR 54.9816–8T(a), 26 CFR 54.9816–8T(e), 29 CFR 2590.718–8(a), 29 CFR 2590.718–8(e), 45 CFR 149.510(a) and 45 CFR 149.510(e), are applicable beginning on October 7, 2021 so that the Departments can begin certifying IDR entities before the Federal IDR process becomes applicable. The term ''group health plan'' includes both insured and self-insured group health plans. Group health plans include private employment-based group health plans subject to ERISA, non-Federal governmental plans (such as plans sponsored by states and local governments) subject to the PHS Act, and church plans subject to the Code. Individual health insurance coverage includes coverage offered in the individual market, through or outside of an Exchange, and includes student health insurance coverage as defined at 45 CFR 147.145. In addition, under the OPM interim final rules, FEHB carriers must comply with the Departments' interim final rules, subject to OPM regulation and contract provisions. The No Surprises Act amended section 1251(a) of the Affordable Care Act to specify that PHS Act sections 2799A–1, 2799A–2, and 2799A–7 apply to grandfathered health plans for plan years beginning on or after January 1, 2022. Therefore, these interim final rules apply to grandfathered health plans (as defined in 26 CFR 54.9815–1251, 29 CFR 2590.715–1251, and 45 CFR 147.140) for plans years beginning on or after January 1, 2022. In addition, these interim final rules implementing the Federal IDR process apply to certain non-grandfathered health insurance coverage in the individual and small group markets with respect to which CMS has announced it will not take enforcement action with respect to certain specified market requirements even though the coverage is out of compliance with those requirements (sometimes referred to as grandmothered or transitional plans). These interim final rules implementing the Federal IDR process do not apply to health reimbursement arrangements (HRAs), or other account-based group health plans, as described in 26 CFR 54.9815–2711(d)(6)(i), 29 CFR 2590.715–2711(d)(6)(i), and 45 CFR 147.126(d)(6)(i), that make reimbursements subject to a maximum fixed dollar amount for a period, as the benefit design of these plans makes concepts related to surprise billing, including the IDR process, inapplicable. Additionally, the Departments expect that account-based group health plans typically will be integrated with other coverage that will have protections against surprise billing (such as individual coverage HRAs) or will be otherwise exempt from these requirements (such as excepted benefit HRAs). Therefore, under these interim final rules, these requirements do not apply to individual coverage HRAs and other account-based plans, consistent with the existing applicability provisions in 26 CFR 54.9816–2T, 29 CFR 2590.716–2, and 45 CFR 149.20 with respect to other requirements in 26 CFR part 54, 29 CFR subpart D, and 45 CFR part 149. The Departments note that by statute certain plans and coverage are not subject to the interim final rules implementing the Federal IDR process. This includes a plan or coverage consisting solely of excepted benefits [48] as well as short-term, limited-duration insurance as defined under PHS Act section 2791(b)(5).[49] Excepted benefits are described in Code section 9832, ERISA section 733 and PHS Act section 2791. Under PHS Act section 2791(b)(5), short-term, limited-duration insurance is excluded from the definition of individual health insurance coverage and is therefore exempt from these interim final rules regarding the Federal IDR process and the statutory provisions these interim final rules implement. In addition, these interim final rules do not apply to retiree-only plans, because ERISA section 732(a) and Code section 9831(a) generally provide that part 7 of ERISA and chapter 100 of the Code respectively do not apply to plans with fewer than two participants who are current employees (including retiree-only plans, which cover fewer than two participants who are current employees). Title XXVII of the PHS Act, as amended by the Affordable Care Act, no longer contains a parallel provision at section 2721(a) of the PHS Act. However, as explained in prior rulemaking, HHS will not enforce the requirements of title XXVII of the PHS Act with respect to non-Federal governmental retiree-only plans and encourages states to adopt a similar approach with respect to health insurance coverage of retiree-only plans.[50] HHS intends to continue to follow this same approach, including with respect to the new market reforms established in the No Surprises Act.

[48] Code section 9831, ERISA section 732, and PHS Act section 2722; 26 CFR 54.9831–1(c), 29 CFR 2590.732(c), and 45 CFR 146.145(b).

[49] 26 CFR 54.9801–2, 29 CFR 2590.701–2, and 45 CFR 144.103.

[50] 75 FR 34537, 34540 (June 17, 2010).

IV. External Review and Section 110 of the No Surprises Act

Section 110 of the No Surprises Act states that ''[i]n applying the provisions of section 2719(b) of the [PHS Act] to group health plans and health insurance issuers offering group or individual health insurance coverage, the Secretary of HHS, Secretary of Labor, and Secretary of the Treasury, shall require, beginning not later than January 1, 2022, the external review process described in paragraph (1) of such section to apply with respect to any adverse determination by such a plan or issuer under Code section 9816 or 9817, ERISA section 716 or 717 or PHS Act section 2799A–1 or 2799A–2, including with respect to whether an item or service that is the subject to such a determination is an item or service to which such respective section applies.'' The statute defines the terms group health plan and health insurance issuer by reference to PHS Act section 2791, ERISA section 733, and Code section 9832, as applicable.

These interim final rules implement section 110 of the No Surprises Act in two ways. First, these interim final rules amend the scope of claims eligible for external review set forth in the regulations implementing PHS Act section 2719 to include adverse benefit determinations related to compliance with the surprise billing and cost-sharing protections under the No Surprises Act. Additionally, these interim final rules clarify the scope of external review in light of new surprise billing and cost-sharing protections under the No Surprises Act and provide examples of which types of adverse benefit determinations will be eligible for external review. Second, these interim final regulations extend the external review requirement to grandfathered health plans and health insurance issuers for adverse benefit determinations involving items and services covered by requirements of Code section 9816 or 9817, ERISA section 716 or 717, or PHS Act section 2799A–1 or 2799A–2, as added by the No Surprises Act. The Departments solicit comment on whether and to what extent additional guidance or changes to the existing regulations are needed to protect participants, beneficiaries, and enrollees from surprise medical bills, consistent with section 110 of the No Surprises Act.

A. Scope of Claims Eligible for External Review

Under PHS Act section 2719 and its implementing regulations, non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage must comply with any applicable state external review process, if that process includes, at a minimum, the consumer protections set forth in the NAIC Uniform External Review Model Act.[51] However, if the state external review process does not meet this standard, or if a plan or issuer is not subject to state insurance regulation, the plan or issuer must comply with the Federal external review process, as described in 26 CFR 54.9815–2719(d), 29 CFR 2590.715–2719(d), and 45 CFR 147.136(d).

State external review processes that meet the minimum standards must provide for the external review of adverse benefit determinations based on requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit. The Federal external review process must be available for any adverse benefit determination by a plan or issuer that involves medical judgment, as well as a rescission of coverage. In the Departments' view, the scope of claims eligible for external review under state processes that meet the minimum standards for approval is substantially similar to the scope of claims eligible for external review under the Federal process.

In 2010, the Departments issued interim final rules that set forth the original scope of claims eligible for external review under the Federal external review process.[52] Specifically, any adverse benefit determination (including final internal adverse benefit determinations) could be reviewed unless it was related to a participant's or beneficiary's failure to meet the requirements for eligibility under the terms of a group health plan (for example, worker classification and similar issues were not within the scope of the Federal external review process). In response to stakeholder comments, the Departments issued an amendment in 2011 suspending the original rule and narrowing the scope to claims that involve: (1) Medical judgment (including, but not limited to, those based on the plan's or issuer's requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit, or its determination that a treatment is experimental or investigational), as determined by the external reviewer; and (2) a rescission of coverage (whether or not the rescission has any effect on any particular benefit at the time).[53] The Departments finalized the narrowed scope in the 2015 final rules.[54]

Although the scope of Federal external review was narrowed in comparison to the scope as outlined in the 2010 interim final regulations, the Departments note that the scope of claims that are eligible for external review in general is broad, as many adverse benefit determinations involve medical judgment. The 2015 final regulations issued by the Departments include the following examples: (1) Whether treatment by a specialist is medically necessary or appropriate (pursuant to the plan's standard for medical necessity or appropriateness); (2) whether treatment involved ''emergency care'' or ''urgent care,'' affecting coverage or the level of coinsurance; (3) a determination that a medical condition is a preexisting condition; (4) whether a participant or beneficiary is entitled to a reasonable alternative standard for a reward under the plan's wellness program; and (5) whether a plan or issuer is complying with the nonquantitative treatment limitation provisions of the Mental Health Parity and Addiction Equity Act.[55]

The Departments have similarly provided a number of additional examples in preambles to rulemaking under PHS Act section 2719 to provide further clarification on the broad scope of the external review process. In the preamble to interim final rules issued in 2011, the Departments stated that examples of medical judgment would include the appropriate health care setting for providing medical care to an individual (such as outpatient versus inpatient care or home care versus rehabilitation facility); a plan's general exclusion of an item or service (such as speech therapy), if the plan covers the item or service in certain circumstances based on a medical condition (such as, to aid in the restoration of speech loss or impairment of speech resulting from a medical condition); and the frequency, method, treatment, or setting for a recommended preventive service, to the extent not specified in the recommendation or guideline of the U.S. Preventive Services Task Force, the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention, or the Health

[51] Available at *https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/affordable-care-act/for-employers-and-advisers/naic-uniform-review-model-act.pdf.*

[52] 75 FR 43329 (July 23, 2010).

[53] 76 FR 37207 (June 10, 2011).

[54] 80 FR 72191 (Nov. 18, 2015).

[55] 26 CFR 54.9815–2719(d)(1); 29 CFR 2590.715–2719(d)(1); 45 CFR 147.136(d)(1).

Resources and Services Administration.[56] In the preamble to final rules issued in 2015, the Departments also clarified that issues related to how a claim is coded may also involve medical judgment because ''[m]edical judgment is necessary to determine whether the correct code was used in the patient's case.'' [57]

Consistent with this principle, the Departments are of the view that many claims that result in an adverse benefit determination involving items and services subject to the surprise billing and cost-sharing protections under the No Surprises Act generally would be eligible for external review under the current scope as specified in the 2015 final regulations. However, as stated above, section 110 of the No Surprises Act directs the Departments to require the external review process under PHS Act section 2719 to apply with respect to any adverse determination by a plan or issuer under PHS Act section 2799A–1 or 2799A–2, ERISA section 716 or 717, or Code section 9816 or 9817, including with respect to whether an item or service that is subject to such a determination is an item or service to which the respective section applies. The Departments are of the view that it is important to ensure that consumers can avail themselves of external review in these situations and ensure that they are afforded full protection against surprise medical costs (including cost sharing), as intended by the No Surprises Act. Accordingly, these interim final rules amend the 2015 final rules to broaden the scope of external review requirements and explicitly require, to the extent not already covered, that any adverse determination that involves consideration of whether a plan or issuer is complying with PHS Act section 2799A–1 or 2799A–2, ERISA section 716 or 717, or Code section 9816 or 9817 is eligible for external review.

These interim final rules also amend the 2015 final regulations to add five new examples (examples number 3 through 7 in the regulation text) to clarify how the external review requirements apply to certain adverse benefit determinations involving items and services within the scope of the surprise billing and cost-sharing protections for out-of-network emergency services, nonemergency services performed by nonparticipating providers at participating facilities, and air ambulance services furnished by nonparticipating providers of air ambulance services under section Code section 9816 or 9817, ERISA section 716 or 717, or PHS Act section 2799A–1 or 2799A–2. The first new example illustrates that any determination of whether a claim is for treatment for emergency services that involves medical judgment or consideration of compliance with the cost-sharing and surprise billing protections is eligible for external review.

The second new example clarifies that whether a claim for items and services furnished by a nonparticipating provider at an in-network facility is subject to the protections under the No Surprises Act is eligible for external review because adjudication of the claim requires consideration of health care setting and level of care or compliance with cost-sharing and surprise billing protections.

The third new example clarifies that whether an individual was in a condition to receive a notice about the availability of the protections under the No Surprises Act and give informed consent to waive those protections is a claim eligible for external review because adjudication of the claim involves consideration of compliance with the cost-sharing and surprise billing protections and medical judgment.

The fourth new example illustrates that whether a claim for items and services is coded correctly, consistent with the treatment an individual actually received, is a claim eligible for external review because adjudication of the claim involves medical judgment.

The fifth new example illustrates that consideration of whether cost-sharing was appropriately calculated for claims for ancillary services provided by an out-of-network provider at an in-network facility involves consideration of compliance with the cost-sharing and surprise billing protections and is a claim eligible for external review.

The Departments solicit comment on these examples and whether any additional examples are needed. The Departments intend to ensure that this provision is implemented in a manner that affords consumers broad protection under section 110 of the No Surprises Act.

B. Application to Grandfathered Plans and Coverage

PHS Act section 2719 and its implementing regulations do not currently apply to coverage offered by health insurance issuers and group health plans that are grandfathered health plans because section 1251 of the Affordable Care Act provides that PHS Act section 2719 does not apply to grandfathered plans and coverage.

These interim final rules amend the regulations under PHS Act section 2719 to require grandfathered plans and coverage to provide for external review of claims covered by the protections of the No Surprises Act for plan years (or, in the individual market, policy years) beginning on or after January 1, 2022. This change is grounded in the text of section 110 of the No Surprises Act, in addition to the policy reasons stated earlier in this preamble regarding the Departments' intent to implement this provision broadly. Section 110 states that external review requirements shall ''apply with respect to any adverse determination by such a plan or issuer under section 2799A–1 or 2799A–2 of the PHS Act, section 716 or 717 of ERISA, or section 9816 or 9817 of the Code[.]'' These sections of the PHS Act, ERISA, and the Code, as well as all the other provisions of the No Surprises Act, as discussed in section I.A of this preamble, are all applicable to grandfathered plans and coverage. Thus, to ensure that adverse benefit determinations under grandfathered plans and coverage for claims subject to those provisions are eligible for external review, external review requirements must be applicable to grandfathered plans and coverage for those claims. The Departments solicit comment on this amendment, including whether any additional guidance is warranted to help grandfathered plans and issuers comply with these requirements.

The Departments recognize that the internal claims and appeals rules under 29 CFR 2560.503–1, as incorporated under regulations implementing PHS Act section 2719,[58] do not apply to issuers offering grandfathered coverage in the individual market, or grandfathered non-Federal Government plans. Those grandfathered plans and issuers offering that grandfathered coverage must make external review available for adverse benefit determinations under PHS Act section 2799A–1 or 2799A–2 when an enrollee has exhausted applicable appeal rights under state law or under the terms of the enrollee's coverage. In cases where these plans and issuers are not subject to a requirement to have an internal appeals process and have not otherwise instituted such a process, they must allow a claimant to request external review of an adverse benefit determination of claims covered by the protections under PHS Act sections 2799A–1 or 2799A–2 upon receipt of the adverse benefit determination.

[56] 76 FR 37207, 37216 (June 10, 2011).

[57] 80 FR 72191, 72209 (Nov. 18, 2015).

[58] 26 CFR 54.9815–2719; 29 CFR 2590.715–2719(c)(2)(i); 45 CFR 147.136.

V. Federal IDR Process for FEHB Carriers—Office of Personnel Management

OPM amends existing 5 CFR 890.114(a) to include references to the Departments' regulations to clarify that FEHB carriers are also subject to the Federal IDR process set forth in those regulations with respect to a qualified IDR item or service furnished by an FEHB 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 FEHB carrier's contract. Through new paragraph 5 CFR 890.114(d), OPM adopts the Departments' rules as necessary to properly integrate the new standards with existing FEHB Program structure and sets forth the circumstances in which OPM will enforce these rules as applied to FEHB carriers, including by requiring carrier notice to the Director, in addition to the Departments, of an FEHB carrier's notice of initiation, or receipt of a provider's notice of initiation, the Federal IDR process. OPM 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 rules, all out-of-network rate determinations regarding qualified IDR items or services 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.

VI. Overview of the Interim Final Rules Regarding Protections for the Uninsured—The Department of Health and Human Services

A. Good Faith Estimates for Uninsured (or Self-Pay) Individuals

1. Scope

The No Surprises Act adds PHS Act section 2799B–6(2), which requires health care providers and health care facilities, upon scheduling an item or service to be furnished to an individual or upon request of an individual, to inquire about such individual's health coverage status and to provide a notification (in clear and understandable language) of the good faith estimate of the expected charges for furnishing such item or service (including any item or service that is reasonably expected to be provided in conjunction with such scheduled or requested item or service and such item or service reasonably expected to be so provided by another provider or facility), with the expected billing and diagnostic codes for any such item or service.

In the case that the individual requesting a good faith estimate for an item or service or seeking to schedule an item or service to be furnished, is not enrolled in a certain type of plan or coverage or is not seeking to file a claim with such type of plan or coverage, PHS Act section 2799B–6(2)(B), and these interim final rules at 45 CFR 149.610, require providers and facilities to furnish the good faith estimate to the individual. These requirements under 45 CFR 149.610 apply only to good faith estimate notifications for uninsured (or self-pay) individuals as described in 45 CFR 149.610(a)(2)(xii) of these interim final rules. As discussed in section I.C of this preamble, these interim final rules do not include requirements implementing PHS Act section 2799B–6(2)(A), which requires providers and facilities to furnish good faith estimates to individuals' plans or issuers.

2. Definitions

For purposes of 45 CFR 149.610, HHS is defining certain terms at 45 CFR 149.610(a). Specifically, ''authorized representative'' means an individual authorized under state law to provide consent on behalf of the uninsured (or self-pay) individual, provided that the individual is not a provider affiliated with the facility or an employee of the facility represented in the good faith estimate, unless such provider or employee is a family member of the uninsured (or self-pay) individual. HHS considered defining authorized representative using the same definition as in 45 CFR 149.410 and 149.420; however, the definition in these interim final rules contain amendments to account for concepts that are not relevant to uninsured (or self-pay) individuals such as removing references to nonparticipating providers, participants, beneficiaries, and enrollees.

These interim final rules define, ''convening health care provider or convening health care facility (convening provider or convening facility)'' as the provider or facility who receives the initial request for a good faith estimate from an uninsured (or self-pay) individual and who is or, in the case of a request, would be responsible for scheduling the primary item or service as defined in these interim final rules. As discussed elsewhere in this preamble, the convening provider is responsible for providing the good faith estimate to an uninsured (or self-pay) individual.

HHS considered putting the responsibility for providing the good faith estimate on the ''treating health care provider,'' as defined in 45 CFR 149.30, but for many scheduled items or services, multiple providers and facilities could participate in delivering an individual's care, or be considered, a ''treating health care provider''. Because it is likely that an individual would only schedule an item or service or request a good faith estimate from one of the treating providers or facilities, the convening provider or facility would likely need to request additional scheduling from other providers or facilities to participate in delivering care. Therefore, such a provider or facility would need to alert the other providers or facilities who are providing items or services in conjunction with the scheduled item or service, when items or services are scheduled or a good faith estimate is requested. Furthermore, HHS understands that multiple providers and facilities may bill an individual for the respective items or services provided during a period of care. Therefore, it is important to define who is responsible for furnishing the good faith estimate to the individual that is inclusive of all the items or services to be provided by co-providers and co-facilities involved in the scheduled items or services or the items or services for which a good faith estimate is requested.

In these interim final rules, ''co-health care provider or co-health care facility (co-provider or co-facility)'' means a provider or facility other than a convening provider or a convening facility that furnishes items or services that are customarily provided in conjunction with a primary item or service (as defined for purposes of this section). Because PHS Act section 2799B–6(2) requires that the good faith estimate include any item or service that is reasonably expected to be provided in conjunction with such scheduled item or service (or such item or service for which a good faith estimate is requested) and such an item or service reasonably expected to be so provided by another health care provider or health care facility, HHS is distinguishing co-providers and co-facilities from the convening provider or convening facility who will furnish the good faith estimate inclusive of estimates from co-providers and co-facilities.

''Diagnosis code'' means the code that describes an individual's disease,

disorder, injury, or other related health conditions using the International Classification of Diseases (ICD) code set. In establishing requirements for implementation of HIPAA's Administrative Simplification provisions, HHS adopted specific code sets for diagnoses and procedures for use in standard health care transactions. The definition of diagnosis code used in this section aligns with the definition contained in the HIPAA Administrative Simplification standards at 45 CFR part 162.[59]

For purposes of 45 CFR 149.610, ''expected charge'' means, for an item or service, the cash pay rate or rate established by a provider or facility for an uninsured (or self-pay) individual, reflecting any discounts for such individuals, where the good faith estimate is being provided to an uninsured (or self-pay) individual; or the amount the provider or facility would expect to charge if the provider or facility intended to bill a plan or issuer directly for such item or service when the good faith estimate is being furnished to a plan or issuer.

HHS understands that providers and facilities establish gross charges or chargemaster rates that are considered their standard charge for an item or services and then often discounts are applied depending on the payer (with the exception of state laws that specify payment rates). For instance, in providing a good faith estimate to a plan or issuer, the provider or facility may include as the expected charge the undiscounted gross charge or chargemaster rate, which would then be used by the plan or issuer to determine the out-of-pocket payment amount of an insured individual. HHS understands that providers and facilities often make adjustments to their gross charges or chargemaster rates to establish a self-pay rate for uninsured (or self-pay) individuals. HHS is of the view that if an individual is not enrolled in a plan or coverage or is enrolled but is not seeking to have a claim for such item or service submitted to their plan or coverage, the expected charges included in the good faith estimate should reflect what the provider or facility expects to bill or charge the payer (in this case the uninsured or self-pay individual), and therefore for the purpose of these interim final rules, HHS has defined expected charges specific to what the uninsured (or self-pay) individual would be expected to pay.

HHS is of the view that the estimate of expected charges must reflect the anticipated billed charges, including any expected discounts or other relevant adjustments that the provider or facility expects to apply to an uninsured (or self-pay) individual's billed charges because of the role of the good faith estimate in the patient-provider dispute resolution process under PHS Act section 2799B–7 and as specified in 45 CFR 149.620. Under PHS Act section 2799B–7, an uninsured (or self-pay) individual can seek a determination from an SDR entity if the total billed charge from a provider or facility is substantially in excess of the expected charges listed in the good faith estimate for the provider or facility. Therefore, as discussed in detail below, these interim final rules require that for each item or service listed in the good faith estimate, a provider or facility must include the expected charge for each item or service, reflecting any available discounts or other relevant adjustments that the provider or facility expects to apply to an uninsured (or self-pay) individual's billed charges. For instance, certain hospital organizations that meet the general requirements for tax exemption under Code section 501(c)(3), are also required to meet the Financial Assistance Policy (FAP) requirements under Code sections 501(r)(4) through (6).[60] In this example, any adjustments expected to be applied under the FAP would be factored in and reflected in the amount reported in the good faith estimate for items or services. To promote more transparency, HHS considered requiring both undiscounted list prices and discounted prices to be included when discounted prices apply. HHS seeks comment on whether providers and facilities should be required to include both the list price and discounted price for an item or service when discounts apply.

Consistent with PHS Act section 2799B–6(2), these interim final rules define the term ''good faith estimate'' to mean a notification of expected charges for a scheduled or requested item or service,[61] including items or services that are reasonably expected to be provided in conjunction with such scheduled or requested item or service, provided by a convening provider, convening facility, co-provider, or co-facility.

''Health care facility (facility)'' is defined more broadly than the definition in 45 CFR 149.30, which applies in the context of balance billing protections for non-emergency services. For purposes of 45 CFR 149.610, ''health care facility (facility)'' means an institution (such as a hospital or hospital outpatient department, critical access hospital, ambulatory surgical center, rural health center, federally qualified health center, laboratory, or imaging center) in any state in which state or applicable local law provides for the licensing of such an institution, that is licensed as such an institution pursuant to such law or is approved by the agency of such state or locality responsible for licensing such institution as meeting the standards established for such licensing. While HHS considered applying the definition of health care facility from 45 CFR 149.30, doing so would limit the scope of providers and facilities for which 45 CFR 149.610 applies to only those providers relevant to the balance billing protections related to nonemergency items or services furnished by participating providers in nonparticipating facilities. The provisions in PHS Act section 2799B–6 do not specify such limitations.

For purposes of 45 CFR 149.610, ''health care provider (provider)'' means a physician or other health care provider who is acting within the scope of practice of that provider's license or certification under applicable State law, including a provider of air ambulance services. As the Departments noted in the July 2021 interim final rules, the No Surprises Act does not define ''provider.'' Some provisions use the word in a manner that includes providers of air ambulance services, while other provisions that use the word are inapplicable to providers of air ambulance services by the terms of the provisions. In this case, HHS is of the view that interpreting the term to include providers of air ambulance services in this context is critical to ensuring individuals obtain the benefits of a good faith estimate for a service that can be extremely costly. HHS recognizes that individuals will likely not be able to obtain a good faith estimate for emergency air ambulance services, as these are not generally scheduled in advance. However, making these requirements applicable to providers of air ambulance services helps to ensure that individuals can obtain a good faith estimate upon request or at the time of scheduling non-emergency air ambulance services, for which coverage often is not provided by a plan or issuer and thus even individuals with coverage often must self-pay.

[59] *https://www.cms.gov/regulations-and-guidance/administrative-simplification/code-sets.*

[60] Financial Assistance Policy and Emergency Medical Care Policy. *https://www.irs.gov/charities-non-profits/financial-assistance-policy-and-emergency-medical-care-policy-section-501r4.*

[61] For purposes of simplicity of language, these interim final rules in some instances refer to a requested good faith estimate for an item or service, as a requested item or service.

''Items or services'' has the same meaning given the term in 45 CFR 147.210(a)(2), which includes all encounters, procedures, medical tests, supplies, prescription drugs, durable medical equipment, and fees (including facility fees), provided or assessed in connection with the provision of health care. The definition of items or services in 45 CFR 147.210(a)(2) encompasses and accurately defines the types of items or services that are expected to be reported in the good faith estimate including items or services such as those related to dental health, vision, substance use disorders and mental health. HHS also clarifies that some items or services may not be included in a good faith estimate because they are not typically scheduled in advance and are not typically the subject of a requested good faith estimate, such as urgent, emergent trauma, or emergency items or services; however, HHS clarifies that to the extent an urgent care appointment is scheduled at least 3 days in advance, these interim final rules require a provider or facility to provide a good faith estimate.[62]

These interim final rules also define the term ''period of care'' to mean the day or multiple days during which the good faith estimate for scheduled or requested item or service (or set of scheduled or requested items or services) are furnished or are anticipated to be furnished, regardless of whether the convening provider, convening facility, co-providers, or co-facilities are furnishing such items or services, and also includes the period of time during which any facility equipment and devices, telemedicine services, imaging services, laboratory services, and preoperative and postoperative services that would not be scheduled separately by the individual, are furnished. HHS considered using the term episode of care but understands that the term episode of care is used within many different contexts regarding the provision of health care items or services.[63] In the context of this section, HHS is of the view that it is important to use the term period of care in order to clarify which items or services are expected to be provided in a good faith estimate.

''Primary item or service'' means the item or service to be furnished by the convening provider or convening facility that is the initial reason for the visit. HHS is of the view that additional distinctions beyond the definition of ''items or services'' must be made in order for providers and facilities to furnish clear and understandable good faith estimates. HHS considered using the term ''scheduled item or service'' which would more directly align with the statutory language. However, such distinction would have excluded the statutory provision whereby a good faith estimate must be issued upon the request of an uninsured (or self-pay) individual when items or services have not been scheduled. HHS is of the view that using the term ''primary item or service'' provides clarity for providers and facilities to establish and identify a main item or service for which a good faith estimate is being issued. Based on the primary item or service, the provider or facility could subsequently identify and include all items or services that would be furnished in conjunction with the primary item or service, and such items or services reasonably expected to be provided by a co-provider or co-facility.

''Service code'' means the code that identifies and describes an item or service using the CPT, HCPCS, DRG or National Drug Code (NDC) code sets. As noted earlier, in establishing requirements for implementation of HIPAA's Administrative Simplification provisions, HHS adopted specific code sets for diagnoses and procedures for use in standard health care transactions. The definition of service code used in this section aligns with the definition contained in the HIPAA Administrative Simplification standards at 45 CFR part 162.[64]

These interim final rules define the term ''uninsured (or self-pay) individual'' to mean an individual who does not have benefits for an item or service under a group health plan, group or individual health insurance coverage offered by a health insurance issuer, Federal health care program (as defined in section 1128B(f) of the Social Security Act), or a health benefits plan under chapter 89 of title 5, United States Code; or an individual who has benefits for such item or service under a group health plan or individual or group health insurance coverage offered by a health insurance issuer, or a health benefits plan under chapter 89 of title 5, United States Code but who does not seek to have a claim for such item or service submitted to such plan or coverage. These individuals are often referred to as self-pay individuals, therefore these interim final rules include the term self-pay when discussing uninsured individuals. As discussed elsewhere in this preamble, for the purposes of the interim final rules at 45 CFR 149.610 that implement PHS Act sections 2799B–6(1) and 2799B–6(2)(B), HHS is adopting the definition of uninsured (or self-pay) individuals from PHS Act sections 2799B–7 in order to align these two related sections.

HHS understands, and is of the view that it is appropriate, that consumers may request a good faith estimate without actually scheduling items or services to compare costs and make a decision about from which provider or facility they will seek care, or whether they will submit a claim to insurance or self-pay. These individuals would be considered self-pay for purposes of the requirement on the provider or facility to provide a good faith estimate. HHS clarifies that if an individual requests a good faith estimate as a self-pay individual and then ultimately decides to submit a claim to the individual's plan or issuer for the billed charges, the individual is no longer considered a self-pay individual as defined in these interim final rules and would not be eligible to use the patient-provider dispute resolution process as defined in 45 CFR 149.620. HHS also clarifies that for purposes of 45 CFR 149.610 and 149.620, the definition of uninsured (or self-pay) individuals includes individuals enrolled in short-term, limited-duration insurance, as defined in regulations at 26 CFR 54.9801–2, 29 CFR 2590.701–2, and 45 CFR 144.103, and not also enrolled in a group health plan, group or individual health insurance coverage offered by a health insurance issuer, Federal health care program (as defined in section 1128B(f) of the Social Security Act), or a health benefits plan under chapter 89 of title 5, United States Code.

HHS seeks comment on the terms defined in these interim final rules for purposes of this section. HHS is particularly interested in receiving information related to the appropriateness and usability of these definitions and whether additional terms should be included or defined.

3. Requirements for Providers and Facilities

For purposes of PHS Act sections 2799B–6, 2799B–6(1), and 2799B–6(2)(B) that are being implemented in these interim final rules, providers and facilities must meet certain requirements related to uninsured (or self-pay) individuals. Section 2799B–6 places the requirement to provide a good faith estimate, within the statutorily defined timeframes, upon

[62] Certain urgent, emergent trauma, or emergency care services may be subject to other protections discussed in the July 2021 interim final rules (86 FR 36872).

[63] *https://www.healthaffairs.org/do/10.1377/hblog20190326.202031/full/.*

[64] *https://www.cms.gov/regulations-and-guidance/administrative-simplification/code-sets.*

providers and facilities with whom an individual schedules an item or service, or from whom an individual requests a good faith estimate for an item or service, defined in these interim final rules as the convening provider or facility. However, HHS notes that section 2799B–6(2) requires that a good faith estimate of expected charges include any item or service that is reasonably expected to be provided in conjunction with such scheduled item or service and such items or services reasonably expected to be so provided by another provider or facility, defined in these interim final rules as a co-provider or co-facility.

In order for good faith estimates to provide individuals with the most accurate information available, HHS is of the view that it is not feasible to fully implement the statutory provisions under PHS Act section 2799B–6(2) without establishing certain requirements for convening providers and facilities and co-providers and co-facilities. In implementing these provisions, HHS is of the view that to the extent possible, an uninsured (or self-pay) individual is entitled to receive a clear and understandable document that informs the uninsured (or self-pay) individual of the expected costs associated with the care that they are considering or are scheduled to receive, and in order to do so, the expected charges that inform the good faith estimate should be provided by all providers and facilities who are reasonably expected to furnish the items or services that would be billed to the uninsured (or self-pay) individual. HHS seeks comment on publicly available resources, methods, and potential standardized formatting or design that could facilitate communication of good faith estimate information in a clear and understandable manner.

To this end, HHS is of the view that issuance of separate good faith estimate documents from each provider and facility involved in furnishing care for a primary item or service would place undue administrative burden upon uninsured (or self-pay) individuals to then aggregate various good faith estimates received in order to obtain a clear and understandable representation of all expected charges for an item or service. However, HHS also acknowledges that in some instances, it would not be practical nor feasible to expect a convening provider or facility to have sufficient knowledge of the expected charges for each item or service provided by a co-provider or co-facility. HHS is also of the view that convening providers and facilities should not be held responsible for the accuracy of expected charges for items or services for which the convening provider or facility does not bill the uninsured (or self-pay) individual (for instance, under the patient-provider dispute resolution process as described in 45 CFR 149.620).

HHS notes that the accuracy of the good faith estimate is relevant because if the actual billed charges substantially exceed the amounts reported in the good faith estimate, an uninsured (or self-pay) individual could seek a determination under the patient-provider dispute resolution process under 45 CFR 149.620. HHS is also of the view that it would not be appropriate to solely require that a convening provider or facility be accountable through the patient-provider dispute resolution process for items or services for which the convening provider or facility did not bill the uninsured (or self-pay) individual.

Therefore, HHS is using its general rulemaking authority to establish requirements under 45 CFR 149.610, discussed in detail below, for convening providers and facilities as well as co-providers and co-facilities for issuance of good faith estimates for uninsured (or self-pay) individuals. HHS is of the view that use of its general rulemaking authority to establish such requirements is necessary in order to implement the provisions of PHS Act section 2799B–6 in a manner that balances the statutory intent of providing uninsured (or self-pay) individuals with clear and understandable information regarding the expected costs of items or services, the responsibilities of various providers and facilities, and the inherent accountability established in the statute through the interaction between the issuance of good faith estimates under PHS Act section 2799B–6 and the patient-provider dispute resolution process under PHS Act section 2799B–7.

i. Requirements for Convening Providers and Facilities

These interim final rules establish in 45 CFR 149.610(b)(1) certain requirements for the convening provider or facility to verify whether an individual meets the definition of an uninsured (or self-pay) individual, to provide oral and written communication regarding the requirement to provide good faith estimates to uninsured (or self-pay) individuals upon scheduling an item or service or upon request, and to provide timely good faith estimates to uninsured (or self-pay) individuals. To determine whether a good faith estimate must be provided to an individual under 45 CFR 149.610(b)(1), the convening provider or facility must inquire and determine if the individual meets the definition of an uninsured (or self-pay) individual as established in 45 CFR 149.610(a)(2).

HHS is of the view that conveying information about the availability of good faith estimates prior to or upon scheduling an item or service aligns with and is most relevant when uninsured (or self-pay) individuals are considering whether to proceed with medical care while interacting with their providers or facilities. Requiring that providers and facilities notify uninsured (or self-pay) individuals of the availability of good faith estimates will help ensure that all uninsured (or self-pay) individuals understand that they can request a good faith estimate and will also receive a good faith estimate upon scheduling an item or service and upon request.

Therefore, HHS is using its general rulemaking authority to establish in 45 CFR 149.610(b)(1)(iii) that the convening provider or facility must inform uninsured (or self-pay) individuals that good faith estimates of expected charges are available to uninsured (or self-pay) individuals upon scheduling an item or service or upon request. Information regarding the availability of good faith estimates for uninsured (or self-pay) individuals must be provided in writing and orally. The convening provider or facility must provide written notice in a clear and understandable manner prominently displayed (and easily searchable from a public search engine) on the convening provider's or convening facility's website, in the office, and on-site where scheduling or questions about the cost of items or services occur. In addition, the convening provider or facility must orally inform uninsured (or self-pay) individuals of the availability of a good faith estimate when questions about the cost of items or services occur. Information regarding the availability of a good faith estimate must be made available in accessible formats and languages spoken by individuals considering or scheduling items or services with such convening provider or convening facility.

HHS anticipates providing a model notice for notifying uninsured (or self-pay) individuals of the availability of good faith estimates. However, HHS is not requiring the use of such model notice in order to allow providers or facilities flexibility to develop notices that would be most effective for their patient populations. HHS also recognizes the potential value in having a standardized notice that uninsured (or

self-pay) individuals can anticipate across providers and facilities. Therefore, HHS seeks comment on the potential for standardizing notices for use by all convening providers and convening facilities and other alternative or concurrent options for informing uninsured (or self-pay) individuals of the availability of good faith estimates that would meet the requirements under this section.

HHS notes that uninsured (or self-pay) individuals may use different terminology other than ''good faith estimate'' when requesting a good faith estimate. Therefore, these interim final rules at 45 CFR 149.610(b)(1)(iv) specify that convening providers and convening facilities shall consider any discussion or inquiry regarding the potential cost of items or services under consideration as a request for a good faith estimate.

PHS Act section 2799B–6(2) requires that the good faith estimate include any item or service that is reasonably expected to be provided in conjunction with a scheduled or requested item or service by another provider or facility. Therefore, these interim final rules at 45 CFR 149.610(b)(1)(v) require that the convening provider or facility contact all applicable co-providers and co-facilities no later than 1 business day after the request for the good faith estimate is received or after the primary item or service is scheduled, and request submission of expected charges for items or services that meet the requirements for co-providers and co-facilities under 45 CFR 149.610(b)(2) and (c)(2). The convening provider or convening facility must indicate in their request the date that the good faith estimate information must be received from the co-provider or co-facility. The co-provider or co-facility is responsible for providing timely information to the convening provider or convening facility as discussed later in this preamble. HHS is of the view that the convening provider or convening facility would not have accurate estimates to include in the good faith estimate without information being provided in a timely manner by the co-provider or co-facility. HHS seeks comments on methods and standardized processes, including use of HIPAA standard transactions, that could facilitate accurate and efficient transmission of good faith estimate information from co-providers or co-facilities to convening providers or convening facilities.

PHS Act section 2799B–6 requires that providers and facilities furnish the good faith estimate of the expected charges within certain defined timeframes. Specifically, PHS Act section 2799B–6 states that in the case of an individual who schedules an item or service to be furnished to such individual by such provider or facility at least 3 business days before the date such item or service is to be so furnished, that the notification of the good faith estimate of expected charges shall be provided no later than 1 business day after the date of such scheduling; in the case of such an item or service scheduled at least 10 business days before the date such item or service is to be so furnished (or if requested by the individual), that the notification of the good faith estimate of expected charges shall be provided no later than 3 business days after the date of such scheduling or such request. These interim final rules at 45 CFR 149.610(b)(1)(vi) codify these timeframes for good faith estimates.

HHS recognizes that circumstances may arise where the scope of information included in a good faith estimate changes (such as, a provider or facility represented in the good faith estimate is no longer able to furnish the items or services reported in the good faith estimate). In such circumstances, these interim final rules establish at 45 CFR 149.610(b)(1)(vii) and (viii) that the convening provider or convening facility must issue an uninsured (or self-pay) individual with a new good faith estimate no later than 1 business day before the item or service is scheduled to be furnished. If any changes in expected providers or facilities represented in a good faith estimate occur less than 1 business day before that the item or service is scheduled to be furnished, the replacement provider or replacement facility must accept the good faith estimate as their expected charges for the items or services being furnished that were provided by the original provider or facility and represented in the good faith estimate. These interim final rules also establish at 45 CFR 149.610(b)(2)(ii) and (iii) similar requirements for co-providers and co-facilities. HHS acknowledges the challenges these requirements impose on providers and facilities, and the potential disincentive that such a requirement could have on a provider's or facility's willingness to provide an item or service under such circumstances due to the fact that the patient-provider dispute resolution process, at 45 CFR 149.620, uses the good faith estimate to determine the eligibility of an item or service for dispute resolution. However, HHS is of the view that such requirements are necessary for consumer protections against facing surprise medical bills and without such a requirement an uninsured (or self-pay) individual would be unable to avail themselves of the patient-provider dispute resolution process in these circumstances.

HHS expects that any replacement provider or facility considering whether to furnish items or services will review the applicable good faith estimate and use that information to determine whether to furnish the applicable items or services. HHS is of the view that requiring the replacement providers or facilities to accept as their good faith estimate the expected charges reported in the existing good faith estimate mitigates the risk of providers or facilities circumventing the requirements of PHS Act 2799B–6 through the substitution of providers or facilities. Such requirements also provide important consumer protections intended by PHS Act 2799B–6 that are aimed to protect uninsured (or self-pay) individuals from unexpected medical bills. However, HHS seeks comment on whether this approach could have unintended consequences, such as delays in care if providers were to refuse to serve as replacements, and ways in which to alleviate any such effects.

In instances where a good faith estimate is provided upon the request of an uninsured (or self-pay) individual, upon the subsequent scheduling of the item or service to be furnished, these interim final rules at 45 CFR 149.610(b)(1)(ix) establish that a new good faith estimate must be provided to the uninsured (or self-pay) individual for the now scheduled item or service, and within the timeframes specified for good faith estimates for scheduled items or services under 45 CFR 149(b)(1)(vi)(A) and (B). HHS recognizes that uninsured (or self-pay) individuals might choose to request a good faith estimate in order to better understand anticipated costs, for instance in situations where an individual may wish to compare costs across providers or facilities. If an uninsured (or self-pay) individual had not previously scheduled the primary item or service, the individual may not have been evaluated for underlying conditions that could impact the accuracy of the good faith estimate. HHS encourages convening providers or facilities to review any previously issued good faith estimate related to the primary item or service and make all applicable changes when providing the new good faith estimate. HHS also encourages convening providers or convening facilities to communicate these changes upon delivery of the new good faith estimate to help patients understand what has changed between the initial

good faith estimate and the new good faith estimate.

HHS acknowledges that there are circumstances where recurring items or services are expected to be furnished to an uninsured (or self-pay) individual (for example, an uninsured (or self-pay) individual may need multiple physical therapy visits that would occur outside of the period of care for a surgical procedure). These interim final rules establish at 45 CFR 149.610(b)(1)(x) that the convening provider or facility may issue a single good faith estimate for recurring primary items or services if certain requirements are met. The good faith estimate for recurring items or services must include in a clear and understandable manner the expected scope of the recurring items or services (such as: timeframes, frequency, and total number of recurring items or services) in the good faith estimate. The scope of such a good faith estimate must not exceed 12 months. If additional recurrences of furnishing such items or services are expected beyond 12 months, a convening provider or convening facility must provide an uninsured (or self-pay) individual a new good faith estimate. Providers must also communicate such changes (such as timeframes, frequency, and total number of recurring items or services) upon delivery of the new good faith estimate to help patients understand what has changed between the initial good faith estimate and the new good faith estimate.

ii. Requirements for Co-Providers and Co-Facilities

Under these interim final rules at 45 CFR 149.610(b)(2)(i), a co-provider or co-facility must submit, upon the request of the convening provider or convening facility, good faith estimate information for items or services that are reasonably expected to be furnished by the co-provider or co-facility in conjunction with the primary item or service (as specified under the content requirements discussed later in this section of the preamble). Good faith estimate information submitted by co-providers or co-facilities must be received by the convening provider or facility no later than 1 business day after the co-provider or co-facility receives the request. In addition, co-providers and co-facilities must notify and provide new good faith estimate information to a convening provider or convening facility if the co-provider or co-facility anticipates any changes to the scope of good faith estimate information previously submitted to a convening provider or convening facility (such as anticipated changes to the expected charges, items, services, frequency, recurrences, duration, providers, or facilities). If any changes in the expected co-providers or co-facilities represented in a good faith estimate occur less than 1 business day before that the item or service is scheduled to be furnished, the replacement co-provider or co-facility must accept as its good faith estimate of expected charges the good faith estimate for the relevant items or services included in the good faith estimate for the item or service being furnished that was provided by the replaced provider or facility.

These interim final rules at 45 CFR 149.610(b)(2)(iv) also establish that in the event that an uninsured (or self-pay) individual separately schedules or requests a good faith estimate from a provider or facility that would otherwise be a co-provider or co-facility, that provider or facility is considered a convening provider or convening facility for such item or service and must meet all requirements in paragraphs (b)(1) and (c)(1) for issuing a good faith estimate to an uninsured (or self-pay) individual.

4. Content of a Good Faith Estimate for an Uninsured (or Self-Pay) Individual

In 45 CFR 149.610(c), these interim final rules establish requirements for the content that must be included in a good faith estimate that is issued to an uninsured (or self-pay) individual. As discussed later in this section of the preamble, these interim final rules at 45 CFR 149.610(c)(1) establish the elements that must be included in the good faith estimate issued by the convening provider or convening facility and 45 CFR 149.610(c)(2) establishes the content requirements for good faith estimate information that must be submitted by co-providers or co-facilities to the requesting convening provider or convening facility.

Specifically, the good faith estimate issued by the convening provider or convening facility to the uninsured (or self-pay) individual must include:

- Patient name and date of birth;
- Description of the primary item or service in clear and understandable language (and if applicable, the date the primary item or service is scheduled);
- Itemized list of items or services, grouped by each provider or facility, reasonably expected to be provided for the primary item or service, and items or services reasonably expected to be furnished in conjunction with the primary item or service, for that period of care including: (1) Those items or services reasonably expected to be furnished by the convening provider or convening facility, and (2) those items or services expected to be furnished by co-providers or co-facilities;
- Applicable diagnosis codes, expected service codes, and expected charges associated with each listed item or service;
- Name, NPI, and TIN of each provider or facility represented in the good faith estimate, and the state(s) and office or facility location(s) where the items or services are expected to be furnished by such provider or facility;
- List of items or services that the convening provider or convening facility anticipates will require separate scheduling and that are expected to occur before or following the expected period of care for the primary item or service. The good faith estimate must include a disclaimer directly above this list that states that separate good faith estimates will be issued to an uninsured (or self-pay) individual upon scheduling or upon request of the listed items or services and that for items or services included in this list, information such as diagnosis codes, service codes, expected charges and provider or facility identifiers do not need to be included as that information will be provided in separate good faith estimates upon scheduling or upon request of such items or services; and include instructions for how an uninsured (or self-pay) individual can obtain good faith estimates for such items or services;
- A disclaimer that informs the uninsured (or self-pay) individual that there may be additional items or services the convening provider or convening facility recommends as part of the course of care that must be scheduled or requested separately and are not reflected in the good faith estimate;
- A disclaimer that informs the uninsured (or self-pay) individual that the information provided in the good faith estimate is only an estimate of items or services reasonably expected to be furnished at the time the good faith estimate is issued to the uninsured (or self-pay) individual and that actual items, services, or charges may differ from the good faith estimate;
- A disclaimer that informs the uninsured (or self-pay) individual of their right to initiate the patient-provider dispute resolution process if the actual billed charges are substantially in excess of the expected charges included in the good faith estimate, as specified in 45 CFR 149.620; this disclaimer must include instructions for where an uninsured (or self-pay) individual can find information about how to initiate the patient-provider dispute resolution

process and state that the initiation of the patient-provider dispute resolution process will not adversely affect the quality of health care services furnished to an uninsured (or self-pay) individual by a provider or facility; and

- A disclaimer that the good faith estimate is not a contract and does not require the uninsured (or self-pay) individual to obtain the items or services from any of the providers or facilities identified in the good faith estimate.

Given that good faith estimate information submitted by co-providers or co-facilities must be included as part of the good faith estimate issued to the uninsured (or self-pay) individual, these interim final rules establish under 45 CFR 149.610(d)(2) that good faith estimate information submitted by co-providers or co-facilities to convening providers or convening facilities must include:

- Patient name and date of birth;
- An itemized list of items or services expected to be provided by the co-provider or co-facility that are reasonably expected to be furnished in conjunction with the primary item or service as part of the period of care;
- Applicable diagnosis codes, expected service codes, and expected charges associated with each listed item or service;
- Name, NPI, and TIN of the co-provider or co-facility, and the state(s) and office or facility location(s) where the items or services are expected to be furnished by the co-provider or co-facility; and
- A disclaimer that the good faith estimate is not a contract and does not require the uninsured (or self-pay) individual to obtain the items or services from any of the providers or facilities identified in the good faith estimate.

HHS expects that these requirements, along with the required methods and format for providing good faith estimates (see 45 CFR 149.610(e)) will result in good faith estimates that inform uninsured (or self-pay) individuals about the expected charges for the primary item or service, including the items or services reasonably expected to be furnished in conjunction with the primary item or service during a period of care.

The itemized list of items or services contained in a good faith estimate to an uninsured (or self-pay) individual must reflect the expected charges from the convening provider or facility and co-providers or co-facilities during a period of care. As discussed earlier, these interim final rules define a ''period of care'' as the day or multiple days during which the good faith estimate for scheduled or requested items or services (or a set of items or services) are furnished or are anticipated to be furnished, regardless of whether the convening provider or convening facility or co-providers or co-facilities are furnishing such items or services, and also includes the period of time during which any facility equipment and devices, telemedicine services, imaging services, laboratory services, and preoperative and postoperative services that would not be scheduled separately by the individual, are furnished. It is the intent of this definition of ''period of care'' to clarify that the good faith estimate should include all of the items or services that are typically scheduled as part of a primary item or service for which an individual does not need to engage in additional scheduling.

These interim final rules also establish at 45 CFR 149.610(c)(1)(vi) that in instances where a convening provider or convening facility anticipates that certain items or services will need to be separately scheduled (such as those items or services typical of the standard of care), the convening provider or facility must include a separate list of items or services that the convening provider or facility anticipates will require separate scheduling and that are expected to occur either prior to or following the expected period of care for the primary item or service. Additionally, the good faith estimate must include a disclaimer directly above this list that notifies the uninsured (or self-pay) individual that: (1) Separate good faith estimates will be issued to an uninsured (or self-pay) individual upon scheduling of the listed items or services or upon request; and (2) for items or services included in this list, information such as diagnosis codes, service codes, expected charges, and provider or facility identifiers may not be included as that information will be provided in separate good faith estimates upon scheduling of such items or services or upon request; and (3) include instructions for how an uninsured (or self-pay) individual can obtain good faith estimates for such items or services.

HHS also considered requiring that the good faith estimate include contact information for a provider's or facility's financial assistance office. HHS seeks comment on whether or not such information should be required on the good faith estimate.

HHS understands the value in having one good faith estimate that includes all items or services furnished prior to, as part of, and following the primary item or service, regardless of whether the items or services must be separately scheduled. HHS also understands that including all this information in one good faith estimate could potentially be helpful in allowing an uninsured (or self-pay) individual to fully understand their anticipated costs. However, HHS also appreciates the complexity in obtaining such information by a convening provider or convening facility, as the convening provider or convening facility may not be privy to or be able to reasonably predict which additional providers or facilities an uninsured (or self-pay) individual may choose to engage with outside of the period of care for the primary item or service. HHS seeks comment on whether the good faith estimate content should be expanded to include additional information and expected charges for items or services that are anticipated to be furnished prior to or following the period of care for the primary item or service but require separate scheduling by the uninsured (or self-pay) individual. HHS is particularly interested in the benefits, challenges, and resources that could facilitate provision of good faith estimates that include items or services beyond the period of care for the scheduled or requested primary items or services.

HHS provides the following example for illustrative purposes only and notes that this example should not be considered or construed to be comprehensive or applicable to any specific individual or set of circumstances. In the instance of a knee surgery, a good faith estimate could include an itemized list of items or services in conjunction with and including the actual knee surgery (such as physician professional fees, assistant surgeon professional fees, anesthesiologist professional fees, facility fees, prescription drugs, and durable medical equipment fees) that occur during the period of care. An individual would not typically schedule days in the hospital post-procedure separately from scheduling the primary service of a knee surgery. HHS would therefore expect that all the items or services that are reasonably expected to be provided from admission through discharge as part of that scheduled knee surgery, from all physicians, facilities, or providers be included in the good faith estimate.

Additionally, in this illustrative example, a provider or facility would furnish separate good faith estimates upon scheduling or upon request for any items or services that are necessary prior to or following provision of the

primary item or service beyond the period of care. Examples could include certain pre-operative or post-operative items or services that are not typically scheduled during the period of care for the knee surgery, such as certain laboratory tests or post-discharge physical therapy as discussed earlier.

HHS acknowledges that unforeseen factors could occur during the course of treatment, which could involve additional services, resulting in higher actual billed charges after receipt of care than was anticipated at the time the good faith estimate was provided to the uninsured (or self-pay) individual. These interim final rules do not require the good faith estimate to include charges for unanticipated items or services that are not reasonably expected and that could occur due to unforeseen events.

HHS expects that providers and facilities will use the coding that best describes the item or service for each item or service listed in the good faith estimate. When a single service code is available that captures reporting and billing for the component parts of an item or service, the single service code and expected charge for that single service code would be reported in the good faith estimate to capture the most comprehensive coding level; the component parts would not be included in the good faith estimate as they would not be separately reported or billed. For example, CPT code 85027 (*complete (CBC), automated (Hgb, Hct, RBC, WBC and platelet count)*) represents a laboratory test that measures a patient's hematocrit, hemoglobin, red blood cell count, leukocyte (white blood cell) counts, and platelet count. There are also individual CPT codes for each of the component parts of the service represented by CPT code 85027 (CPT codes: 85014 (*hematocrit (Hct)*), 85018 (*hemoglobin (Hgb)*), 85041 (*red blood cell (RBC), automated*), 85048 (*leukocyte (WBC), automated*), and 85049 (*platelet, automated)*). However, HHS expects that the good faith estimate would include expected charges for CPT code 85027, not expected charges for each component part since there is a single CPT code available that better captures reporting for all of the component parts of the laboratory service.[65]

Items or services included in the good faith estimate must be itemized (by each applicable service code), and clearly grouped and displayed as corresponding to the respective provider or facility that is expected to furnish those items or services. For each provider or facility represented in the good faith estimate, the total amount of expected charges must be included and displayed. HHS is of the view that certain identifying information (such as the provider's or facility's NPI and TIN) must be included in the good faith estimate to ensure that each provider or facility is accurately identified, particularly in instances where more than one provider or facility have the same name, but are separate and distinct entities for purposes of billing for items or services.

Chart 1 provides a visual example of how itemized lists of expected items or services could be displayed in the good faith estimate as suggested in the HHS model notice. HHS notes that this example is included for demonstration purposes only, is not required, and is not a mandatory or standardized format. HHS seeks comment on options for displaying and methods for standardizing the formatting for the itemized lists of items or services, and the required disclaimers. HHS also seeks comment regarding the potential benefits and challenges of using a standardized form that could serve as a base for good faith estimates issued to uninsured (or self-pay) individuals. As uninsured (or self-pay) individuals may be unfamiliar with reading and understanding itemized lists of items or services typically charged for by providers or facilities, HHS seeks comment regarding whether the notice should be required to include additional information to explain concepts such as itemized lists of items or services, content within the required disclaimers, or other information included within the good faith estimate. HHS is also interested in information regarding publicly available methods for displaying required information in good faith estimates in a clear and understandable manner.

CHART 1—EXAMPLE OF HOW ITEMIZED LISTS OF EXPECTED ITEMS OR SERVICES COULD BE DISPLAYED IN A GOOD FAITH ESTIMATE FOR UNINSURED (OR SELF-PAY) INDIVIDUALS

DETAILS OF SERVICES AND ITEMS FOR [PROVIDER/FACILITY 1]

Service/item	Address where service/ item will be provided	Diagnosis code	Service code	Quantity	Expected cost
	[Street, City, State, ZIP]	[ICD code]	[Service Code Type: Service Code Number].	.....	.....
Total Expected Charges from [Provider/Facility 1]				.....	$

Additional Health Care Provider/Facility Notes

DETAILS OF SERVICES AND ITEMS FOR [PROVIDER/FACILITY 2]

Service/item	Address where service/ item will be provided	Diagnosis code	Service code	Quantity	Expected cost
	[Street, City, State, ZIP]	[ICD code]	[Service Code Type: Service Code Number].	.....	.....

[65] CPT codes and descriptions are copyright 2020 American Medical Association. All Rights Reserved. CPT is a registered trademark of the American Medical Association (AMA).

DETAILS OF SERVICES AND ITEMS FOR [PROVIDER/FACILITY 2]—Continued

Service/item	Address where service/ item will be provided	Diagnosis code	Service code	Quantity	Expected cost
Total Expected Charges from [Provider/Facility 1]				.....	$

Additional Health Care Provider/Facility Notes

5. Required Methods for Providing Good Faith Estimates for Uninsured (or Self-Pay) Individuals

In 45 CFR 149.610(e), these interim final rules establish required methods for providing good faith estimates to uninsured (or self-pay) individuals. Consistent with statutory requirements, these interim final rules establish at 45 CFR 149.610(e)(1) that the good faith estimate must be provided in written form either on paper or electronically (for example, electronic transmission of the good faith estimate through the convening provider's patient portal or electronic mail), pursuant to the uninsured (or self-pay) individual's requested method of delivery, and within the timeframes specified under 45 CFR 149.610(b). For good faith estimates provided electronically, the good faith estimate must be provided in a manner that the uninsured (or self-pay) individual can both save and print, and must be provided and written using clear and understandable language and in a manner calculated to be understood by the average uninsured (or self-pay) individual.[66]

HHS notes that the good faith estimate is necessary for initiating the patient-provider dispute resolution process under 45 CFR 149.620, and thus must be issued in written form. Additionally, 45 CFR 149.610(e)(2) of these interim final rules establishes that to the extent that an uninsured (or self-pay) individual requests a good faith estimate be provided other than by paper or electronically (for example, by phone or orally in person), the convening provider or facility may orally discuss the information included in the good faith estimate. However, in order to meet the requirements of this section, the convening provider or convening facility must issue the good faith estimate in written form. The good faith estimate may be provided to an uninsured (or self-pay) individual's authorized representative instead of the individual, to the extent not prohibited under state law. HHS notes that authorized representatives from state Consumer Assistance Programs (CAPs) or legal aid organizations may also be resources for assisting individuals with good faith estimates. HHS recognizes and notes that similar discussions related to authorized representatives (and communication needs of underserved populations discussed elsewhere in this preamble) were also discussed in the July interim final rules. These interim final rules adopt similar standards for authorized representatives as the July 2021 interim final rules, with amendments to account for concepts that are not relevant to uninsured (or self-pay) individuals such as removing references to nonparticipating providers, participants, beneficiaries and enrollees.

In interpreting the statutory requirements regarding the use of clear and understandable language, HHS recognizes that communication, language, and literacy barriers are associated with decreased quality of care, poorer health outcomes, and increased utilization.[67] The use of appropriate language services and appropriate literacy levels in health care settings is associated with increased quality of care, improved patient safety outcomes, and lower utilization of costly medical procedures.[68] HHS is of the view that it is imperative that providers and facilities make these efforts to provide good faith estimate information in a manner understandable to the uninsured (or self-pay) individual to help achieve the goal of the statute and ensure that uninsured (or self-pay) individuals are aware of the good faith estimate information and the options available to them. HHS is of the view that when providing a good faith estimate, providers or facilities should also take into account any vision, hearing, or language limitations; communication needs of underserved populations; individuals with limited English proficiency; and persons with health literacy needs. These factors meaningfully contribute to whether the uninsured (or self-pay) individual can understand and ask any questions about the total expected costs for items or services.

Providers and facilities are also required to comply with other state and Federal laws regarding language access, to the extent applicable. HHS reminds providers and facilities that are recipients of Federal financial assistance that they must comply with Federal civil rights laws that prohibit discrimination. These laws include Section 1557 of the Patient Protection and Affordable Care Act,[69] Title VI of the Civil Rights Act of 1964,[70] and Section 504 of the Rehabilitation Act of 1973.[71] Section 1557 and Title VI require covered entities to take reasonable steps to ensure meaningful access to individuals with limited English proficiency, which may include provision of language assistance services such as providing qualified interpreters, written or sight translation of written good faith estimates in paper or electronic form into languages other than English. When language assistance services are provided, they must be provided free of charge and be accurate and timely. Section 1557 and Section 504 require covered entities to take appropriate steps to ensure effective communication with individuals with disabilities, including provision of appropriate auxiliary aids and services in a timely manner and free of charge to the individual. Auxiliary aids and services may include sign language interpreters, large print materials, accessible information and communication technology, open and closed captioning, and other aids or services for persons who are blind or have low vision, or who are deaf or hard of hearing. Information provided through information and communication technology also must be accessible to individuals with disabilities, unless certain exceptions apply.

HHS seeks comment from persons in and representatives of racial/ethnic

[66] For additional resources, see Federal Plain Language Guidelines at *https://www.plainlanguage.gov/guidelines/*.

[67] Flores G. Language barriers to health care in the United States. N Engl J Med 2006; 355:229–231.

[68] *Id.*

[69] 42 U.S.C. 18116.

[70] 42 U.S.C. 2000d *et seq.*

[71] 29 U.S.C. 794.

minority and underserved communities, including those with limited English proficiency and those with disabilities who require information in alternate and accessible formats, lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons, and stakeholders who serve such communities, on whether the provisions and protections related to communication, language, and literacy sufficiently address barriers that exist to ensuring all individuals can read, understand, and consider their options related to good faith estimates. HHS also seeks comment on how to best provide additional help and resources for these individuals, including state CAPs, legal services or other aid that may help patients with good faith estimates. HHS also seeks comment on additional or alternate policies HHS may consider to help address and remove such barriers. In furtherance of the goal of reducing disparities in health care and coverage, HHS intends to analyze data related to individuals' use of the patient-provider dispute resolution process described under 45 CFR 149.620, as added by PHS Act section 2799B–7, and the appeals process described under 45 CFR 147.136, as added by PHS Act section 2719, to understand where barriers to coverage or accessible information persist. HHS is seeking comment on how to use data related to these two processes to understand, analyze, and address continued disparities.

HHS is seeking comment on how the required methods for providing a good faith estimate to uninsured (or self-pay) individuals established under 45 CFR 149.610 may affect small or rural providers or facilities. HHS is particularly interested in whether there are alternatives to these interim policies that HHS could consider for potential future rulemaking that could meet the statutory requirements for provision of good faith estimates to uninsured (or self-pay) individuals.

6. Additional Compliance Provisions

HHS is of the view that compliance provisions (established at 45 CFR 149.610(f) of these interim final rules) are necessary to ensure that providers and facilities have taken reasonable steps to ensure the accuracy of the information included in a good faith estimate. These interim final rules further clarify in 45 CFR 149.610(e)(1) that a good faith estimate issued to an uninsured (or self-pay) individual is considered part of the patient's medical record and must be maintained in the same manner as a patient's medical record, and that convening providers and facilities must provide a copy of any previously issued good faith estimate furnished within the last 6 years to an uninsured (or self-pay) individual upon the request of the uninsured (or self-pay) individual.

While HHS acknowledges that some states have existing state laws related to the furnishing of good faith estimates, HHS is of the view that uninsured (or self-pay) individuals should still have access to a good faith estimate that meets the minimum requirements established in these interim final rules. Therefore at 45 CFR 149.610(f)(2) these interim final rules establish that providers or facilities that issue good faith estimates under state processes that do not meet the minimum requirements under this section fail to comply with the requirements of 45 CFR 149.610.

In circumstances in which a provider or facility, acting in good faith, makes an error or omission in a good faith estimate, HHS is establishing at 45 CFR 149.610(f)(3) that a provider or facility will not fail to comply with this section solely because, despite acting in good faith and with reasonable due diligence, the provider or facility makes an error or omission in a good faith estimate required under this section, provided that the provider or facility corrects the information as soon as practicable. However, if the services are furnished before the error in the good faith estimate is addressed, the provider or facility may be subject to patient-provider dispute resolution if the billed charges are substantially in excess of the good faith estimate (as described in 45 CFR 149.620).

Additionally, to the extent compliance with this section requires a provider or facility to obtain information from any other entity or individual, these interim final rules specify at 45 CFR 149.610(f)(4) that the provider or facility will not fail to comply with this section because it relied in good faith on the information from the other entity, unless the provider or facility knows, or reasonably should have known, that the information is incomplete or inaccurate. HHS notes that providers and facilities (including convening providers, convening facilities, co-providers or co-facilities) who experience other providers' or facilities' failures to comply with the requirements in these interim final rules may file a complaint for enforcement investigation under 45 CFR 149.450. If the provider or facility learns that the information is incomplete or inaccurate, the provider or facility must provide corrected information to the uninsured (or self-pay) individual as soon as practicable, and as noted above, may be subject to patient-provider dispute resolution if items or services furnished before a corrected good faith estimate could be issued to an uninsured (or self-pay) individual.

7. Applicability of the Good Faith Estimate Requirements

These interim final rules establish under 45 CFR 149.610(g)(1) that the requirements of this section are applicable for good faith estimates requested on or after January 1, 2022 by uninsured (or self-pay) individuals or for good faith estimates required to be provided to uninsured (or self-pay) individuals in connection with items or services scheduled on or after January 1, 2022. HHS recognizes that some providers or facilities may need to establish efficient and secure communication channels for transmission of good faith estimate information between convening providers or facilities and co-providers and co-facilities. While HHS notes that there are longstanding established standards for data exchange between providers established under HIPAA,[72] HHS is seeking comment on any existing challenges related to secure transmission of good faith estimate information between providers and facilities. HHS is also interested in whether publicly available standardized processes exist or could be developed that would facilitate and support efficient and timely transmission of good faith estimate information. HHS also seeks comments on how the Hospital Price Transparency requirements for hospitals to display standard charges in a consumer-friendly manner (45 CFR 180.60), and, specifically, the voluntary use of online price estimator tools (45 CFR 180.60(a)(2)), may be leveraged to provide a good faith estimate under these final rules. HHS also seeks comments on whether there are other opportunities for the convening provider to use the Hospital Price Transparency machine-readable file requirements (45 CFR 180.50) to inform good faith estimates with expected charges of co-providers or co-facilities from the comprehensive machine-readable files, whether or not the comprehensive machine-readable files can assist uninsured (or self-pay) individuals in determining if the good faith estimate charges are reasonable and/or accurate, and what limitations exist in using the comprehensive machine-readable files for purposes of

[72] *https://www.cms.gov/regulations-and-guidance/administrative-simplification/hipaa-aca.*

meeting the requirements of this section for provision of the good faith estimates to uninsured (or self-pay) individuals. General information regarding relevant interoperability or data exchange standards would also be of interest.

These interim final rules at 45 CFR 149.610(g)(2) establish that nothing in 45 CFR 149.610 alters or otherwise affects a provider's or facility's duty to comply with requirements under other applicable state or Federal laws, including those governing the accessibility, privacy, or security of information required to be disclosed under this section, or those governing the ability of properly authorized representatives to access uninsured (or self-pay) individuals' information held by providers or facilities, except to the extent a state law prevents the application of this section.

HHS understands that it may take time for providers and facilities to develop systems and processes for receiving and providing the required information from co-providers and co-facilities. Therefore, for good faith estimates provided to uninsured (or self-pay) individuals from January 1, 2022 through December 31, 2022, HHS will exercise its enforcement discretion in situations where a good faith estimate provided to an uninsured (or self-pay) individual does not include expected charges from co-providers or co-facilities. HHS notes that nothing prohibits a co-provider or co-facility from furnishing the information before December 31, 2022, and nothing would prevent the uninsured (or self-pay) individual from separately requesting a good faith estimate directly from the co-provider or co-facility, in which case the co-provider and co-facility would be required to provide the good faith estimate for such items or services. Otherwise during this period, HHS encourages convening providers and convening facilities to include a range of expected charges for items or services reasonably expected to be provided and billed by co-providers and co-facilities. To the extent states are the primary enforcer of these requirements, HHS encourages states to take a similar approach, and will not consider a state to be failing to substantially enforce these requirements if it takes such an approach from January 1, 2022 through December 31, 2022.

8. Applicability of Requirements to Notices Provided Under 45 CFR 149.420

The July 2021 interim final rules included provisions at 45 CFR 149.420(d) establishing the information that must be included in a written notice, if a non-participating provider or non-participating emergency facility seeks to obtain consent from a participant, beneficiary, or enrollee (or their authorized representative) to waive the balance bill protections. Specifically, the written notice must be provided in a form and manner specified by HHS in guidance, and must, among other things, include the good faith estimated amount that such nonparticipating provider may charge the participant, beneficiary, or enrollee for the items and services involved (including any item or service that is reasonably expected to be furnished by the nonparticipating provider in conjunction with such items or services). In the July 2021 interim final rules, HHS stated that in calculating the good faith estimated amount required to be included in the notice under 45 CFR 149.420(d)(2), the provider or facility is expected to apply the same process and considerations used to calculate the good faith estimate that is required under PHS Act section 2799B–6(2).

HHS recognizes that providers and facilities have some discretion in the assumptions that they make regarding which items or services to include in a good faith estimate, and that some natural variation may occur across providers and facilities in terms of which items or services they would include in an estimate. However, HHS is of the view that it is critical for providers and facilities to apply the same process and considerations in developing the good faith estimate required under PHS Act section 2799B–6(2) (as partially implemented in these interim final rules at 45 CFR 149.610) as in 45 CFR 149.420(d)(2) to avoid consumers receiving two different estimates describing care from the same provider or facility for the same care.[73]

Under 45 CFR 149.610, the ''expected charge'' for an item or service may vary depending on whether the good faith estimate is being provided to an uninsured (or self-pay) individual, or to a plan or issuer. HHS clarifies that the good faith estimate in the notice described in 45 CFR 149.420(c) must be developed using the definition of the expected charge that would apply when the good faith estimate is provided to a plan or issuer (that is, the amount the provider or facility would expect to charge if the provider or facility intended to bill a plan or issuer directly for such item or service). Because the notice in 45 CFR 149.420(c) would only be provided with respect to individuals enrolled in a group health plan or health insurance coverage, HHS is of the view that requiring the good faith estimate to align with the good faith estimate that would be provided under PHS Act section 2799B–6(2)(A) to a plan or issuer will help to avoid situations in which participants, beneficiaries, or enrollees subsequently receive an advanced explanation of benefits from their plan or issuer that is generated from a different estimate than the one provided in the notice, or in which participants, beneficiaries, or enrollees receive differing estimates regarding notice and consent under 45 CFR 149.420(d)(2) and regarding self-pay liability under 45 CFR 149.610. In instances where an individual receives a notice with a good faith estimate reflecting the amount that would be billed to a plan or issuer but intends to self-pay and the item or service is scheduled in advance, the individual would separately receive a good faith estimate reflecting the amount they would be charged as a self-pay individual under the requirements in 45 CFR 149.610. HHS acknowledges that the Departments are not codifying requirements regarding PHS Act section 2799B–6(2)(A), which requires providers and facilities to furnish good faith estimates to plans or issuers, and that HHS will defer enforcement of this requirement until rulemaking is effective to fully implement this requirement. That non-enforcement position does not extend to the requirement to provide a good faith estimate as part of the notice under 45 CFR 149.420(c). However, HHS seeks comment on whether providers and facilities should be allowed to calculate the good faith estimate under 45 CFR 149.420(d)(2) using the expected charge applicable to an uninsured (or self-pay) individual until such rulemaking occurs. HHS also seeks comment on whether it would be feasible for providers and facilities to provide an estimate or range of estimated costs for insured consumers upon request during this period of non-enforcement.

HHS recognizes that the good faith estimates required under 45 CFR 149.420(d)(2) and 45 CFR 149.610 may also differ if items or services from different provider(s) or facilities are included in the estimate. For example,

[73] For individuals who are seeking to submit a claim to their plan or coverage, the second estimate would be sent to the plan or issuer and used to develop the advanced explanation of benefits required to be provided under Code section 9816(f), ERISA section 716(f), and PHS Act section 2799A–1(f). As discussed previously, the Departments will defer enforcement of these requirements until the Departments have issued rulemaking regarding the requirements. The Departments recognize that participants, beneficiaries, and enrollees would not receive a second estimate (in the advanced explanation of benefits) from their plan or issuer until this rulemaking goes into effect.

an estimate required in the notice under 45 CFR 149.420(d)(2) would only include items or services provided by a nonparticipating provider that seeks to obtain consent to balance bill. In contrast, the good faith estimate required under these interim final rules would not be limited to items or services furnished by such providers. However, HHS expects that the estimates regarding items or services provided by a specific provider or facility in the notice provided under 45 CFR 149.420(c) would include the same items or services for that specific provider or facility as the good faith estimate provided under 45 CFR 149.610. Although the grand total of a good faith estimate under each of the two rules might differ depending on the number of providers furnishing estimates as part of one good faith estimate, HHS is of the view that the requirements in each of the two rules generally take into account the same process and considerations for calculating the good faith estimate.

B. Patient-Provider Dispute Resolution

1. Scope

PHS Act section 2799B–7 directs the Secretary of HHS to establish a process called a patient-provider dispute resolution process. Under this process an uninsured (or self-pay) individual who received a good faith estimate of the expected charges for an item or service, pursuant to PHS Act section 2799B–6, implemented at 45 CFR 149.610, may seek a determination from an SDR entity for the amount to be paid by the uninsured (or self-pay) individual to the provider or facility for such item or service. Uninsured (or self-pay) individuals are eligible for the patient-provider dispute resolution process after being furnished an item or service for which they received a good faith estimate if the individual is billed, by the provider or facility, charges that are substantially in excess of the good faith estimate.

HHS is adding new 45 CFR 149.620 to implement this patient-provider dispute resolution process. These interim final rules include specific definitions related to the patient-provider dispute resolution process; specify the items and services eligible for the process; establish requirements for what uninsured (or self-pay) individuals must provide to initiate the process; and specify the information providers and facilities must provide to an SDR entity to inform payment determinations. These interim final rules also establish requirements for SDR entities contracted to resolve the patient-provider dispute, including how SDR entities determine the payment amount, and certification standards that HHS will consider when contracting with SDR entities. These interim final rules also specify the administrative fee associated with the patient-provider dispute resolution process, and the minimum requirements for state patient-provider dispute resolution processes to operate in place of the Federal patient-provider dispute resolution process.

2. Definitions

For purposes of these interim final rules, the definitions under 45 CFR 149.610 apply. Definitions related to confidentiality set forth in § 149.510(a)(2), including the definitions for *breach, individually identifiable health information (IIHI),* and *unsecured IIHI* also apply to this section. These interim final rules also define three additional terms: ''billed charge,'' ''substantially in excess,'' and ''total billed charges'' under new 45 CFR 149.620(a)(2).

These interim final rules define ''billed charge'' to mean the amount billed by a provider or facility for an item or service. These interim final rules define ''total billed charges'' to mean the total of billed charges, by a provider or facility, for all primary items or services and all other items or services furnished in conjunction with the primary items or services to an uninsured (or self-pay) individual, regardless of whether such items or services were included in the good faith estimate.

These interim final rules define the term ''substantially in excess'' to mean with respect to the total billed charges by a provider or facility, an amount that is at least $400 more than the total amount of expected charges for the provider or facility listed on the good faith estimate. In defining ''substantially in excess,'' HHS notes that PHS Act section 2799B–7 does not include a definition for ''substantially in excess.'' HHS reviewed other uses of the term in existing Federal law. For example, section 1128(b)(6) of the Social Security Act provides that the Secretary of HHS may exclude any individual or entity from participation in any Federal health care program if the Secretary determines that the individual or entity submitted bills or requests for payment (where such bills or requests are based on charges or cost) under title XVIII of the Social Security Act or a state health care program containing charges (or, in applicable cases, requests for payment of costs) for items or services furnished substantially in excess of such individual's or entity's usual charges (or, in applicable cases, substantially in excess of such individual's or entity's costs) unless the Secretary finds there is good cause for such bills or requests containing such charges or costs. However, HHS notes that section 1128(b)(6) of the Social Security Act similarly does not include a definition for ''substantially in excess.'' Regardless, HHS is of the view that the term ''substantially in excess'' as used in PHS Act section 2799B–7 should be distinguished from the language of section 1128(b)(6) of the Social Security Act, as the provisions operate differently. Specifically, PHS Act section 2799B–7 specifies that an uninsured (self-pay) individual is eligible to seek a payment determination regarding the amount to be paid when the total billed charges substantially exceed the total expected charges in the good faith estimate. HHS is of the view that such a process should provide clear criteria that would make it easy for uninsured (or self-pay) individuals, providers, facilities, SDR entities, and HHS to determine eligibility for dispute resolution. HHS is also of the view that such eligibility criteria should be based on objective factors that are known in advance and are simple for providers, facilities, and uninsured (or self-pay) individuals to understand, which will reduce uncertainty over which items or services are subject to dispute resolution and which are not.

HHS considered establishing a definition for ''substantially in excess'' to mean that the total billed charges are greater than the total expected charges in the good faith estimate by a percentage of the total expected charges in the good faith estimate (for example, 20 percent of the total expected charges). However, HHS is mindful of the limitations in relying on percentages for determining the threshold of eligibility for dispute resolution. In particular, when using percentages, the dollar thresholds would vary significantly based on the magnitude of the expected charges in the good faith estimate. For example, if for an item or service, the expected charge in the good faith estimate is $300, 20 percent would equal $60, meaning the billed charges would need to equal or exceed $360 to be eligible for dispute resolution. However, if for an item or service, the expected charge in the good faith estimate is $25,000, the difference between the billed charge and the expected charge in the good faith estimate would need to be $5,000 or greater to be eligible for dispute resolution. In other words, basing the definition of ''substantially in excess'' on a percentage of the total expected

charges in the good faith estimate would make dispute resolution easier to access in cases where the associated dollar amounts are small. Conversely, in cases where the associated dollar amounts are very large, the threshold would be significantly larger in terms of dollars and more difficult for the claims to meet, which could result in many uninsured (or self-pay) individuals being unable to access dispute resolution despite receiving bills for items or services in amounts far greater, in absolute value, than the expected charges in the good faith estimate.

To address these limitations, HHS considered alternative approaches that included defining ''substantially in excess'' to mean that the total billed charges are greater than the total expected charges in the good faith estimate by the lesser of a percentage of the total expected charges in the good faith estimate or a flat maximum dollar amount. While this approach would mitigate concerns over higher cost items and services meeting the ''substantially in excess'' threshold, it would not address concerns over the uninsured (or self-pay) individual being easily able to bring dispute resolution claims for lower cost items or services. HHS is concerned that under such an approach, dispute resolution for lower cost items or services could be overused, thus potentially increasing costs for providers and facilities which could be passed on to individual consumers in the form of higher prices.

Similarly, HHS considered defining ''substantially in excess'' to mean an amount that is the greater of either a percentage of the total expected charges in the good faith estimate or a flat minimum dollar amount. By specifying a flat minimum dollar threshold amount, such an approach would address concerns over overuse of the patient-provider dispute resolution process for items or services at the lower end of costs. However, HHS remains concerned that such an approach could effectively put dispute resolution out of reach for uninsured (or self-pay) individuals in situations where the total expected charges for items or services are high, particularly for those who need to undergo more complex procedures. As an example, under this approach, when the total billed charges must be either equal to or greater than a flat minimum amount or predefined percentage above the expected charges, if the applicable flat amount is $400 and the applicable percentage of the expected charges in the good faith estimate were equal to 10 percent, total expected charges of $25,000 would mean the total billed charges must exceed the total expected charges in the good faith estimate by $2,500 or more in order to access dispute resolution. If, in this example, the total billed charges are less than $27,500, the uninsured (or self-pay) individual would be unable to resolve the unexpected bill using the patient-provider dispute resolution process. Even for individuals with sufficient savings or income, such a threshold would likely pose a major financial burden, and such a situation would be exacerbated for lower income individuals and those who lack sufficient savings. HHS is of the view that whether an individual needs to receive a high cost item or service is independent from an individual's income or assets or coverage status, and basing the definition of ''substantially in excess'' for the purposes of eligibility for the patient-provider dispute resolution process on the expected charges of an item or service without any consideration for the financial means of the uninsured (or self-pay) individual would create a massive gap in the consumer protections intended under PHS Act section 2799B–7. To provide another example, suppose an uninsured (or self-pay) individual has total expected charges in the good faith estimate equal to $2,100 and the ''substantially in excess'' standard is the greater of 10% of the total expected charges in the good faith estimate or $400. Under such a definition, the substantially in excess threshold would be $400, and if the total billed charges are $2,500 or greater, then the items or services are eligible for dispute resolution. Now, consider another uninsured (or self-pay) individual with total expected charges of $21,000; in this uninsured (or self-pay) individual's case, the total billed charges would need to exceed the total expected charges in the good faith estimate by $2,100 or more in order to be eligible for dispute resolution. The uninsured (or self-pay) individual with expected charges of $21,000 is in no less need of protection from surprise medical bills than the uninsured (or self-pay) individual with expected charges of $2,100, but in practice such individual would more likely be unable to access these important protections intended by the patient-provider dispute resolution due to the higher threshold.

HHS also considered a tiered percentage approach in which lower-cost services must exceed a higher percentage value, with a lower percentage value applicable for higher-cost items or services. However, HHS is of the view that such an approach would add undue complexity to the patient-provider dispute resolution process in determining whether items or services meet the ''substantially in excess'' threshold and would present the same concerns previously described. HHS also considered basing the definition of ''substantially in excess'' on billed charges that exceed a certain percentile for the same or similar services using an independent database. However, such a mechanism appears inconsistent with the statute, which contemplates costs for items or services to be determined ''substantially in excess'' based on the good faith estimate provided, rather than based on a specific benchmark, such as an independent database.

HHS is of the view that basing the definition of ''substantially in excess'' on a flat dollar amount, such as $400, allows for a straightforward way to calculate the eligibility of an item or service for patient-provider dispute resolution, and reduces the concerns described earlier regarding lower-cost items or services too easily meeting the eligibility threshold for dispute resolution and making it more difficult for higher-cost items and services to meet the eligibility threshold. HHS acknowledges that such an approach may result in situations in which the difference between the total billed charges and the total expected charges in the good faith estimate is small in relative terms but the item or service is eligible for dispute resolution. As an example, if the expected charge for an item or service in the good faith estimate is $100,000, basing ''substantially in excess'' on a flat $400 threshold, a billed charge of $100,400 (0.4% difference) or more would make the item or service eligible for dispute resolution, which could be argued by some as not ''substantially in excess.'' However, as discussed earlier in this section of the preamble, HHS is of the view that while the definition of ''substantially in excess'' should encompass the difference between the total billed charges and the total expected charges in the good faith estimate, focusing solely on the expected costs of items or services risks shutting out many uninsured (or self-pay) individuals from the patient-provider dispute resolution process and undermines the intended protections in PHS Act section 2799B–7. Additionally, even when the total expected charges are high, a relatively small additional charge may still create significant financial difficulties for the uninsured (or self-pay) individual. HHS did consider whether to have different flat dollar thresholds based on the

uninsured (or self-pay) individual's income, however, HHS is of the view that such a policy would be confusing to uninsured (or self-pay) individuals who would need to provide documentation to verify their income, which increases the burdens placed on such individuals and could pose a deterrent to participation. Based on consideration of the different approaches discussed earlier in this section of the preamble, HHS determined that the best approach for defining ''substantially in excess'' would be to base it on a flat dollar difference between the total billed charges and the total expected charges in the good faith estimate.

Because HHS views the patient-provider dispute resolution process established under PHS Act section 2799B–7 to be intended to protect uninsured (or self-pay) individuals from unexpected higher health care costs, it is appropriate to determine whether an amount is substantially in excess based on the perspective of individuals who are likely to be uninsured or underinsured, and not only the perspective of the average individual or the provider or facility. To that end, HHS looked to existing research to assess what amount Americans may struggle to cover in unexpected expenses. HHS is of the view that looking to Americans' ability to cover unexpected expenses is an important consideration when establishing protections for unexpected medical expenses, which remain a common unexpected expense for many. In a 2016 survey, the Federal Reserve reported that 22 percent of respondents experienced what they described as a major unexpected medical expense that they had to pay out-of-pocket in the previous 12 months.[74] Further, concerns over the potential costs of medical care may result in many Americans choosing to forego needed care.[75] Another recent study found that in 2020, 17.8 percent of individuals had medical debt reported to a credit bureau, the study also found that individuals collectively had greater medical debt in collections than all forms of nonmedical debt combined (the authors defined nonmedical debt as other sources of debt in collections, including credit cards, personal loans, utilities, and phone bills).[76]

In 2019, the Federal Reserve found that nearly 4 in 10 adults would have difficulty covering an emergency expense costing $400, with 12 percent of adults unable to pay their current month's bills if they also had an unexpected $400 expense.[77] The ability to cover an unexpected expense also varies significantly by social risk and demographic factors, for example, income, race, perceived health, and depression.[78] A 2016 survey by the Federal Reserve found that among respondents with a family income under $40,000, only 34 percent reported they would be able to pay an unexpected $400 expense using cash or its functional equivalent (including money currently in their checking/savings accounts, or available on a credit card that they would pay in full at their next statement). In addition, the Federal Reserve found that while 61 percent of non-Hispanic white respondents said that they would pay for an unexpected $400 expense using cash or its functional equivalent, for Hispanic and non-Hispanic black respondents, only 38 percent and 36 percent respectively reported that they would be able to pay for an unexpected $400 expense using cash or its functional equivalent.[79]

Other surveys have found results that were consistent with the Federal Reserve's findings. One such survey found that only 39 percent of Americans would cover an unexpected $1,000 expense using their savings.[80] The same survey also found that this number varied significantly with age and income, finding that only 33 percent of those in the millennial generation and only 21 percent of those making less than $30,000 per year would cover a hypothetical $1,000 expense using savings.[81] A survey by the Robert Wood Johnson Foundation found that 67 percent of those making less than $35,000 per year reported they would have difficulty paying off a hypothetical $1,000 expense.[82] Research by the Pew Charitable Trust also found that 55 percent of Americans to be ''savings-limited, meaning they can replace less than one month of their income through liquid savings.''[83] For Americans at the bottom quintile of income, this amount is even less, with the typical family having less than 2 weeks of income in savings.[84]

While research shows that some Americans are financially prepared to cover unexpected costs, many Americans are unable to weather such unexpected expenses.[85] The Pew Charitable Trust found that more than half of families that experienced a financial shock (such as an unplanned expense or loss of income) reported having trouble making ends meet, and this number increased for younger, minority, and low-income households. The Pew Charitable Trust also found that households that experienced such events typically had lower savings and higher credit card debts than those that did not.[86]

While health care costs are not the only unexpected expenses people face, they constitute a large source of surprise expenses. The Robert Wood Johnson Foundation found that 38 percent of lower-income Americans and 31 percent of middle-income Americans reported experiencing significant problems with paying medical bills.[87] Many Americans, particularly those who are uninsured, report that they went without needed care, or delayed care, due to costs. For example, the Federal Reserve found that 38 percent of those with incomes below $40,000 went without some form of medical care in 2019.[88] Among uninsured individuals,

[74] Board of Governors of the Federal Reserve System, Report on the Economic Well-Being of U.S. Households in 2015 (May 2016), available at: *https://www.federalreserve.gov/2015-report-economic-well-being-us-households-201605.pdf.*

[75] For example, 24 percent of adults went without some form of medical care due to an inability to pay, down from 27 percent in 2017 and well below the 32 percent reported in 2013. Dental care was the most frequently skipped treatment (17 percent), followed by visiting a doctor (12 percent) and taking prescription medicines (10 percent). Board of Governors of the Federal Reserve System, Report on the Economic Well-Being of U.S. Households in 2018 (May 2019), available at: *https://www.federalreserve.gov/publications/2019-economic-well-being-of-us-households-in-2018-dealing-with-unexpected-expenses.htm.*

[76] Kluender R., Mahoney N., Wong F., Yin W. Medical Debt in the U.S., 2009–2020. JAMA. 2021;326(3):250–256. doi:10.1001/jama.2021.8694.

[77] Board of Governors of the Federal Reserve System, Report on the Economic Well-Being of U.S. Households in 2018 (May 2019), available at: *https://www.federalreserve.gov/publications/2019-economic-well-being-of-us-households-in-2018-dealing-with-unexpected-expenses.htm.*

[78] Board of Governors of the Federal Reserve System, Report on the Economic Well-Being of U.S. Households in 2015 (May 2016), available at: *https://www.federalreserve.gov/2015-report-economic-well-being-us-households-201605.pdf.*

[79] Board of Governors of the Federal Reserve System, Report on the Economic Well-Being of U.S. Households in 2015 (May 2016), available at: *https://www.federalreserve.gov/2015-report-economic-well-being-us-households-201605.pdf.*

[80] *https://www.bankrate.com/banking/savings/financial-security-january-2021/.*

[81] *https://www.bankrate.com/banking/savings/financial-security-january-2021/.*

[82] *https://www.rwjf.org/en/library/research/2019/12/life-experiences-and-income-inequality-in-the-united-states.html.*

[83] *https://www.pewtrusts.org/~/media/Assets/2015/01/FSM_Balance_Sheet_Report.pdf.*

[84] *https://www.pewtrusts.org/~/media/Assets/2015/01/FSM_Balance_Sheet_Report.pdf.*

[85] *https://www.pewtrusts.org/~/media/assets/2015/10/emergency-savings-report-1_artfinal.pdf.*

[86] *https://www.pewtrusts.org/~/media/assets/2015/10/emergency-savings-report-1_artfinal.pdf.*

[87] *https://www.rwjf.org/en/library/research/2019/12/life-experiences-and-income-inequality-in-the-united-states.html.*

[88] *https://www.federalreserve.gov/publications/2019-economic-well-being-of-us-households-in-2018-dealing-with-unexpected-expenses.htm.*

47 percent went without some form of medical care due to concerns over costs.[89] Research reinforces the findings of the Federal Reserve and indicates that additional risk factors such as perceived health and depression increase an individual's likelihood of reporting that health care is unaffordable.[90] [91] For these groups facing high health care related financial burdens, which include those most likely to be uninsured and underinsured,[92] unexpected expenses of $400 or more would reasonably constitute a substantial amount.

HHS also considered setting the flat dollar lower than $400. However, as discussed in greater detail in section VI.B.8 of this preamble, HHS expects to contract with SDR entities directly and will pay the SDR entity costs. Based on conversations with stakeholders and research of similar state processes, HHS found that the amount that dispute resolution entities charge for similar dispute resolution processes is around $400 per case. A study by the Commonwealth Fund similarly found costs for dispute resolution ranging between $300 and $600.[93] HHS found that other state dispute resolution processes could potentially charge the uninsured (or self-pay) individual high fees to initiate a dispute. For example, in New York, the cost to the uninsured (or self-pay) individual for dispute resolution could be as much as $395, and in Maine as much as $450.[94] However, as is further discussed in section VI.B.8 of this preamble, HHS will only charge a small administrative fee, meaning that uninsured (or self-pay) individuals will be mostly insulated from the costs of dispute resolution. HHS acknowledges that the costs to the government for conducting dispute resolution would not be a consideration for the uninsured (or self-pay) individual in determining whether to initiate a dispute, as they would not be required to pay those costs. However, HHS is of the view that it would not make sense to conduct dispute resolution cases where the amount in dispute is less than the cost for the dispute resolution entity. As a result, HHS is of the view that setting the substantially-in-excess floor equal to $400 is a reasonable and appropriate approach and would ensure that the minimum amount in dispute for the patient-provider dispute resolution process is comparable to the expected costs for dispute resolution.

In addition, HHS considered whether to set the substantially-in-excess threshold floor at a higher amount than $400. However, HHS remains concerned that setting the flat dollar floor for the substantially-in-excess threshold greater than $400 could ultimately result in many uninsured (or self-pay) individuals, particularly those who received lower cost items or services, being unable to access the patient-provider dispute resolution process. As a result, HHS is of the view that limiting patient-provider dispute resolution to items or services where the total billed charges exceed the total expected charges in the good faith estimate by $400 or greater strikes the appropriate balance that helps ensure that amounts in dispute are sufficiently large to justify the costs of maintaining and operating the dispute resolution process; that burdens on providers, facilities, and the Federal Government are minimized; and that all uninsured (or self-pay) individuals are able to access the dispute resolution process to resolve unexpected billed amounts.

As HHS obtains additional experience with the patient-provider dispute resolution process, HHS intends to review data on the use of the process, such as the volume of dispute resolution cases, differences between the total expected charges in the good faith estimate and the total billed charges in cases that go to dispute resolution, data on payment determination amounts by SDR entities, the success rate for uninsured (or self-pay) individuals who initiate dispute resolution, and characteristics of initiation requests that are determined ineligible, and in future years may propose adjustments to the definition of ''substantially in excess.''

HHS seeks comment on the definition for ''substantially in excess,'' including whether the $400 amount should be set higher or lower, whether there is any other specific dollar value that would be more appropriate, or whether a different method for determining ''substantially in excess'' should be considered. HHS also seeks comment on the terms defined in these interim final rules, including the appropriateness and usability of the definitions, and whether additional terms should be defined in future rulemaking. HHS also seeks comment on how these definitions may impact market incentives, including the accuracy of good faith estimates.

3. Eligibility for Patient-Provider Dispute Resolution

The patient-provider dispute resolution process in PHS Act section 2799B–7 applies to uninsured (or-self-pay) individuals who received, pursuant to PHS Act section 2799B–6, a good faith estimate of the expected charges for scheduled or requested items or services from a provider or facility, and who after being furnished such item or service is billed by such provider or facility charges substantially in excess of such estimate. To clarify what items and services are eligible for the patient-provider dispute resolution process, HHS is adding 45 CFR 149.620(b) which specifies that items or services provided by a convening provider, convening facility, co-provider, or co-facility are eligible for the patient-provider dispute resolution process if the total billed charges (by the particular convening provider, convening facility, or co-provider or co-facility listed in the good faith estimate), are substantially in excess of the total expected charges for that specific provider or facility listed on the good faith estimate, as required under 45 CFR 149.610, regardless of whether the items or services included in the total billed charges were listed in the good faith estimate, or whether the co-provider or co-facility was listed on the good faith estimate.

Good faith estimates for scheduled items or services, or when requested, as specified in 45 CFR 149.610, are intended to provide a comprehensive estimate of expected charges for items or services furnished during the period of care. PHS Act section 2799B–6 and 45 CFR 149.610 require providers or facilities to include any item or service that is reasonably expected to be provided in conjunction with an item or service, including an item or service reasonably expected to be so provided by another provider or facility.

HHS is of the view that an uninsured (or self-pay) individual should be able

[89] *https://www.federalreserve.gov/publications/2019-economic-well-being-of-us-households-in-2018-dealing-with-unexpected-expenses.htm.*

[90] Kielb E.S., Rhyan C.N., Lee J.A. Comparing Health Care Financial Burden With an Alternative Measure of Unaffordability. *Inquiry.* 2017;54:46958017732960. doi:10.1177/0046958017732960.

[91] Amin K., Claxton G., Ramirez G., Cox C. How Does Cost Affect Access to Care? *Peterson-KFF Health System Tracker.* January 2021. Available at *https://www.healthsystemtracker.org/chart-collection/cost-affect-access-care/#item-start.*

[92] Kielb E.S., Rhyan C.N., Lee J.A. Comparing Health Care Financial Burden With an Alternative Measure of Unaffordability. *Inquiry.* 2017;54:46958017732960. doi:10.1177/0046958017732960. Also see, Amin K., Claxton G., Ramirez G., Cox C. How Does Cost Affect Access to Care. *Peterson-KFF Health System Tracker.* January 2021. Available at *https://www.healthsystemtracker.org/chart-collection/cost-affect-access-care/#item-start.* Also see, Tolbert J., Orgera K., Key Facts About the Uninsured Population. *Kaiser Family Foundation.* November 2020. Available at *https://www.kff.org/uninsured/issue-brief/key-facts-about-the-uninsured-population/.*

[93] *https://www.commonwealthfund.org/blog/2020/how-states-are-using-independent-dispute-resolution-resolve-out-network-payments-surprise.*

[94] *https://www.dfs.ny.gov/system/files/documents/2020/10/idr_patient_application.pdf* and *https://dispute.maximus.com/me/indexME.*

to initiate the patient-provider dispute resolution process when the total billed charge for an item or service from a particular provider or facility represented in the good faith estimate exceeds the substantially in excess threshold defined at 45 CFR 149.620(a)(2). Therefore, these interim final rules specify that an item or service provided by a convening provider, convening facility, co-provider or co-facility are eligible for the patient-provider dispute resolution process if the total billed charges (by the particular convening provider or facility, or co-provider or co-facility listed in the good faith estimate), are substantially in excess of the of total expected charges for that specific provider or facility listed on the good faith estimate, as required under 45 CFR 149.610.

As an example, an uninsured (or self-pay) individual receives a good faith estimate that lists expected charges for 3 services, A, B, and C. Services A and B are provided by provider Y and service C is provided by co-provider Z. The total billed charges for services A and B must exceed the total expected charges for services A and B by at least $400 more than the amount listed in the good faith estimate in order for the uninsured (or self-pay) individual to be eligible to initiate patient-provider dispute resolution against provider Y. Similarly, the billed charge for service C must exceed the expected charges for service C by at least $400 more than the amount listed in the good faith estimate in order for the uninsured (or self-pay) individual to be eligible for the patient-provider dispute resolution against co-provider Z.

An item or service is eligible for patient-provider dispute resolution based on the total billed charges from the provider or facility, regardless of whether such items or services are included in a good faith estimate. HHS recognizes that unforeseen factors during the course of treatment may occur, which could involve additional items or services from providers and facilities, and may result in higher billed charges after receipt of care than was anticipated at the time the good faith estimate was provided to the uninsured (or self-pay) individual. However, HHS is of the view that if an item or service is eligible for patient-provider dispute resolution only if it is explicitly listed in the good faith estimate, providers and facilities may be incentivized to omit items and services from the good faith estimate in order to avoid the patient-provider dispute resolution process. It is HHS's view that Congress intended to create a process which allows uninsured (or self-pay) individuals to dispute the final billed charges, if such charges are substantially in excess of the expected charges in the good faith estimate; and therefore any item or service that was not included in the good faith estimate, yet resulted in total billed charges substantially in excess of the total expected charges in the good faith estimate, should be eligible for patient-provider dispute resolution.

Therefore, if the total billed charges, which includes charges for new items or services, exceeds the total expected charges by at least $400 more than the amount in the good faith estimate, the items or services are eligible for patient-provider dispute resolution, despite the new items or services not being itemized in the good faith estimate. For example, co-provider Z bills an uninsured (or self-pay) individual for services C, D, and E, even though services D and E were not included in the good faith estimate. If the differences between the total billed charges for services C, D, and E are substantially in excess of the total expected charges in the good faith estimate for service C, then the uninsured (or self-pay) individual is eligible to initiate patient-provider dispute resolution against co-provider Z for services C, D, and E.

Although convening providers and convening facilities are required to include expected charges from co-providers and co-facilities in the good faith estimate, HHS understands that there may be instances when an uninsured (or self-pay) individual may receive a bill that includes providers or facilities that were not included in the good faith estimate: Specifically, if a co-provider or co-facility that is reflected on the good faith estimate is substituted at the last moment to a different co-provider or co-facility. While PHS Act section 2799B–7 requires that an item or service where the total billed charges are substantially in excess of the total expected charges in the good faith estimate will be eligible for patient-provider dispute resolution, expected charges for the replacement co-provider or co-facility may not be available. Regardless, HHS is of the view that the consumer protections of PHS Act section 2799B–7 should still apply in these circumstances as they are aimed to protect uninsured (or self-pay) individuals from unexpected medical bills, and allowing a co-provider or co-facility to circumvent these protections simply due to not being directly represented on the good faith estimate would undermine these protections. Therefore, HHS is adding 45 CFR 149.620(b)(2) that specifies that an item or service billed by a co-provider or co-facility that replaced the original co-provider or co-facility covered under a good faith estimate is eligible for dispute resolution if the total billed charge is substantially in excess of the expected charges included on the good faith estimate for the original co-provider or co-facility. However, if the replacement co-provider or co-facility provides the uninsured (or self-pay) individual with a new good faith estimate of expected charges in accordance with 45 CFR 149.610(b)(2) then the determination of whether an item or service billed by the replacement co-provider or co-facility is eligible for dispute resolution is based on whether the total billed charges for the replacement co-provider or co-facility are substantially in excess of the total expected charges included in the good faith estimate provided by the replacement co-provider or co-facility.

HHS is of the view that had the convening provider known that the items or services from these particular co-providers or co-facilities would be needed, they would have been included on the good faith estimate. Therefore, HHS is of the view that such an approach for an item or service billed by a replacement co-provider or co-facility is necessary and appropriate to ensure such item or service is eligible for dispute resolution if the total billed charges are substantially in excess of the total expected charges in the good faith estimate even if the billing provider or facility did not provide the original estimate of expected charges in the good faith estimate. HHS acknowledges the challenges these requirements impose on providers and facilities, and the potential disincentive that such a requirement could have on a provider's or facility's willingness to provide an item or service under such circumstances given the patient-provider dispute resolution process, at 45 CFR 149.620, uses the expected charges contained in the good faith estimate to determine the eligibility of an item or service for patient-provider dispute resolution. However, HHS is of the view that such requirements are necessary for the intended consumer protections regarding surprise medical bills, and that, without such a requirement, an uninsured (or self-pay) individual may be unable to avail themselves of the patient-provider dispute resolution process in these circumstances. HHS also recognizes that these particular situations may be more complex for an uninsured (or self-pay) individual to determine eligibility for dispute resolution. HHS seeks comment

on the approach for eligibility in cases where the co-provider or co-facility has been replaced with a different co-provider or co-facility, comments on whether there are other complex situations where clarification would be helpful, and the feasibility of such an approach to eligibility, as well as comments on alternative approaches.

HHS considered whether to base eligibility for patient-provider dispute resolution on whether an individual item or service listed on a good faith estimate is billed an amount substantially in excess of the expected charge for the item or service. However, HHS is of the view that basing the eligibility for patient-provider dispute resolution on each individual item or service would add complexity as each item or service listed on the good faith estimate would need to be assessed separately for eligibility. Additionally, by basing the eligibility for patient-provider dispute resolution on an individual item or service, providers and facilities could potentially avoid dispute resolution by ensuring that no single billed charge exceeds the estimate provided on the good faith estimate by more than the substantially in excess threshold, even though the total of all billed charges for a provider or facility might substantially exceed the total expected charges in the good faith estimate. As a result, to fully protect the uninsured (or self-pay) individual, the individual items and services would need to be totaled by provider or facility, with the total billed charges by provider or facility subject to the substantially in excess standard. HHS is of the view that, because the uninsured (or self-pay) individual understood the items or services to most likely cost the amount listed in the good faith estimate with respect to each provider or facility, focusing on the total billed charges by each provider or facility ensures that patient-provider dispute resolution is available when the total billed charges for each provider or facility substantially exceeds the amount that the individual expects to pay.

HHS also considered basing the eligibility on the total billed charges for all items or services and all providers or facilities listed on the good faith estimate. However such an approach would be significantly more complex given that the good faith estimate could consist of estimates from multiple providers and facilities who would bill the uninsured (or self-pay) individual separately. It could also potentially increase the burden on the uninsured (or-self pay) individual who would likely need to submit multiple bills from multiple providers or facilities. Additionally, such an approach could require a provider or facility to respond to a notice requesting additional documentation from an SDR entity due to the billing of other providers, even when the provider or facility did not bill an uninsured (or self-pay) individual an amount substantially in excess of the good faith estimate.

As discussed in section VI.A.2 of this preamble, these interim final rules define expected charges, for an item or service, as, the cash pay rate or rate established by a provider or facility for an uninsured (or self-pay) individual, reflecting any discounts for such individuals, where the good faith estimate is being provided to an uninsured (or self-pay) individual; or the amount the provider or facility would expect to charge if the provider or facility intended to bill a plan or issuer directly for such item or service when the good faith estimate is being furnished to a plan or issuer. Therefore, HHS would anticipate that the expected charges in the good faith estimate include applicable discounts and rates the provider or facility would ultimately charge an uninsured (or self-pay) individual rather than a standard list price or chargemaster rate. However, HHS remains concerned about the potential incentives for providers and facilities to inflate good faith estimates, for example, by overestimating the costs for items or services, providing a higher list price (or chargemaster rate) rather than the price the uninsured (or self-pay) individual would be expected to pay when accounting for any discounts, upcoding to a more expensive service, or adding additional unnecessary services which could lead to higher good faith estimates overall and could discourage uninsured (or self-pay) individuals from obtaining needed care. Furthermore, HHS is also concerned that providers or facilities may interpret an individual's decision to seek care after receiving the good faith estimate as their ability to pay the expected charges and therefore be disincentivized to offer the uninsured (or self-pay) individuals with charity care or discounted rates. HHS acknowledges that the availability of the patient-provider dispute resolution process may lead providers or facilities to estimate prices higher than they otherwise would have. However, HHS is very concerned that a provider or facility may increase the good faith estimate amount specifically to circumvent the ability of the uninsured (or self-pay) individual to access the patient-provider dispute resolution process, resulting in uninsured (or self-pay) individuals being charged higher prices and as a result the uninsured (or self-pay) individual foregoing needed care due to concerns over the potential costs. Additionally, this behavior could potentially lead to a situation where an uninsured (or self-pay) individual ultimately receives an inflated good faith estimate, but after receiving treatment is billed an amount higher than the good faith estimate yet less than the substantially in excess threshold, and is therefore unable to access dispute resolution due to the expected charges in the good faith estimate being overestimated. HHS acknowledges that an uninsured (or self-pay) individual may not necessarily know if a good faith estimate is inflated. However, as discussed in section VI.A.4 of this preamble, the good faith estimate will provide an itemized list of the expected items or services in advance, including the applicable diagnosis codes, expected service codes, and expected charges associated with each listed item or service. HHS is of the view that this will provide needed transparency for uninsured (or self-pay) individuals about the items or services they expect to be provided and the estimated costs with which they can compare with good faith estimates from other providers or through price transparency information such as the Hospital Price Transparency requirements described in 45 CFR part 180. HHS seeks comment on what other resources are available to assist individuals in determining the reasonableness of the good faith estimates they receive, particularly those who are uninsured (or self-pay) and with low health literacy. HHS also seeks comments on ways to raise awareness of these resources and on other resources that could be utilized by uninsured (or self-pay) individuals.

HHS notes that a provider or facility intentionally providing expected charges they know to be incomplete or inaccurate in the good faith estimate could violate the requirements in PHS Act section 2799B–6, which requires that the estimates being provided be good faith estimates, and thus could be subject to enforcement actions under PHS Act section 2799B–4. HHS is of the view that it is important for an uninsured (or self-pay) individuals to be able to file complaints regarding a provider or facility who they believe is not complying with the good faith estimate requirements and patient-provider dispute resolution process requirements, such as in cases where an individual believes a provider or facility is inflating the good faith estimate.

Therefore, HHS is amending the regulations at 45 CFR 149.450 to expand the scope to include subpart G of part 149, which includes 45 CFR 149.610 and 45 CFR 149.620, among the provisions for which HHS can receive and resolve complaints concerning a provider's or facility's failure to meet the specified requirements. HHS seeks comment on this approach.

HHS also considered whether there should be an additional backstop that would allow an uninsured (or self-pay) individual to access patient-process dispute resolution based on allegations that the provider or facility willfully overestimated the expected charges in the good faith estimate in order to avoid dispute resolution. Under such an approach, the good faith estimate would be reviewed to ensure that the good faith estimate reasonably reflect only the expected charges for the item or service, and that the good faith estimate did not include items or services extraneous to those that were reasonably expected to be provided in conjunction with such scheduled item or service. If HHS were to determine that such requirements had not been met, the uninsured (or self-pay) individual would be deemed eligible to initiate the patient-provider dispute resolution process for such items or services. However, these interim final rules do not include such an approach as HHS was concerned this approach would add significantly more complexity to the patient-provider dispute resolution process. HHS seeks comment on this potential approach of allowing uninsured (or self-pay) individuals to initiate dispute resolution for good faith estimates they believe to have been overinflated in order for providers and facilities to avoid dispute resolution.

As noted elsewhere in this preamble, with regards to an item or service furnished by co-providers and co-facilities, providers and facilities subject to these interim final rules may need additional implementation time to develop appropriate communication channels that may not yet exist among various co-providers or co-facilities. As stated in section VI.A.7 of this preamble, with respect to good faith estimates provided to uninsured (or self-pay) individuals on or after January 1, 2022 through December 31, 2022, HHS will exercise its enforcement discretion in situations where the good faith estimate does not include expected charges for items and services from a co-provider or co-facility. During this period, HHS encourages convening providers and facilities to include a range of expected charges for such items and services during the period of care. HHS understands that it may take time for providers and facilities to develop systems and processes for receiving and providing the required information regarding items and services provided by co-providers and co-facilities. HHS is of the view that without having such processes in place, co-providers and co-facilities who provide items or services may be subjected to patient-provider dispute resolution in situations where the co-providers or co-facilities were unable to provide complete and accurate pricing information to the convening provider or facility, and as a result would not provide sufficient detail to provide accurate good faith estimates. As a result, during the period of enforcement discretion, further discussed in section VI.A.7 of this preamble, items or services to be provided by a co-provider or co-facility that appear on the good faith estimate that do not include an estimate of expected charges or that appear as a range of expected charges would not be eligible for the patient-provider dispute resolution process. However, HHS emphasizes that this particular application for patient-provider dispute resolution eligibility would apply only in 2022 to allow additional time for the convening provider and convening facility to build the necessary systems and processes to receive accurate estimates from co-providers and co-facilities. HHS notes, that nothing prevents a co-provider or co-facility from furnishing the information as required in 45 CFR 149.610 before December 31, 2022, and under such circumstances, a co-provider or co-facility must comply with the patient-provider dispute resolution requirements in 45 CFR 149.620. Additionally, nothing would prevent the uninsured (or self-pay) individual from separately requesting a good faith estimate directly from the co-provider or co-facility in which case the patient-provider dispute resolution requirements in 45 CFR 149.620 would apply. HHS seeks comment on the approach for eligibility for the patient-provider dispute resolution process, including the feasibility of such approach, including the approach for eligibility for co-providers and co-facilities in 2022, as well as comment on alternative approaches to increase consumer protections against unexpected medical bills from co-providers and co-facilities during 2022.

HHS also recognizes that uninsured (or self-pay) individuals in underserved and racial/ethnic minority communities, including individuals with vision, hearing, or language limitations, individuals with limited English proficiency, lesbian, gay, bisexual, transgender, and queer (LGBTQ+) individuals, and persons with health literacy needs, may face additional barriers to paying for high unexpected health care costs, understanding their rights related to good faith estimates, patient-provider dispute resolution, and how and when to initiate the dispute resolution process. HHS seeks comment from underserved and racial/ethnic minority communities on additional barriers individuals from these communities may face in understanding and exercising their rights related to these topics, and how to address them. HHS also seeks feedback on outreach and education activities, efforts, and resources available for underserved and racial/ethnic minority communities, including individuals with vision, hearing, or language limitations, individuals with limited English proficiency, lesbian, gay, bisexual, transgender, and queer (LGBTQ+) individuals, and persons with health literacy needs, to help ensure that these rights and tools are available, accessible, and understood such that they can be used equitably by all uninsured (or self-pay) individuals in appropriate circumstances. HHS also recognizes that groups such as CAPs and legal aid organizations play an important role in helping consumers, particularly those in underserved and racial/ethnic minority communities, including individuals with vision, hearing, or language limitations; individuals with limited English proficiency; and persons with health literacy needs, with complex heath care issues, which may also include assistance with the patient-provider dispute resolution process. HHS seeks comment on how to best to support the efforts of these organizations in assisting uninsured (or self-pay) individuals throughout the patient-provider dispute resolution process.

4. Initiation of Patient-Provider Dispute Resolution

PHS Act section 2799B–7 requires patient-provider dispute resolution be available when an uninsured (or self-pay) individual is billed by a provider or facility for items or services in an amount that is ''substantially in excess'' of the expected charges in the good faith estimate for the provider or facility.

HHS is specifying under 45 CFR 149.620(c) that when an uninsured (or self-pay) individual is billed for items or services where the total billed charges for a provider or facility is substantially in excess of the total expected charges in the good faith estimate for the

provider or facility, the uninsured (or self-pay) individual or their authorized representative (excluding any providers or facilities directly represented in the good faith estimate, providers associated with such providers or facilities, or non-clinical staff associated with such providers or facilities), may submit a notification (initiation notice) to the Secretary of HHS to initiate the patient-provider dispute resolution process. HHS is of the view that a provider should generally not be permitted to represent the uninsured (or self-pay) individual in dispute resolution for items or services where the provider was represented on the good faith estimate, even if the provider would not be a party to the dispute. HHS is of the view that there is a likelihood of an inherent financial or professional conflict of interest. These same concerns extend to employees of the facility at which the items or services are furnished. However, HHS acknowledges that many providers would generally not be inclined to assist the uninsured (or self-pay) individuals with initiating a dispute resolution even without this restriction. HHS further clarifies that providers may serve as authorized representatives for uninsured (or self-pay) individuals, provided they do not meet the previously described exclusion criteria. HHS also clarifies that CAPs and legal aid organizations can also serve as authorized representatives for the purpose of the patient-provider dispute resolution process as such organizations may have experience assisting consumers with billing issues. Additionally, all materials created for the patient-provider dispute resolution process, including the Federal IDR portal, will be compliant with the language access requirements of section 508 of the Rehabilitation Act of 1973 to meet accessibility needs.[95] HHS seeks comment on what additional supports are necessary for community organizations, such as CAPs and legal aid organizations, to assist uninsured (or self-pay) individuals with the dispute resolution process. Providers and facilities are also required to comply with other state and Federal laws regarding language access, to the extent applicable. HHS reminds providers and facilities that are recipients of Federal financial assistance that they must comply with Federal civil rights laws that prohibit discrimination. These laws may include Section 1557 of the Patient Protection and Affordable Care Act, Title VI of the Civil Rights Act of 1964, and Section 504 of the Rehabilitation Act of 1973, as applicable. Section 1557 of the Patient Protection and Affordable Care Act and Title VI of the Civil Rights Act of 1964 require covered entities to take reasonable steps to ensure meaningful access for individuals with limited English proficiency, which may include provision of language assistance services, such as providing qualified interpreters or written translation of written good faith estimates in paper or electronic form into languages other than English. When language assistance services are provided, they must be provided free of charge and be accurate and timely. Section 1557 of the Affordable Care Act and Section 504 of the Rehabilitation Act of 1973 require covered entities to take appropriate steps to ensure effective communication with individuals with disabilities, including provision of appropriate auxiliary aids and services in a timely manner and free of charge to the individual. Auxiliary aids and services may include interpreters, large print materials, accessible information and communication technology, open and closed captioning, and other aids or services for persons who are blind or have low vision, or who are deaf or hard of hearing. Information provided through information and communication technology also must be accessible to individuals with disabilities, unless certain exceptions apply. HHS also seeks comment on what additional supports are necessary for persons in and representatives of minority and underserved communities, including those with limited English proficiency, those with disabilities who require information in alternate and accessible formats, and stakeholders who serve such communities.

The initiation notice must be submitted to the Secretary of HHS, and postmarked within 120 calendar days of receiving the initial bill containing charges for the item or service that is substantially in excess of the expected charges in the good faith estimate, for the provider or facility. HHS is specifying calendar days instead of business days in this instance, because it is HHS' experience in administering other consumer-facing programs such as the Federally Facilitated Marketplace, that consumers have an easier time calculating and responding to deadlines that are measured by calendar days rather than business days. HHS considered whether to specify a timeframe shorter than 120 calendar days. However, HHS is concerned that requiring the initiation notice to be submitted in less than 120 calendar days would not provide sufficient time for an uninsured (or self-pay) individual to collect and submit the required information. HHS also considered a timeframe greater than 120 calendar days, or no time limit; but HHS is of the view that due to the requirement, as discussed later in this section, that once the patient-provider dispute resolution process has been initiated, a provider or facility must not move the bill for the disputed item or service into collection or threaten to do so, or if the bill has already moved into collection, the provider or facility should cease collection efforts, as well as the requirement that the provider or facility suspend the accrual of any late fees on unpaid bill amounts until after the dispute resolution process has concluded, providing for a longer timeframe could increase uncertainty for a provider or facility over whether an uninsured (or self-pay) individual will file a dispute resolution request. As a result, HHS is of the view that having a clear timeframe with which an uninsured (or self-pay) individual can initiate a dispute resolution request is both necessary and appropriate. HHS seeks comment on the appropriateness of allowing individuals 120 calendar days to initiate the dispute resolution process, and whether more or less time should be allowed for an uninsured (or self-pay) individual to initiate dispute resolution, or whether there should not be a time limit at all.

The initiation notice may be submitted through the Federal IDR portal, electronically, or on paper, in a form and manner specified by the Secretary of HHS. The initiation notice must include: (1) Information sufficient to identify the items or services under dispute, including the date of service or date the item was provided and a description of the item or service; (2) a copy of the bill for the items and services under dispute (the copy can be a photocopy or an electronic image so long as the document is readable); (3) a copy of the good faith estimate for the items and services under dispute (the copy can be a photocopy or an electronic image so long as the document is readable); (4) the contact information of the parties involved, including name, email address, phone number and mailing address; (5) the state where the items or services in dispute were furnished; and (6) the uninsured (or self-pay) individual's

[95] For 508 standards, see the US Access Board's final rule at: *https://www.federalregister.gov/documents/2017/01/18/2017-00395/information-and-communication-technology-ict-standards-and-guidelines; see also Information and Communication Technology Revised 508 Standards and 255 Guidelines,* U.S. Access Board, *https://www.access-board.gov/ict/* (last visited Sept. 10, 2021).

communication preference, through the Federal IDR Portal, or electronic or paper mail.

In addition to the required information, the uninsured (or self-pay) individual must submit with the initiation notice an administrative fee to the SDR entity as described in 45 CFR 149.620(g) and section VI.B.8 of this preamble. The amount of the administrative fee, as well as the manner in which it must be submitted, will be clarified in guidance by HHS. PHS Act section 2799B–7(c) contemplates that the uninsured (or self-pay) individual pay an administrative fee, and that such fee should be set in a manner not to create a barrier to access the process. While HHS acknowledges that requiring an uninsured (or self-pay) individual to pay an administrative fee upfront may discourage some individuals from initiating the patient-provider dispute resolution process, HHS is of the view that requiring a nominal upfront administrative fee will help prevent the submission of unnecessary claims to the patient-provider dispute resolution process and ensure that dispute resolution resources are available in necessary cases. HHS also notes that as further discussed in section VI.B.8 of this preamble, if the uninsured (or self-pay) individual prevails in the dispute resolution process, the SDR entity will adjust the final payment determination amount to include a reduction in the final payment determination amount that accounts for the uninsured (or self-pay) individual's administrative fee payment, thus allowing the uninsured (or self-pay) individual to recoup the administrative fee paid.

The date of initiation of the patient-provider dispute resolution process will be the date of receipt of such initiation notice. HHS will provide additional information in guidance on how the uninsured (or self-pay) individual can submit the initiation notice, including necessary steps for the process and a standard notification form to ensure the uninsured (or self-pay) individual is able to include all the necessary information to initiate the dispute resolution process. In addition to the guidance, uninsured individuals will be informed of how to initiate the patient-provider dispute resolution process through information that providers and facilities must include on the good faith estimates, as discussed in section VI.A.4 of this preamble. HHS also intends to conduct outreach and education to consumer advocates, CAPs, legal aid organizations and other stakeholders to assist consumers through this process.

HHS expects to leverage the Federal IDR portal described in section III of this preamble to facilitate the operation of the patient-provider dispute resolution process. The Federal IDR portal will allow uninsured (or self-pay) individuals or their authorized representatives to submit the initiation notices, upload documentation, receive notices from HHS and the SDR entity, upload additional supporting documentation, and view the SDR entity's payment determination. HHS expects that providers and facilities will also utilize the Federal IDR portal to receive notices from HHS and the SDR entity, upload documentation, upload additional supporting documentation, and view the SDR entity's determination. HHS intends for the SDR entity to utilize the Federal IDR portal in all cases, as HHS is of the view that utilizing the Federal IDR portal to facilitate the patient-provider dispute resolution process is preferable and will allow for more efficient operation of the process, faster and easier receipt of notices and submission of documentation, and would allow all the relevant information on a specific patient-provider dispute resolution case to be accessible in one place. HHS is aware that an individual or a provider or facility may not be able to utilize the Federal IDR portal depending on various factors and as a result the individual, provider, or facility may choose to communicate with HHS or the SDR entity using other methods, including electronic or paper mail. Additionally, HHS recognizes that minority and underserved communities, including those with limited English proficiency and those with disabilities may prefer information in alternate and accessible formats and may not be best served by using the Federal IDR portal. HHS intends to put in place processes to ensure accessibility of the system for these communities, and HHS seeks comments on this approach.

Once the initiation notice has been received, HHS will select an SDR entity according to the process further described in section VI.B.6 of this preamble. After the SDR entity has been selected, the SDR entity will provide notice to the uninsured (or self-pay) individual and the provider or facility through the Federal IDR portal, or electronic or paper mail, that a patient-provider dispute resolution initiation request has been received and is under review, the SDR entity will also include information identifying the item or service under dispute, and the date the initiation notice was received. The SDR entity will also notify the uninsured (or self-pay) individual, and the provider or facility, that while the dispute resolution process is pending, the provider or facility must not move bills for the disputed items or services into collection or threaten to do so, or if the bill has already moved into collection, the provider or facility should cease collection efforts until the dispute has been settled. The provider or facility must also suspend the accrual of any late fees on unpaid bill amounts until after the dispute resolution process has concluded. Additionally, the provider or facility must not take or threaten to take retributive action against an uninsured (or self-pay) individual for utilizing the patient-provider dispute resolution process. The notice will also provide information to the uninsured (or self-pay) individual about the availability of consumer assistance resources that can assist them with the dispute.

The SDR entity will review the initiation notice submitted by the uninsured (or self-pay) individual to ensure that the disputed items or services meet the eligibility criteria for the patient-provider dispute resolution process and that the initiation notice contains all the required information. The SDR entity will notify the uninsured (or self-pay) individual electronically or by mail, depending on the individual's preference, of the outcome of the review including in cases where the initiation notice is determined to be incomplete or the item or service is determined ineligible for dispute resolution, in which case the uninsured (or self-pay) individual would be provided 21 calendar days to submit any missing information or provide supplemental information to demonstrate the item or service is eligible for the dispute resolution process. To assist consumers with understanding the timeline to submit the supplemental information, such insufficiency notice will provide a date by which the additional information must be postmarked or submitted electronically. HHS is of the view that providing the uninsured (or self-pay) individual with 21 calendar days is appropriate as it provides consumers with an opportunity to resolve any deficiencies in the initiation notice and access the dispute resolution process if eligible. If the insufficiency notice is not made available to an individual in a format that is accessible to individuals with disabilities or with low-English proficiency within 14 calendar days of such a request from the individual, a 14-calendar day extension will be granted to allow sufficient time for document

submission, so that the individual, in this situation, will have a total of 35 calendar days to submit supplemental information. HHS also considered a timeframe greater than 21 calendar days, or no time limit, however, HHS is concerned that due to the requirement that a provider or facility must not move the bill for the disputed item or service into collection or threaten to do so, or if the bill has already moved into collection, the provider or facility should cease collection efforts, and the provider or facility suspend the accrual of any late fees on unpaid bill amounts until after the dispute resolution process has concluded, providing for a longer timeframe could increase burdens and uncertainty for a provider or facility. The 21-calendar-day timeframe is also consistent with external review processes in some states.[96] HHS seeks comments on whether 21 calendar days is a sufficient timeframe for uninsured (or self-pay) individuals to submit additional documentation through the mail or electronically, or whether a different timeframe should be considered.

Once the SDR entity has determined that an item or service is eligible for dispute resolution, the SDR entity must provide notification of the determination to both parties (the uninsured (or self-pay) individual and the provider or facility) through the Federal IDR portal, or electronic or paper mail, and must request that the provider or facility provide certain information within 10 business days as described in 45 CFR 149.620(d) and in section VI.B.7.ii of this preamble.

While the dispute resolution process is pending, the provider or facility must not move bills for the disputed items or services into collection or threaten to do so until after dispute resolution process has concluded, or if the bill has already moved into collection, the provider or facility should cease collection efforts until the dispute has been settled. The provider or facility must also suspend the accrual of any late fees on unpaid bill amounts until after the dispute resolution process has concluded. PHS Act section 2799B–7 established a process that would provide a mechanism for an uninsured (or self-pay) individual who is billed an amount for an item or service that is substantially in excess of the expected charges in the good faith estimate to seek a determination on the amount to be paid. If the provider or facility were to move the bill, if fully or partially unpaid, to collection or to accrue late fees prior to the SDR entity determining a payment amount, the consumer protections intended in PHS Act section 2799B–7 would be undermined. In order for an uninsured (or self-pay) individual to avoid moving the bill into collection or the accrual of late fees, the uninsured (or self-pay) individual would effectively be required to pay the bill in full prior to determination and seek a refund from the provider or facility if the individual prevails. HHS is of the view that through the patient-provider dispute resolution process, the uninsured (or self-pay) individual is actively working in good faith to resolve a payment dispute and should not be effectively punished for utilizing such process by the accrual of late fees or movement of the bill into collections. HHS is of the view that use of its general rulemaking authority to establish such requirements is necessary and appropriate in order to implement the provisions of PHS Act section 2799B–7 in a manner that furthers the statutory intent to protect consumers by ensuring that uninsured (or self-pay) individuals can use the patient-provider dispute resolution process without being penalized for utilizing such process or being required to pay the billed charges upfront to avoid late fees or collections activities. HHS seeks comment on this approach of disallowing the movement of a bill into collections and the suspension of the accrual of late fees.

In addition, HHS is using its general rulemaking authority to establish requirements under 45 CFR 149.620 to prohibit a provider or facility from taking or threatening to take any retributive action against an uninsured (or self-pay) individual for utilizing the patient-provider dispute resolution process to seek resolution for a disputed item or service. If a provider or facility were to take or threaten to take retributive action against an uninsured (or self-pay) individual, such action could create a chilling effect for the uninsured (or self-pay) individual to utilize the dispute resolution process, which would undermine the consumer protections intended in PHS Act section 2799B–7. As a result, HHS is of the view that it is necessary and appropriate to require a provider or facility to not take or threaten to take any retributive action against an uninsured (or self-pay) individual for utilizing the patient-provider dispute resolution process.

5. Certification of Selected Dispute Resolution Entities

PHS Act section 2799B–7 requires the Secretary of HHS to recognize or establish a process to contract with and certify entities to resolve payment disputes between uninsured (or self-pay) individuals. Additionally, PHS Act section 2799B–7 requires entities certified under this process to satisfy, at a minimum, the criteria in PHS Act section 2799A–1(c). HHS intends to contract with and certify only that number of entities it believes will be necessary to timely resolve the volume of patient-provider disputes, rather than pursue an open process under which all entities who meet IDR entity requirements will be certified to resolve patient-provider payment disputes. Moreover, HHS will compensate SDR entities directly for their services under a contract that complies with the Federal Acquisition Regulation (FAR) as further implemented or supplemented by the HHS Acquisition Regulation.[97] Through this contract process, HHS will assess the dispute resolution entity for compliance with all applicable SDR entity certification requirements. HHS is of the view that this approach will reduce the overall cost of the program, which is funded primarily through appropriations to HHS, reduce the administrative burden associated with collecting fees from a large number of certified entities who may have differing fee schedules, and will allow for HHS to control the cost of the program to ensure that low-income individuals are able to access the patient-provider dispute resolution process. For the first year of the patient-provider dispute resolution program under PHS Act section 2799B–7, HHS anticipates contracting with between 1 and 3 SDR entities. HHS is of the view that 1 to 3 SDR entities will be sufficient in the first year to conduct the dispute resolution process for the anticipated number of cases outlined in the Economic Impact and Paperwork Burden section of these interim final rules. It will also ensure through the contracting process that the volume estimates are tenable for the contracted SDR entities. Additionally, given the timeline required by statute to implement the patient-provider dispute resolution process and the timeline under which these rules will become effective, HHS is of the view that contracting with a limited number of entities may be necessary to ensure the timely launch of the program.[98] HHS is of the view that attempting to procure

[96] Some state processes have a 15-business day time frame which would generally translate to 21 calendar days. *See e.g., https://insurance.mo.gov/consumers/health/externalreviewprocess.php.*

[97] *See* 48 CFR, Chapter 3 (HHS-specific regulations governing federal acquisitions for services).

[98] *See* FAR 6.302–2 (allowing less than full and open competition where an agency's need for services is of an unusual and compelling urgency).

SDR entity services from more than 3 entities will increase the burden associated with certifying IDR entities for the Federal IDR process discussed in section III of this preamble and with contracting SDR entities for the patient-provider dispute resolution process, and will limit HHS' ability to effectively launch the programs in accordance with statutory deadlines. HHS also is of the view that contracting with more than 3 SDR entities in the first year will unsustainably increase the administrative burden associated with launching both programs, and may impose sufficient risk to cause delays in implementation.

For these reasons, HHS is of the view that contracting with a limited number of SDR entities is preferable to adopting an ''any willing provider'' model. Accordingly, through this contract process, HHS will assess an entity's compliance with the SDR entity certification requirements to ensure the entity satisfies the certification criteria discussed later in this section of the preamble.

SDR entities will be assessed on whether they meet the applicable certification requirements during the contracting process with HHS and such process will be separate and distinct from the certification process applicable to IDR entities that will provide IDR services for providers, providers of air ambulance services, facilities, plans and issuers as required under 26 CFR 54.9816–8T and 54.9817–2T, 29 CFR 2590.716–8 and 2590.717–2, and 45 CFR 149.510, and 45 CFR 149.520. Although an SDR entity may apply for certification as an IDR entity, SDR entities are not required to do so. However, consistent with the statutory requirement, SDR entities will be required to meet the same requirements as certified IDR entities, with a few exceptions outlined later in this section of this preamble. SDR entities will be required to report on those data elements from providers and facilities that HHS deems necessary to accurately describe and assess the administration of the patient-provider dispute resolution program. Therefore, the requirements laid out in section III.D.5 of this preamble will also apply to SDR entities as a condition of receiving a contract award from HHS for the patient-provider dispute resolution program.

For example, PHS Act section 2799A–1(c)(4)(A)(v) requires a certified IDR entity to maintain the confidentiality of individually identifiable health information (IIHI) obtained in the course of conducting determinations. Under these interim final rules, HHS outlines certain standards related to confidentiality, including security, privacy, and breach notification requirements that apply to an IDR entity seeking certification. See section III.D.5 of this preamble for further discussion on the applicable confidentiality requirements. Under 45 CFR 149.620(d)(1), HHS specifies that an SDR entity must satisfy the Federal IDR entity certification criteria specified in 45 CFR 149.510(e), with a few exceptions specified in 45 CFR 149.620(d)(2). As part of this requirement, an SDR entity must comply with all the confidentiality requirements that apply to certified IDR entities in 26 CFR 54.9816–8T(e)(2)(v), 29 CFR 2590.716–8(e)(2)(v) and 45 CFR 149.510(e)(2)(v). Similarly, the definitions related to confidentiality in 45 CFR 149.510(a)(2) also apply for 45 CFR 149.620. Therefore, the definitions for ''breach,'' ''individually identifiable health information (IIHI)'' and ''unsecured IIHI'' that apply for IDR entities also apply for SDR entities. HHS seeks comment on the confidentiality requirements for an SDR entity, including whether additional requirements should be considered.

In addition, like IDR entities, SDR entities are required to comply with other state and Federal laws regarding language access, to the extent applicable. HHS reminds SDR entities that they, along with providers and facilities that are recipients of Federal financial assistance, must comply with Federal civil rights laws that prohibit discrimination. These laws include Section 1557 of the Patient Protection and Affordable Care Act, Title VI of the Civil Rights Act of 1964, and Section 504 of the Rehabilitation Act of 1973. Section 1557 of the Patient Protection and Affordable Care Act and title VI of the Civil Rights Act of 1964 require covered entities to take reasonable steps to ensure meaningful access to individuals with limited English proficiency, which may include provision of language assistance services, such as providing qualified interpreters or written translations in paper or electronic form into languages other than English. When language assistance services are provided, they must be provided free of charge and be accurate and timely. Section 1557 of the Patient Protection and Affordable Care Act and Section 504 of the Rehabilitation Act of 1973 require covered entities to take appropriate steps to ensure effective communication with individuals with disabilities, including provision of appropriate auxiliary aids and services in a timely manner and free of charge to the individual. Auxiliary aids and services may include sign language interpreters, large print materials, accessible information and communication technology, open and closed captioning, and other aids or services for persons who are blind or have low vision, or who are deaf or hard of hearing. Information provided through information and communication technology also must be accessible to individuals with disabilities, unless certain exceptions apply. HHS also seeks comment on what additional measures are necessary for persons in racial/ethnic minority and underserved communities, including those with limited English proficiency, those with disabilities who require information in alternate and accessible formats, lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons, and stakeholders who serve such communities.

Unlike the process for certifying IDR entities, HHS intends to contract only with SDR entities that will be able to conduct patient-provider dispute resolution in all applicable states where the patient-provider dispute resolution process will apply. As such, SDR entities will need to submit information on their ability to operate nationwide through the contract process. Additionally, IDR entity fees that certified IDR entities will charge as the cost for providing dispute resolution services will not apply in the case of SDR entities, which will be paid for their services through contracts with HHS. Therefore, SDR entities will not be required to submit a fee schedule for batched and non-batched claims. Additionally, SDR entities will not be required to submit policies and procedures regarding holding IDR entity fees in a trust or escrow account, though they will still be required to submit policies and procedures regarding holding administrative fees and remit them to HHS in a manner specified by HHS.

Additionally, an SDR entity must also submit a conflict-of-interest mitigation policy that will not apply to IDR entities. Given that HHS intends to contract with a limited number of SDR entities under this program, HHS is of the view that additional standards for conflict-of-interest mitigation should apply to SDR entities, as there will likely be fewer entities available to conduct dispute resolution. Therefore, in addition to the requirement for certified IDR entities to submit policies and procedures for the ongoing auditing, mitigation, and reporting of conflicts of interest within their

organizations, SDR entities will be expected to include a mitigation plan for situations when no one in the entire organization will be able to conduct dispute resolution on a case due to an entity-level conflict of interest, which could include utilizing a subcontractor without a conflict of interest that meets SDR entity requirements to conduct the patient-provider dispute resolution for that case. Since there is a possibility that a single SDR entity will be contracted for this process, or that all available SDR entities indicate a conflict of interest that cannot be mitigated, HHS is of the view that additional requirements must be applied through these regulations and the contracting process to ensure that in the event that an entity-level conflict of interest occurs, SDR entities will be able to initiate strategies to fairly and impartially resolve disputes in the absence of another available SDR entity. Through the acquisition process, HHS will ensure compliance with FAR subpart 9.5 regarding organizational and consultant conflicts of interest in order to mitigate the potential for entity-level conflicts of interest that may preclude all available SDR entities from fairly and impartially resolving disputes.

While details on expectations for documentation and review for certified IDR entities will come through guidance, similar details and documentation requests will be done through the acquisition process for SDR entities. As such, all requirements laid out in this section and the applicable requirements outlined in section III.D.5 of this preamble for certified IDR entities will be assessed through the Federal acquisition process to ensure SDR entities have sufficient expertise and capabilities to conduct dispute resolution cases for the patient-provider dispute resolution process.

In subsequent years, case volume and other factors as necessary will be used by HHS to determine and adjust the number of contracted SDR entities needed for the patient-provider dispute resolution process. HHS is of the view that this approach will reduce the overall cost and administrative oversight burdens of the program, which is funded primarily through appropriations to HHS. Since contracting will allow HHS to negotiate lower rates for conducting dispute resolution cases with a limited number of entities, rather than paying set fee schedules associated with each SDR entity as in the Federal IDR process, HHS will be able to reduce both costs to HHS and administrative burdens associated with collecting varying fees from a large number of entities. HHS also is of the view that this approach will allow HHS to control the fees assessed to uninsured (or self-pay) individuals entering the patient-provider dispute resolution process to ensure that low-income individuals can participate in the process.

HHS seeks comment on the SDR entity contracting process, including the applicable certification requirements, specifically as to whether these are the appropriate standards regarding the patient-provider dispute resolution process, if additional standards should be applied, and if so, what those standards should be.

6. Selection of an SDR Entity for Patient-Provider Dispute Resolution

PHS Act section 2799B–7 requires the Secretary of HHS to provide a method to select a patient-provider dispute resolution entity to conduct individual dispute resolutions between patients and providers. As described more fully in section VI.B.5 of this preamble, during the first year of the program, HHS expects to contract with between 1 to 3 SDR entities to conduct patient-provider dispute resolutions.

Similar to the IDR process and for the same reasons described in section III.B.1 of this preamble, the general conflict-of-interest standards laid out in section III.B.1 of this preamble will also apply to SDR entities contracted by HHS for the patient-provider dispute resolution process. These standards include the mandatory period which prohibits personnel who have been a party to the payment determination being disputed, or who were employees or agents of such a party within 1 year immediately preceding dispute resolution assignment, from being assigned to a case.

As discussed in section VI.B.5 of this preamble, SDR entities will also be required to have in place an approved mitigation plan for addressing conflicts of interest. For example, such a mitigation plan could include processes under which any specific dispute resolution personnel who presents a conflict of interest could be walled off from having any role in or knowledge of the relevant payment dispute. To address conflicts of interest that exist at the entity level, the SDR entity could design a plan under which it would subcontract payment disputes to a different entity that meets SDR entity requirements. As part of the contract process, and as discussed in section VI.B.5 of this preamble, the SDR entity must submit specific mitigation plans such as proof of a subcontractor who meets the SDR entity requirements for HHS to assess, and approve as part of the acquisition process, and in accordance with the conflict-of-interest requirements set forth in FAR subpart 9.5. HHS is of the view that this approach will sufficiently mitigate the potential that conflicts of interest that exist to the extent that a case may not able to be resolved fairly and impartially, because having a subcontractor provides an avenue for cases to be sent for dispute resolution when the SDR entity has a conflict of interest. HHS also is of the view that ensuring that processes are in place to identify and address potential conflicts of interest is important to ensure impartiality in payment determinations and the timely and efficient resolution of disputes.

Upon receiving a request to initiate patient-provider dispute resolution case from an uninsured (or self-pay) individual, HHS will select 1 of the contracted SDR entities to serve as the entity to conduct the dispute resolution process. Selection of an SDR entity that will resolve a particular dispute will occur in round robin fashion to ensure equal allocation of cases to SDR entities, unless conflicts of interest arise. In the event that the assigned SDR entity has a conflict of interest that cannot be sufficiently mitigated by applying the SDR entity's conflicts mitigation plan, the next SDR entity in line will be selected. HHS is of the view that this approach will help ensure the selection process runs smoothly, supports the timely resolution of disputes consistent with applicable regulations, and that SDR entity caseloads are allocated efficiently. Upon receiving an assignment from the Secretary of HHS to make a determination for an item or service, the SDR entity shall ensure that no conflict of interest exists, and in such case no conflict exists, the SDR entity shall notify the uninsured (or self-pay) individual and the provider or facility of the selection of the SDR entity as described in section VI.B.4 of this preamble.

In the event that an SDR entity attests that a conflict of interest exists in relation to an assigned payment dispute, the SDR entity must notify the Secretary of HHS no later than 3 business days following selection. Additionally, either party (the uninsured (or self-pay) individual, or the provider or facility) may attest that a conflict of interest exists in relation to the SDR entity assigned to a payment dispute, in which case the SDR entity must notify the Secretary of HHS no later than 3 business days following receipt of the attestation.

In the event a conflict of interest exists, HHS will then automatically

select a different SDR entity from the remaining pool of contracted entities using a round robin approach. If no other contracted SDR entity, and no subcontracted entity, is able to provide the patient-provider dispute resolution services due to conflicts of interest that cannot be sufficiently mitigated or any other reason, HHS may seek to contract with an additional SDR entity as needed, to conduct dispute resolution in this case. HHS recognizes that while the Department expects these particular situations to be very rare, contracting with an additional SDR entity could take time and would make meeting the required patient-provider dispute resolution timeframes challenging. HHS notes that, as discussed in section VI.B.10 of this preamble, the time periods specified in these interim final rules may be extended in the case of extenuating circumstances at HHS' 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. In these rare cases, HHS anticipates that it may be appropriate to exercise such discretion if needed. For example, in the event that HHS needs to contract with an additional SDR entity, the time periods specified in this section may be extended at HHS' discretion to allow for HHS to contract with that SDR entity. HHS seeks comment on this approach, including comment on the feasibility of such approach and comment on alternative approaches HHS should consider. HHS also seeks comment on whether it is feasible or appropriate to seek assistance from the pool of certified IDR entities to provide patient-provider dispute resolution services in these circumstances.

These interim final rules also define certain terms related to conflict-of-interest standards applicable to SDR entities certified and contracted to resolve patient-provider disputes. Such an approach to conflict of interest is similar to the approach taken by the Federal IDR process discussed in section III.D.5 of this preamble. HHS is of the view that maintaining consistent standards between the Federal IDR process and the patient-provider dispute resolution process is a straightforward approach and serves to minimize stakeholder confusion over what the applicable standard will be. In general, a ''conflict of interest'' means, with respect to a party to a payment determination, or SDR entity, a material relationship, status, or condition of the party, or SDR entity that impacts the ability of the SDR entity to make an unbiased and impartial payment determination. For purposes of the patient-provider dispute resolution process, a conflict of interest exists when an SDR entity is: A provider or a facility, an affiliate or a subsidiary of a provider or facility, or an affiliate or subsidiary of a professional or trade association representing a provider or facility. A conflict of interest also exists when an SDR entity, or any personnel assigned to a determination, has a material familial, financial, or professional relationship with a party to the payment determination being disputed, or with any officer, director, or management employee of the provider, the provider's group or practice association, or the facility that is a party to the dispute. HHS is of the view that these requirements are necessary to ensure that payment disputes between an uninsured (or self-pay) individual and a provider or facility are conducted by impartial third parties. HHS seeks comment on this approach, including the feasibility of such approach, and whether additional requirements related to conflict of interest should be considered.

7. Payment Determination for Patient-Provider Dispute Resolution

i. Determination of Payment Amount Through Settlement

While the SDR entity payment determination is pending, HHS recognizes that the two parties to the patient-provider dispute resolution process (the uninsured (or self-pay) individual and the provider or facility) may agree to resolve the dispute by settling on a payment amount. Therefore, new 45 CFR 149.620(f)(1) states that at any point after the dispute resolution process has been initiated but before the date on which a determination is made by the SDR entity, the parties can settle the payment amount through either an offer of financial assistance or an offer to accept a lower amount, or an agreement by the uninsured (or self-pay) individual to pay the billed charges in full.

In the event that the parties agree to settle on a payment amount, the provider or facility should notify the SDR entity through the Federal IDR Portal, electronically, or in paper form, as soon as possible, but no later than 3 business days after the date of the agreement. The settlement notification must contain at a minimum, the settlement amount, the date upon which settlement was reached, and documentation demonstrating that the provider or facility and uninsured (or self-pay) individual have agreed to the settlement. The settlement notice must also document that the provider or facility has applied a reduction to the uninsured (or self-pay) individual's settlement amount that is equal to at least half the amount of the administrative fee paid as discussed in section VI.B.8 of this preamble. Once the SDR entity receives the notification of the settlement, the SDR entity shall close the dispute resolution case as settled and the agreed upon payment amount will apply for the items or services.

HHS also clarifies that payment of the billed charges (or a portion of the billed charges) by the uninsured (or self-pay) individual (or by another party on behalf of the uninsured (or self-pay) individual) does not demonstrate agreement by the uninsured (or self-pay) individual to settle at that amount or any other amount. For example, if the uninsured (or self-pay) individual has already made payment or entered into a payment plan and then chooses to enter dispute resolution, the fact that they previously paid, or agreed to pay, all or part of the billed charges may not be used by the provider or facility to prove that a settlement has been reached to avoid the patient-provider dispute resolution process.

HHS is of the view that providing an opportunity for the uninsured (or self-pay) individual and the provider or facility to come to terms on a payment amount that is mutually agreeable for the parties involved is appropriate as it may help resolve payment disputes quickly without the need for a determination by an SDR entity. Such a process can also incentivize a provider or facility to offer to accept a lower amount or to provide financial assistance to the uninsured (or self-pay) individual. However, HHS clarifies that neither party (the uninsured (or self-pay) individual or the provider or facility) is required to negotiate a settlement for the billed charges, and the decision to enter into a settlement on the payment amount is optional. In cases where there is no settlement, the SDR entity will make a determination as discussed in section VI.B.7.iii of this preamble.

HHS recognizes that to the extent that a provider or facility believes that a settlement may be more beneficial for them than the SDR entity determination, the provider or facility may be incentivized to seek a settlement. While such an outcome may be desirable in that it can lead to a quick resolution and could lead to provider or facility offering to accept a lower payment amount or other financial assistance to the uninsured (or self-pay) individual, HHS is concerned that the uninsured (or

self-pay) individual, particularly those without representation, would be at a disadvantage when negotiating with the provider or facility. HHS seeks comment on these concerns, including whether additional consumer protections should be considered, and ways HHS can increase an uninsured (or self-pay) individual's access to effective representation, through legal aid organizations or other groups.

ii. Determination of Payment Amount Through Patient-Provider Dispute Resolution

As part of the SDR determination process, 45 CFR 149.620(f)(2) requires that the health care provider or health care facility must submit information to the SDR entity not later than 10 business days after the receipt of the notice from the SDR entity initiating the patient-provider dispute resolution process described in section VI.B.4. This information must include: (1) A copy of the good faith estimate provided to the uninsured (or self-pay) individual for the items or services under dispute (the copy can be a photocopy or an electronic image so long as the document is readable); (2) a copy of the billed charges provided to the uninsured (or self-pay) individual for items or services under dispute (the copy can be a photocopy or an electronic image so long as the document is readable); and (3) documentation demonstrating that the difference between the billed charges and the expected charges in the good faith estimate reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided. While the statute does not specify what a provider or facility should provide to the SDR entity to inform the SDR entity's determination decision or how long a provider or facility should have to report such information, HHS is of the view that it is both necessary and appropriate to require the provider or facility to provide the copies of the bill and good faith estimate for the item or service in question as such information can be helpful for the SDR entity to verify the eligibility of the dispute in question. Although the uninsured (or self-pay) individual will provide a copy of the bill and good faith estimate, requiring the provider or facility to also provide the bill and good faith estimate will allow the SDR entity to verify the information in the bill and good faith estimate provided by the uninsured (or self-pay) individual and identify any potential discrepancies. HHS believes it is also necessary and appropriate to provide a means for a provider or facility to submit documentation or an explanation to support the billed charges, such as information related to the patient's relevant medical history that is necessary to demonstrate that the item or service is medically necessary and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided. HHS is of the view that such documentation from the provider or facility would assist the SDR entity with making a fair assessment whether the billed charge is appropriate because otherwise the SDR entity would be unfamiliar with the facts that would allow the SDR entity to assess medical necessity, and whether the need for the items or services was foreseeable. The interim final rules require that this information be submitted within 10 business days, this time period is similar to the Federal IDR process requirements for submitting documentation to support a dispute resolution determination as outlined in PHS Act section 2799B–1. HHS is of the view that a 10-business-day time period is sufficient for a provider or facility to gather and submit the required information, as this information should be documented as part of the individual's patient record.

Not later than 30 business days after receipt of the information from the provider described in section 45 CFR 149.620(f)(2)(i), the SDR entity must make a determination on the amount to be paid by such uninsured (or self-pay) individual taking into account the requirements described in section VI.B.7.iii of this preamble. The 30-business day timeframe is also similar to the requirement in the Federal IDR process in PHS Act section 2799A–1(c)(5) where not later than 30 business days after the selection of the certified IDR entity, the certified IDR entity must select one of the offers submitted by the plan or issuer and the provider or facility to be the out-of-network rate for the item or service. HHS is of the view that 30 business days should provide sufficient time for an SDR entity to review the submitted information and issue a determination. The SDR entity is required to assess the information submitted by the provider or facility according to the requirements described in 45 CFR 149.620(f)(3) and discussed in section VI.B.7.iii of this preamble.

iii. Requirements for Determination

45 CFR 149.620(f)(3) sets forth the requirements for SDR entities in making payment determinations. As described in section VI.A.3 of this preamble, the itemized list of items or services in a good faith estimate must reflect the expected charges from the convening provider or facility and items and services reasonably expected to be provided by co-providers or co-facilities and must be built upon accurate information that was known at the time the good faith estimate was given to the uninsured (or self-pay) individual. As a result, the SDR entity should use the expected charges in the good faith estimate as the presumed appropriate amount and unless the provider or facility provides credible information justifying the difference between the total billed charges and the good faith estimate by demonstrating that the difference between the billed charges and the expected charges in the good faith estimate for the item or service reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided. For this purpose, information is credible if upon critical analysis the information is worthy of belief and consists of trustworthy information. This is the same standard the Departments are adopting at 26 CFR 54.9816–8T, 29 CFR 2590.716–8, and 45 CFR 149.510 for the Federal IDR processes discussed in section III.D.4 of this preamble. HHS is of the view that maintaining a consistent standard of review among IDR entities and SDR entities, while still recognizing the inherent differences in the respective processes based on the applicable parties, minimizes program complexity and reduces the potential for confusion among providers and facilities over the applicable standards for review.

As stated previously, HHS acknowledges that unforeseen factors during the course of treatment could result in additional items or services furnished and could result in higher billed amounts after receipt of care than was anticipated at the time the good faith estimate was provided. HHS does not expect that the good faith estimate would include charges for unanticipated items or services that could occur due to unforeseen events. In cases where changes in the underlying circumstances occur during treatment and would reasonably result in higher than expected charges, the SDR entity may consider additional factors that support charges for medically necessary items or services. As information to demonstrate that the difference between

the billed charges and the expected charges for an item or service in the good faith estimate reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, providers or facilities should provide documentation, which can include a written explanation, detailing any change in circumstances, how that change resulted in a higher billed charge than the expected charge for the item or service in the good faith estimate, and why the billed charge reflects the cost of a medically necessary item or service. HHS considered requiring the provider or facility to provide only evidence that the difference between the billed charges and the expected charges for the item or service in the good faith estimate reflects the costs of a medically necessary item or service, and not require the provider or facility demonstrate the item or service is based on unforeseen circumstance that could not have reasonably been anticipated when the good faith estimate was provided. However, HHS is of the view that an item or service that is medically necessary and could reasonably have been anticipated should already be included on the good faith estimate and without such information the uninsured (or self-pay) individual would not have been provided with an accurate estimate of the expected charges. HHS is of the view that not requiring the provider or facility to demonstrate that the item or service could not have been anticipated could incentivize a provider or facility to not list all items or services on the good faith estimate which could lead to less-accurate estimates provided to uninsured (or self-pay) individuals.

Uninsured (or self-pay) individuals may also submit additional documentation through the Federal IDR portal, although they are not required to provide documentation beyond the information included in the initiation notice, such as the good faith estimate and the billed charges.

The SDR entity must review any documentation submitted by the uninsured (or self-pay) individual or their authorized representative, and a provider or facility, and must make a determination as to whether the provider or facility has provided credible information for each billed item or service to demonstrate that the difference between the billed charge and the expected charge in the good faith estimate reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided. The SDR entity should make this determination separately for each unique billed item or service. HHS is of the view that this helps ensure that the SDR entity review is comprehensive and that the facts and circumstances for each billed charge are considered by the SDR entity. HHS is also of the view that this approach ensures that the uninsured (or self-pay) individual is only billed charges that reflect medically necessary items or services and are based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided.

For any item or service where the billed charge is equal to or less than the expected charge in the good faith estimate, the SDR entity will determine the payment amount to be the billed charge. If the billed charge is higher than the expected charge for an item or service in the good faith estimate and the SDR entity determines the provider or facility has not provided credible information that the difference between the billed charge and the expected charge for the item or service in the good faith estimate reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, the SDR entity must determine the amount to be paid by the uninsured (or self-pay) individual for the item or service to be equal to the expected charge for the item or service listed in the good faith estimate. If the SDR entity determines that the provider or facility has provided credible information that the difference between the billed charge and the expected charge for the item or service in the good faith estimate reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, the SDR entity must select as the amount to be paid by the uninsured (or self-pay) individual to be the lesser of: (1) The billed charge; or (2) the median payment amount for the same or similar service in the geographic area, as defined in 45 CFR 149.140(a)(7), that is reflected in an independent database as defined in 45 CFR 149.140(a)(2), or if the amount reflected in the independent database is less than the expected charge in the good faith estimate, the good faith estimate amount.

In cases in which the SDR entity determines that the provider or facility has provided credible information that difference between the billed charge and the expected charge for the item or service in the good faith estimate reflects the costs of a medically necessary item or service that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, HHS considered whether to always require the SDR entity to set the payment amount equal to the billed charge. However, HHS is concerned that such an approach may increase the incentive for providers and facilities to inflate their billed charges, particularly in cases where the provider or facility believes they can justify the additional billed charge. Requiring the SDR entity to select as a payment amount the median payment amount for the same or similar item or service in a geographic area, if lower than the billed charge but higher than the expected charge in the good faith estimate, ensures that the uninsured (or self-pay) individual is protected from billed charges that are above the market rate for items or services provided. HHS acknowledges that under this approach an SDR entity can determine a payment amount lower than the original billed charge in circumstances where a provider or facility submits credible information justifying the additional item or service as reflecting a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided. HHS also recognizes that such an approach could increase the incentive for the uninsured (or self-pay) individual to initiate patient-provider dispute resolution even in cases where the uninsured (or self-pay) individual believes the extra billed charges to be justified. However, HHS is of the view that PHS Act section 2799B–7 establishes important consumer protections from unexpected billed charges that are substantially in excess of the expected charges in the good faith estimate, even in cases where the difference between the billed charge and the expected charges in the good faith estimate may reflect the costs of a medically necessary item or service and is based on unforeseen circumstances that could not reasonably been anticipated when the good faith estimate was provided. These protections ensure that the uninsured (or self-pay) individual is protected from excessive billed charges even

when such billed charges reflect a medically necessary item or service and are based on unforeseen circumstances that could not reasonably been anticipated when the good faith estimate was provided. In addition, HHS is of the view that the median payment amount is a reasonable payment amount, as the methodology was established to calculate a fair market rate for an item or service, and although this methodology was developed for group health plans and health insurance issuers offering group or individual health insurance coverage, it can also be leveraged to determine whether the billed charge is less than a fair market price, instead of creating separate standards regarding median rates as applied to the QPA and payment amounts applied to the patient provider dispute resolution process.

For new items or services not originally listed on the good faith estimate, if the SDR entity determines the provider or facility did not provide credible information that demonstrates that the billed charge for the new item or service reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, the SDR entity will determine a payment amount equal to $0. HHS is of the view that PHS Act section 2799B–7 establishes consumer protections for uninsured (or self-pay) individuals in the event they receive surprise charges that are not reflected in the good faith estimate. HHS is of the view that requiring the uninsured (or self-pay) individual to pay for items or services they did not anticipate, absent a determination that such a billed charge is supported by credible information that the billed charge reflects a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, would run counter to the protections intended in PHS Act section 2799B–7. If the SDR entity determines that a provider or facility has provided credible information that the billed charge for new items or services that did not appear on the good faith estimate reflects the costs of a medically necessary item or service that is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, then the SDR entity must determine the charge to be paid by the uninsured (or self-pay) individual for the new item or service as the lesser of two payment amounts: (1) The billed charge; or (2) the median payment amount for the same or similar service in the geographic area, as defined in 45 CFR 149.140(a)(7), that is reflected in an independent database as defined in 45 CFR 149.140(a)(2).

After making a determination for all items or services subject to patient-provider dispute resolution, the SDR entity must add together the amounts to be paid for all items and services. As further discussed in section VI.B.8 of this preamble, in cases in which the final amount determined by the SDR entity is lower than the total billed charges, the SDR entity must reduce the final amount by an amount equal to the administrative fee amount paid by the individual (to account for the administrative fee charged to the provider or facility) to calculate the final payment determination amount to be paid by the uninsured (or self-pay) individual for the items or services subject to the SDR entity determination. HHS acknowledges that under this approach, particularly in cases where the provider or facility submits credible information to justify the additional billed charges, the SDR entity may still determine a lower payment amount than the billed charge and the provider or facility would end up paying an administrative fee in a large portion of patient-provider dispute resolution cases. However, HHS is of the view that the intent behind the consumer protections in PHS Act section 2799B–7 is to protect the uninsured (or self-pay) individual from unexpected billed charges that are substantially in excess of the expected charges in the good faith estimate, and as a result, the uninsured (or self-pay) individual should be held harmless in cases where the process results in a lower payment amount.

Once the final payment determination amount has been calculated, the SDR entity must inform the uninsured (or self-pay) individual and the provider or facility using the Federal IDR portal, and depending on the individual's or provider's or facility's preference, electronically or by paper mail, of such determination, along with the SDR entity's justification for making such a determination.

To provide an example of how the payment determination would operate in practice, consider a situation in which an uninsured (or self-pay) individual initiates the dispute resolution process against a provider for services A, B, C, and D. Services A and B were listed on the good faith estimate. The expected charge for service A was higher than the billed charge for service A, the expected charge for service B was lower than the billed charge for service B, and services C and D were not included on the good faith estimate and are thus new services. The difference between the total of the billed charges for services A, B, C, and D and the total expected charges for services A and B (services C and D were new services and not included in the good faith estimate) was determined to be at least $400 more than the amount listed in the good faith estimate, and thus these services were found to be eligible for patient-provider dispute resolution. When the SDR entity reviews the documentation submitted by the provider, because the billed charge for service A is less than the expected charge for service A, the SDR entity determines the amount to be paid to be equal the billed charge for service A. If the SDR entity determines the provider did not provide credible information that the difference between the higher billed charge and the expected charge for service B reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, then the SDR entity determines the amount to be paid for service B to be equal to the expected charge for service B on the good faith estimate. If the SDR entity determines the provider did provide credible information that billed charges for services C and D reflects the costs of medically necessary items or services and are based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, the SDR entity would determine the amounts to be paid for services C and D. Due to services C and D being new services, and as a result not having a corresponding expected charges in the good faith estimate, the SDR entity shall determine the payment amounts for services C and D to be the lesser of: (1) The billed charge; or (2) the median payment amount for the same or similar service in that geographic area, as defined in 45 CFR 149.140(a)(7), that is reflected in an independent database as defined in 45 CFR 149.140(a)(2) (had expected charges for services C or D been included in the good faith estimate, the median payment amount for the same or similar service in that geographic area, as defined in 45 CFR 149.140(a)(7), that is reflected in an independent database as defined in 45 CFR 149.140(a)(2) should not be considered if less than the expected charges for the services

contained in the good faith estimate). The SDR entity would then add together all the payment amounts determined for services A, B, C, and D. Due to the uninsured (or self-pay) individual's payment amount being determined to be lower than the initial billed charge, the SDR entity adjusts the final determination amount to reduce it by an amount equal to the uninsured (or self-pay) individual's administrative fee payment, to calculate the final determination amount. The SDR entity then notifies the uninsured (or self-pay) individual and the provider of the determination, the determination amount, and the reasons for the determination and closes the case.

In determining the median payment amount from an independent database, the requirements and methodology set forth in 45 CFR 149.140(c)(3) apply. HHS is of the view that utilizing the same methodology for the calculation of median rates for the QPA, when a plan or issuer does not have sufficient internal information to calculate the QPA, as the methodology for calculating the median payment amounts under the patient-provider dispute resolution process is reasonable and appropriate. This approach will allow an equivalent standard to be applied across multiple instances where the regulation refers to median rates, and will reduce confusion that may result from conflicting standards or definitions. HHS is of the view that creating a separate methodology specifically for the calculation of median payment amounts, using an independent database, as they pertain to the patient-provider dispute resolution process is unnecessary and therefore SDR entities must use this methodology when determining a median payment amount. HHS seeks comment on this methodology as a reasonable way to calculate median payment amounts for purposes of the patient-provider dispute resolution process.

HHS considered whether to allow the SDR entity to have discretion to determine a payment amount lower than the expected charges in the good faith estimate. However, HHS is of the view that such an approach would result in less transparency and predictability for the uninsured (or self-pay) individuals, providers, and facilities regarding the outcome of the patient-provider dispute resolution process. PHS Act sections 2799B–6 and 2799B–7 establishes a backstop for an uninsured (or self-pay) individual that protects them from unexpected bills that substantially exceed the expected charges in the good faith estimate. Given that the provider or facility is required to provide the uninsured (or self-pay) individual with a good faith estimate upon scheduling or upon request prior to furnishing the items or services to the individual. HHS is of the view that the good faith estimate represents charges the uninsured (or self-pay) individual would likely expect to pay for the items or services. Therefore, the good faith estimate represents an appropriate amount to be determined as the payment amount when the uninsured (or self-pay) individual prevails. Additionally, setting the payment amount equal to the good faith estimate protects the uninsured (or self-pay) individual from unexpected billed charges in cases where the extra charges do not reflect the costs of a medically necessary item or service that is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided while providing predictability to uninsured (or self-pay) individuals, providers and facilities on what to expect from the patient-provider dispute resolution process. However, HHS recognizes that such an approach may encourage providers or facilities to be overinclusive regarding the list of expected charges in the good faith estimate, thus leading to higher good faith estimates than they otherwise would have provided.

HHS seeks comment on the approach for the determination of payment amounts by the SDR entity, including the feasibility of the approach, as well as comment on alternative approaches. HHS also seeks comment on ways to reduce the incentives for providers and facilities to over include items or services on the good faith estimate, and the circumstances, if any, in which requiring the SDR entity to set a payment amount below the expected charges in the good faith estimate would be appropriate. HHS also seeks comment on the use of the median amount for the same or similar service in the geographic area, as defined in 45 CFR 149.140(a)(7), that is reflected in an independent database as defined in 45 CFR 149.140(a)(2), including comment on the feasibility of such an approach, and comment on whether a different methodology should also be considered.

iv. Effects of Determination

Under the Federal IDR process established in PHS Act sections 2799A–1(c)(5)(E) and 2799A–2(c)(5)(D), determinations made by a certified IDR entity are binding upon the parties involved, in the absence of a fraudulent claim or evidence of misrepresentation of facts presented to the IDR entity involved. PHS Act section 2799B–7 establishes a separate dispute resolution process to determine payment amounts made to a provider or facility by an uninsured (or self-pay) individual when the uninsured (or self-pay) individual is billed charges substantially in excess of the expected charges in the good faith estimate; however, the statute is silent regarding the effects of such determinations. HHS is of the view that it is both necessary and appropriate to similarly require that determinations made by SDR entities be binding upon all parties involved, in the absence of a fraudulent claim or evidence of misrepresentation of facts presented to the SDR entity involved regarding such claim. HHS is of the view that use of its general rulemaking authority to establish such requirements is necessary and appropriate in order to implement the provisions of PHS Act section 2799B–7 to ensure the consumer protections established under PHS Act section 2799B–7 operate as intended. Without making the determination binding, the consumer protections established in PHS Act section 2799B–7 would be significantly diminished and the cost for administering the program may outweigh the benefits. Therefore, under 45 CFR 149.620(f)(4), a determination made by an SDR entity will be binding upon the parties involved, in the absence of a fraudulent claim or evidence of misrepresentation of facts presented to the SDR entity regarding such claim, except that the provider or facility may provide financial assistance or agree to an offer for a lower payment amount than the SDR entity's determination, or the individual may agree to pay the billed charges in full, or the uninsured (or self-pay) individual and the provider or facility may agree to a different payment amount. HHS seeks comment on the approach regarding SDR entity determinations being binding, including the feasibility of such approach, as well comment on alternative approaches. HHS also seeks comment on subject of judicial review. PHS Act section 2799A–1(c)(5)(E) requires that determinations not be subject to judicial review, except in a case described in any paragraphs (1) through (4) of section 10(a) of title 9, United States Code. HHS seeks comment on the feasibility or desirability of adopting a similar application for the patient-provider dispute resolution process, as well as comment on alternative approaches.

8. Costs of Patient-Provider Dispute Resolution Process

PHS Act section 2799B–7, as added by the No Surprises Act, directs the

Secretary of HHS to establish an administrative fee ''to participate in the patient-provider dispute resolution process in such a manner as to not create a barrier to an uninsured (or self-pay) individual's access to such process.'' Aside from the administrative fee, discussed later in this section, the No Surprises Act does not specifically address requirements for how the costs for the SDR entity to conduct patient-provider dispute resolution determinations (dispute resolution costs) should be funded.

HHS considered various approaches with respect to how the dispute resolution costs should be treated for the patient-provider dispute resolution process. HHS recognizes that it is important for the SDR entity to be appropriately compensated for providing patient-provider dispute resolution services. HHS considered maintaining a similar fee structure as in the Federal IDR process where the non-prevailing party would be required to pay all the costs of the IDR entity. However, HHS is of the view that requiring an uninsured (or self-pay) individual to pay the entire dispute resolution costs in cases where the provider or facility prevails in the dispute resolution process could be prohibitive for individuals to access the dispute resolution process. HHS is also concerned that requiring a provider or facility to pay dispute resolution costs when they do not prevail could impose a burden on the provider or facility and potentially provide an incentive for the provider or facility to raise prices for uninsured (or self-pay) individuals to account for potential dispute resolution costs or avoid treating uninsured (or self-pay) individuals altogether.

HHS is also of the view that while the patient-provider dispute resolution process is similar to the Federal IDR process in several important ways, the patient-provider dispute resolution process does have unique distinctions. In particular, while in the Federal IDR process, both the providers (and providers of air ambulance services) and the payers can initiate the IDR process, and both parties have an incentive to resolve the dispute, in the patient-provider dispute resolution process only the uninsured (or self-pay) individual can initiate the dispute resolution process, and HHS is concerned that the provider or facility would not have the same incentive to participate in the dispute resolution process as the uninsured (or self-pay) individual. Similarly, there will likely be a significant imbalance in both power and knowledge between the provider or facility and the uninsured (or self-pay) individual initiating the dispute resolution process. As a result, HHS is of the view that a different approach to dispute resolution costs is needed for the patient-provider dispute resolution process. As a result, HHS determined that an approach where HHS would pay dispute resolution costs by directly contracting with SDR entities is the appropriate approach, as it would address the concerns discussed earlier in this section of the preamble. HHS is also of the view that such an approach will streamline the patient-provider dispute resolution process and minimize potential burdens on uninsured (or self-pay) individuals, and providers and facilities.

HHS is adopting an approach for the patient-provider dispute-resolution process in which HHS will pay dispute resolution costs through contracts with SDR entities. Such an approach ensures that the uninsured (or self-pay) individual would not be required to pay dispute resolution costs, and as a result, such costs would not pose a barrier to accessing the dispute resolution process. Adopting such an approach in which HHS pays the dispute resolution costs would minimize the burdens placed on uninsured (or self-pay) individuals and on providers or facilities, and reduce the incentives for providers and facilities to increase prices or restrict an uninsured (or self-pay) individual's access to needed care. Adopting an approach where the individual would not be required to bear the dispute resolution costs would help ensure that such costs would not be a barrier to the uninsured (or self-pay) individual's access to the dispute resolution process.

Aside from dispute resolution costs, PHS Act section 2799B–7 requires that the Secretary of HHS establish an administrative fee to participate in the patient-provider dispute resolution process in such a manner as to not create a barrier to an uninsured (or self-pay) individual to participate in such process. HHS is aware that not requiring the uninsured (or self-pay) individual to pay dispute resolution costs could lead to overutilization of the patient-provider dispute resolution process; however, this concern is mitigated by limiting the availability of the patient-provider dispute resolution only to cases where the total billed charge for items or services per provider or facility are billed in excess of the expected charges by at least $400 more than the amount listed in the good faith estimate, as discussed in section VI.B.2 of this preamble. In addition, HHS is of the view that requiring parties to the dispute resolution process to pay an administrative fee to offset some of the Federal costs for implementing the patient-provider dispute resolution program is appropriate. Such a requirement is also similar to the Federal IDR process, which requires all parties to pay an administrative fee to cover Federal costs; however, under that process, the fee is required to equal the estimated costs to the Federal Government, while in the patient-provider dispute resolution process the administrative fee is required to be established so that it would not create a burden for the uninsured (or self-pay) individual to participate in the dispute resolution process.

HHS intends to assess an administrative fee on the non-prevailing party (providers, facilities, and uninsured (or self-pay) individuals) to the patient-provider dispute resolution process. For purposes of the patient-provider dispute resolution process, the prevailing party means the provider or facility when the SDR entity determines the total amount to be paid to be equal to the total billed charges, whereas the prevailing party means the uninsured (or self-pay) individual when the SDR entity determines the total amount to be paid to be less than the total billed charges. Upon the SDR entity determination, if the uninsured (or self-pay) individual is the prevailing party, the SDR entity would apply a reduction, equal to the administrative fee amount paid by the individual, to the final determination amount to be paid by the individual for the items or services. HHS is of the view that requiring the non-prevailing party to pay the entire administrative fee (either in a payment made directly to the SDR entity in the case of the uninsured (or self-pay) individual, or in a reduction in the final payment determination amount as in the case of the provider or facility) ensures that both parties are treated the same with regards to the administrative fee assessed. Additionally, requiring only the non-prevailing party to pay the administrative fee will help ensure that the party that prevails in dispute resolution is not penalized for participating in the process. Under this approach, the uninsured (or self-pay) individual who is the initiating party in the patient-provider dispute resolution process will pay the administrative fee at the process initiation through the SDR entity. HHS is of the view that since the uninsured (or self-pay) individual is the initiating party, waiting for the provider or facility to submit the administrative fee prior to the SDR entity making a determination may result in undue delays to the

process. In cases in which the uninsured (or self-pay) individual prevails in dispute resolution, the SDR entity would apply a reduction equal to the administrative fee paid by the individual to the final determination amount to be paid by the individual for the items or services. HHS is of the view that requiring the provider or facility to pay the administrative fee to the uninsured (or self-pay) individual through a reduction in the final determination amount to be paid is the appropriate approach as it simplifies the number of transactions, rather than requiring the provider or facility to provide a payment directly to the SDR entity. This approach also ensures that in cases in which the uninsured (or self-pay) individual prevails, the SDR entity will reduce the amount the uninsured (or self-pay) individual ultimately is required to pay for an item or services by the amount of the administrative fee paid so that it is not left to the provider or facility to apply the reduction equal to the administrative fee paid to the final payment amount. In cases where the provider or facility prevails in dispute resolution, the SDR entity would not reduce the final payment amount by an amount equal to the amount of the administrative fee paid by the uninsured (or self-pay) individual.

In cases described in section VI.B.7.i of this preamble where the parties to dispute resolution agree to settle the payment amount prior to the SDR entity making a determination, both parties will be responsible for paying half the amount of the administrative fee. In this case, the provider or facility will document in the settlement notice described in section VI.B.7.i of this preamble that it has reduced the settlement amount by at least half of the administrative fee amount paid by the uninsured (or self-pay) individual.

HHS intends to establish an administrative fee in guidance in a manner that will not create a barrier to an uninsured (or self-pay) individual's access to the patient-provider dispute resolution process. In setting the fee HHS is considering expected costs to HHS for operating the patient-provider dispute resolution program, including contractor costs, and costs to HHS for utilizing the Federal IDR portal for patient provider dispute resolution cases. However, due to the requirements in PHS Act section 2799B–7 that such administrative fee must not pose a burden to participate for uninsured (or self-pay) individual to participate in the patient-provider dispute resolution process, HHS is of the view that it is necessary and appropriate to limit the size of the administrative fee. As a result, HHS expects the fee to be no more than $25, which HHS believes would allow HHS to offset some of the costs of operating the dispute resolution process while keeping the administrative fee low enough to ensure uninsured (or self-pay) individuals are able to access the dispute resolution process. HHS considered whether to base the administrative fee on annual household income but is concerned that such an approach would require an uninsured (or self-pay) individual to submit financial documentation to verify their income which could significantly increase complexity to initiate the dispute resolution process and could create additional burdens for an uninsured (or self-pay) individual to participate. HHS intends to evaluate patient-provider dispute resolution case volume, contract costs, and other Federal costs for the program and may adjust this fee in subsequent years through guidance to ensure that the fee continues to mitigate overutilization of the patient-provider dispute resolution process, offsets some of HHS's costs of operating the dispute resolution process, and also does not pose a burden for uninsured (or self-pay) individuals regarding participation in the process. HHS seeks comment on this approach, including comment on whether the administrative fee should be higher or lower, the feasibility of the approach to collecting the administrative fee, including comment on alternative approaches that HHS should consider. HHS also seeks comment on ways to ensure public awareness of the dispute resolution process, including the administrative fee and how payments are handled, as well as comment on potential unintended or disparate impacts of administrative costs on underserved and underrepresented populations.

9. Deferral to State Patient-Provider Dispute Resolution Processes

The No Surprises Act establishes strong consumer protections for uninsured (or self-pay) individuals to have access to the patient-provider dispute resolution process in cases in which billed charges substantially exceed expected charges in the good faith estimate. HHS is of the view that PHS Act section 2799B–7 operates in such a way that all uninsured (or self-pay) individuals, regardless of state, are required to have at least the minimum protections set forth in the statute. However, HHS has considered circumstances where states may wish to develop their own processes for resolving disputes between uninsured (or self-pay) individuals and providers or facilities. HHS is of the view that when a state law is in effect that provides a process for resolving disputes between an uninsured (or self-pay) individual and a provider or facility that meets or exceeds the consumer protections contained in PHS Act section 2799B–7, such a process should continue to apply. In addition, HHS believes that such an approach is consistent with other provisions of the No Surprises Act such as allowing allow the application of a state law established to determine the total amount payable under such a plan, coverage, or issuer for certain emergency services. HHS is adding new 45 CFR 149.620(h) to establish a process by which HHS will determine whether a state patient-provider dispute resolution process provides at least the same level of consumer protections as does the Federal process. HHS will communicate with the state and determine whether a state law provides for such a dispute resolution process, and ensure that such process meets or exceeds certain minimum Federal requirements. If HHS determines that the state has in effect a state law that meets or exceeds the minimum Federal requirements, then HHS will defer to the state process. In such case the patient-provider dispute resolution process operated by HHS will not be available in that state. As further discussed in section VI.B.5 of this preamble, as part of the contracting and certification process for an SDR entity, the entity must demonstrate the ability to operate nationwide, including the ability to operate in states where a state process is terminated so that uninsured (or self-pay) individuals continue to have access to a process that meets Federal standards. HHS will direct any patient-provider dispute resolution requests received by HHS from uninsured (or self-pay) individuals in that state to the state process to adjudicate the dispute resolution initiation request according to the state process. HHS will assess such state process for compliance with the minimum Federal standards to ensure any such state process includes the same or greater level of consumer protection as would apply under the Federal patient-provider dispute resolution process. If HHS determines that such state process meets or exceeds the minimum Federal standards, HHS will discuss such determination with the state as well as notify the state in writing of such determination.

HHS considered what minimum requirements a state law must include in order for HHS to determine that the state's law is at least as consumer

protective as the protections contained in the No Surprises Act. At a minimum, the state process should: (1) Be binding, unless the provider or facility offers for the uninsured (or self-pay) individual to pay lower amount than the determination amount; (2) take into consideration a good faith estimate, that meets the minimum standards established under 45 CFR 149.610, provided by the provider or facility to the uninsured (or self-pay) individual; (3) have a fee to participate in the patient-provider dispute resolution process that is equal to or lower than the Federal administrative fee; and (4) have in place conflict-of-interest standards that at a minimum meet the requirements set forth in 45 CFR 149.620(d) and (e)(3).

In order to ensure that a state process continues to meet or exceed the consumer protections contained in the No Surprises Act, HHS will review changes to the state process on an annual basis (or at other times if HHS receives information from the state that would indicate the state process no longer meets the minimum Federal requirements) to ensure the state process continues to meet or exceed the minimum Federal standards. HHS is of the view that having a process to reassess state dispute resolution processes is important for ensuring that uninsured (or self-pay) individuals receive at least the same level of protection as the Federal standard. In the event that the state process is terminated, or HHS determines that it no longer meets the minimum Federal requirements, HHS will make the Federal process available to ensure that ensures the state's residents have access to a dispute resolution process that meets the minimum Federal requirements.

Although the Federal process will be available for uninsured (or self-pay) individuals except in states where HHS has made a determination that the state has established a State process that includes the same or greater level of consumer protection as would apply under the Federal process, HHS recognizes that some states may have in place other programs that seek to resolve payment disputes between uninsured (or self-pay) individuals and providers or facilities that do not meet the minimum Federal standards and thus would not take the place of the Federal dispute resolution process. However, HHS notes that nothing would prevent the uninsured (or self-pay) individual from voluntarily choosing to use such state programs to resolve a payment dispute instead of utilizing the Federal dispute resolution process. HHS seeks comment on the approach to allow the HHS to defer to a state established patient-provider dispute resolution process that meets certain minimum Federal standards, including the feasibility and appropriateness of such approach, and whether additional minimum Federal standards should be considered.

10. Extension of Time Periods for Extenuating Circumstances

Similar to the provisions set forth in section III.D.8 in this preamble for the Federal IDR process under Code section 9816(c)(9), ERISA section 716(c)(9), PHS Act section 2799A–1(c)(9), and codified at 26 CFR 54.9816–8T(g), 29 CFR 2590.716–8(g), and 45 CFR 149.510(g), the time periods specified in these interim final rules (other than the time for payment of the administrative fees discussed in section VI.B.4 of this preamble) may be extended in the case of extenuating circumstances at HHS' 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. Such extension may be necessary if, for example, a natural disaster impedes efforts by individuals, providers, and facilities to comply with the terms of these interim final rules. Additionally, for the extension to be granted, the parties must attest that prompt action will be taken to ensure that the payment determination under this section is made as soon as administratively practicable. The parties may request an extension by submitting a request for an extension due to extenuating circumstances, such as a natural disaster or other circumstances impeding efforts to comply with the terms of these interim final rules, through the Federal IDR portal if the extension is necessary to address delays due to matters beyond the control of the parties or for good cause.

11. Applicability of the Patient-Provider Dispute Resolution Process

The provisions in PHS Act section 2799B–7 require the patient-provider dispute resolution process to be established by the Secretary of HHS no later than January 1, 2022. Consistent with this statutory provision, the requirements under 45 CFR 149.620 are applicable to uninsured (or self-pay) individuals; providers, facilities, and providers of air ambulance services; and SDR entities, beginning on or after January 1, 2022. The interim final rules regarding SDR entity certification at 45 CFR 149.620(a) and 45 CFR 149.620(d), are applicable beginning on October 7, 2021 so that HHS can begin certifying SDR entities before the patient-provider dispute resolution process becomes applicable.

VII. Waiver of Proposed Rulemaking

Code section 9833, ERISA section 734, and PHS Act section 2792 authorize the Secretaries of the Treasury, Labor, and HHS (collectively, the Secretaries), respectively, to promulgate any interim final rules that they determine are necessary or appropriate to carry out the provisions of chapter 100 of the Code, part 7 of subtitle B of title I of ERISA, and title XXVII of the PHS Act.

Under the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*), a general notice of proposed rulemaking is not required when an agency for good cause finds that notice and comment procedures are impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued. 5 U.S.C. 553(b)(B). In addition, section 553(d) ordinarily requires a 30-day delay in the effective date of a final rule from the date of its publication in the **Federal Register**. This 30-day delay in effective date can be waived, however, if an agency finds good cause to support an earlier effective date. Finally, Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act or CRA) requires a delay in the effective date for major rules unless an agency finds good cause that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, in which case the rule shall take effect at such time as the agency determines. 5 U.S.C. 801(a)(3), 808(2).

The Secretaries and the OPM Director 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 a full public notice and comment process has been completed and find that there is good cause to waive the delay in effective date for certain provisions of these interim final rules.

The No Surprises Act was enacted on December 27, 2020, as title I of Division BB of the Consolidated Appropriations Act, 2021. The IDR and internal claims appeals and external review provisions generally apply for plan years (in the individual market, policy years) beginning on or after January 1, 2022. The provisions related to protections for the uninsured generally apply beginning on January 1, 2022. 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. The provisions related to the certification of IDR and SDR entities, as described in the Applicability Dates section of this final rule, apply beginning October 7, 2021.

These interim final rules require plans, issuers, providers, facilities, and providers of air ambulance services to follow a certain process in determining out-of-network payment amounts for certain specified services. These regulations are intended to work in concert with the protections against surprise billing already instituted in the July 2021 interim final rules. Group health plans and health insurance issuers offering group or individual health insurance coverage will have to account for these changes in establishing premium or contribution rates and in making other changes to benefit designs. In some cases, issuers will need time to secure approval for required changes in advance of plan or policy years.

These interim final rules also set up certification requirements for IDR entities and requirements to which they must adhere in selecting payment offers. IDR entities will need time to acquire the necessary expertise and evidence of qualification to apply for certification in order to be prepared to conduct payment determinations for plan years beginning on or after January 1, 2022.

The Departments and OPM anticipate that plans and issuers will have already taken into consideration the statutory provisions in the No Surprises Act as they developed plan designs for 2022 and preliminary rates. Issuing these rules as interim final rules, rather than as a notice of proposed rulemaking, will allow plans and issuers to account for the regulations as they finalize rates and plan offerings and will allow IDR entities to seek certification and be available to take part in the Federal IDR process when these interim final rules go into effect.

Health plans and issuers, and providers, facilities and providers of air ambulance services, require these rules to be in place to determine the out-of-network rates for emergency services, services by out-of-network providers at in-network facilities in certain circumstances, and air ambulance services. Without these final rules, providers, facilities and providers of air ambulance services will not be able to resort to the Federal IDR process (and are no longer able to balance bill patients), leaving the possibility that they will be undercompensated for their services. Such undercompensation could threaten the viability of these providers, facilities and providers of air ambulance services. This in turn, could lead to participants, beneficiaries and enrollees not receiving needed medical care, undermining the goals of the No Surprises Act. Additionally, and for the same reasons, the failure to promulgate this rule in a timely fashion could lead to additional industry consolidation, potentially driving health costs higher.

The Departments considered whether they could exercise enforcement discretion while a rule was proposed and then finalized. However, the No Surprises Act requires that the government set up and administer a Federal IDR process to determine out-of-network rates. Therefore, the Department must establish set rules for this process, including for the certification of certified IDR entities, in order that certified IDR entities, rather than the Departments, may determine out-of-network rates as contemplated by the No Surprises Act.

These interim final rules place new requirements on providers, facilities and providers of air ambulance services regarding how they must initiate open negotiation and the Federal IDR process, as well as what information they must provide to certified IDR entities when engaging in the Federal IDR process. Providers, facilities, and providers of air ambulance services require time to implement these new requirements to ensure compliance by January 1, 2022.

In addition to the requirements for the Federal IDR process, these interim final rules require providers and facilities to furnish a good faith estimate of expected charges upon request or upon scheduling an item or service. Providers and facilities are required to inquire if an individual is enrolled in a group health plan, group or individual health insurance coverage, or a Federal health care program, and if enrolled in such plan or coverage, if the individual is seeking to have a claim for such item or service submitted to such plan or coverage. In the case that the individual is enrolled in such a plan or coverage (and is seeking to have a claim for such an item or services submitted to such plan or coverage), PHS Act section 2799B–6 requires that the provider or facility furnish the good faith estimate to the individual's plan or the issuer of the coverage to inform the advanced explanation of benefits that plans and issuers are required to provide a participant, beneficiary or enrollee under PHS section 2799A–1(f), Code section 9816(f), and ERISA section 716(f).[99] In the case that the individual requesting or scheduling a good faith estimate for an item or service is uninsured (or self-pay), these interim final rules at 45 CFR 149.610 require providers and facilities to furnish the good faith estimate to the individual. Providers and facilities will need time to implement requirements for furnishing good faith estimates to uninsured (or self-pay) individuals and time to develop processes for sharing and receiving information required for the good faith estimate with co-providers and co-facilities. Issuing these rules as interim final rules, rather than as a notice of proposed rulemaking, should allow providers and facilities to account for the regulations as they implement requirements to inquire about an individual's enrollment in

[99] As stated in the August 20, 2021 FAQs issued by the Departments, the Departments have received feedback from the public about the challenges of developing the technical infrastructure necessary for providers and facilities to transmit to plans and issuers starting January 1, 2022 the good faith estimates required under PHS Act section 2799B–6, which plans and issuers must then include in the advanced explanation of benefits. Accordingly, until rulemaking to fully implement this requirement to provide such a good faith estimate to an individual's plan or coverage is adopted and applicable, HHS will defer enforcement of the requirement that providers and facilities provide good faith estimate information for individuals enrolled in a health plan or coverage and seeking to submit a claim for scheduled items or services to their plan or coverage. Additionally, stakeholders have requested that the Departments delay the applicability date of Code section 9816(f), ERISA section 716(f), and PHS Act section 2799A–1(f) until the Departments have established standards for the data transfer between providers and facilities and plans and issuers and have given enough time for plans and issuers and providers and facilities to build the infrastructure necessary to support the transfers. The Departments agree that compliance with these sections is likely not possible by January 1, 2022, and therefore intend to undertake notice and comment rulemaking in the future to implement these provisions, including establishing appropriate data transfer standards. Until that time, the Departments will defer enforcement of the requirement that plans and issuers must provide an advanced explanation of benefits. HHS will investigate whether additional interim solutions for insured consumers are feasible. The Departments note that any rulemaking to fully implement Code section 9816(f), ERISA section 716(f), and PHS Act sections 2799A–1(f) and 2799B–6(2)(A) will include a prospective applicability date that provides plans, issuers, providers, facilities, and providers of air ambulance services with a reasonable amount of time to comply with new requirements. HHS encourages states that are primary enforcers of these requirements with regard to providers and issuers to take a similar enforcement approach, and will not determine that a state is failing to substantially enforce these requirements if it takes such an approach. See FAQs about Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 49 (August 20, 2021), available at *https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-49.pdf* and *https://www.hhs.gov/guidance/document/faqs-about-affordable-care-act-and-consolidated-appropriations-act-2021-implementation.*

health care coverage and to furnish a good faith estimate to an uninsured (or self-pay) individual when these interim final rules goes into effect.

These interim final rules provide further protections for uninsured (or self-pay) individuals by requiring the Secretary of HHS to establish a process (patient-provider dispute resolution) under which an uninsured (or self-pay) individual may seek a determination from a certified dispute resolution entity for billed charges in excess of the good faith estimate. These interim final rules also place new requirements on uninsured (or self-pay) individuals, and providers or facilities regarding how they must initiate patient-provider dispute resolution, what information they must provide to dispute resolution entities for the dispute resolution process, and costs associated with patient-provider dispute resolution. Similar to the Federal IDR process, these interim final rules also establish certification requirements for SDR entities and requirements to which they must adhere in determining payment amounts. SDR entities will need time to acquire the necessary expertise, and enter into a contract with HHS to provide patient-provider dispute resolution. Issuing these rules as interim final rules, rather than as a notice of proposed rulemaking and waiving the delay in effective date for the provisions related to SDR certification will allow SDR entities to account for the regulations as they seek to contract with HHS and be available for patient-provider dispute resolution determinations when the related provisions in these interim final rules go into effect. Further, uninsured (or self-pay) individuals, providers, and facilities will need to understand what is required of them to engage in the patient-provider dispute resolution process when the interim final rules go into effect.

For the foregoing reasons, the Departments and OPM have determined that it is impracticable and contrary to the public interest to engage in full notice and comment rulemaking before these interim final rules become effective, and that it is in the public interest to promulgate interim final rules. Further, for the same reasons as authorized by section 808(2) of the CRA, the Departments find it is impracticable and contrary to the public interest not to waive the delay in effective date for certain provisions of this IFC under section 801 of the CRA. Therefore, the Departments find there is good cause to waive the CRA's delay in effective date pursuant to section 808(2) of the CRA and establish certain policies in this IFC applicable as of the date of display at the Office of the Federal Register.

VIII. Economic Impact and Paperwork Burden

A. Summary

The Departments and OPM have examined the effects of these interim final rules as required by Executive Order 13563 (76 FR 3821, January 21, 2011, Improving Regulation and Regulatory Review); Executive Order 12866 (58 FR 51735, October 4, 1993, Regulatory Planning and Review); the Regulatory Flexibility Act (September 19, 1980, Pub. L. 96–354); section 1102(b) of the Social Security Act (42 U.S.C. 1102(b)); section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4); Executive Order 13132 (64 FR 43255, August 10, 1999, Federalism); and the Congressional Review Act (5 U.S.C. 804(2)).

B. Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

Under Executive Order 12866, ''significant'' regulatory actions are subject to review by OMB. Section 3(f) of the Executive Order defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. Based on the Departments' estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act). Accordingly, the Departments have prepared a Regulatory Impact Analysis that, to the best of our ability, presents the costs and benefits of this rulemaking.

1.1. Need for Regulation

A surprise medical bill is an unexpected bill from a health care provider or facility that occurs when a participant, beneficiary, or enrollee receives medical services from a provider or facility that, generally unbeknownst to the participant, beneficiary, or enrollee, is a nonparticipating provider or facility with respect to the individual's coverage. In the context of this discussion, medical services include air ambulance services. Surprise bills usually occur in situations where a patient is unable to choose a health care provider, emergency facility, or provider of air ambulance services. When they are unable to choose, they are unable to ensure they only receive care from providers or emergency facilities participating in their plan's or coverage's network.

Surprise bills can cause significant financial hardship and cause individuals to forgo care. A recent survey revealed that two-thirds of adults worry about being able to afford unexpected medical bills for themselves and their families, and 41 percent of adults with health insurance received a surprise medical bill in the previous 2 years.[100] A project carried out by Vox, a news and opinion website, which collected emergency department medical bills reported instances of accident victims who received care at out-of-network hospitals and received bills of over $20,000.[101] These challenges may be more keenly experienced by minority and underserved communities, which are more likely to experience poor communication, underlying mistrust of the medical system, and lower levels of patient engagement than other

[100] Pollitz K., et al., US Statistics on Surprise Medical Billing. JAMA. 2020;323(6):498. doi:10.1001/jama.2020.0065.

[101] Kliff S., Surprise medical bills, the high cost of emergency department care, and the effects on patients [published online August 12, 2019]. JAMA Intern Med. doi:10.1001/jamainternmed.2019.3448.

populations.[102] Communities experiencing poverty and other social risk factors are particularly impacted as surprise medical bills can negatively affect consumers' abilities to eliminate debt and create wealth, and ultimately can impact a family for generations.[103] Policies that address the social risk factors and other barriers underserved communities face to accessing, trusting, and understanding health care costs and coverage can reduce disparities and promote health equity.[104]

It has become common practice in the health care system for plans, issuers, and FEHB carriers to negotiate with health care providers. Plans, issuers, and FEHB carriers offer preference to these providers by listing them as ''in-network providers,'' and in return, providers charge discounted rates to the plans, issuers, and FEHB carriers.[105] Joining a plan's, issuer's, or FEHB carrier's network assures providers of patient volume in exchange for lower reimbursements. However, for specialties for which consumers typically do not shop, such as services rendered by emergency departments, patient volume does not depend on whether specific providers are in-network.[106] There is less of an incentive for these providers to engage in negotiations with plans, issuers, and FEHB carriers.[107] One study looked at claims data from a large commercial issuer for the period 2010–2016 and found that over 39 percent of emergency department visits to in-network hospitals resulted in an out-of-network bill, and 37 percent of inpatient admissions to in-network hospitals resulted in at least one out-of-network bill.[108]

Since the passage of the Emergency Medical Treatment and Labor Act (EMTALA) in 1986, Medicare-participating hospitals are required to provide emergency services, regardless of patients' abilities to pay.[109] Because of emergency physicians' legal obligation under EMTALA, and the inability of patients to make treatment decisions, including by selecting providers, in emergency settings, there are fewer incentives for emergency providers to contract with issuers.[110] A large portion of emergency providers' costs are distributed to patients with health benefits, providing justification for plans, issuers, and FEHB carriers to offer smaller networks. Consequently, in recent years, plans, issuers, and FEHB carriers have been offering narrower networks alongside larger discounts, resulting in lower premiums but with fewer in-network options for consumers.[111]

An additional factor contributing to the current environment is the increasing participation of private equity groups in the health care market through the acquisition of physician groups.[112] Anesthesiology, emergency medicine, family practice, and dermatology were the most common medical specialties in acquired physician groups.[113] The private equity business model often centers on risky investments with short-term horizons. These firms often take on large amounts of debt to acquire an asset, then introduce structural and operational changes to extract value or increase revenue growth potential in the aim of selling the asset for a higher valuation.[114] These firms often take on legally complex governance structures designed to protect the private equity firms from regulatory liability.[115] By 2013, two private equity firms accounted for 30 percent of the physician staffing market.[116] One study found that in 2017, hospitals acquired by private equity groups accounted for 7.5 percent of all nongovernmental hospitals and 11 percent of all discharges from nongovernmental hospitals.[117] Private equity groups are also involved in air ambulance transport services. In 2018, two of the three

[102] Butler S., Sherriff N. How poor communication exacerbates health inequities and what to do about it. Brookings Institution: Report (February 22, 2021). *https://www.brookings.edu/research/how-poor-communication-exacerbates-health-inequities-and-what-to-do-about-it/;* Hamel, L., Lopes, L., Muñana, C., Artiga, S., Brodie, M. Race, Health, and COVID–19: The Views and Experiences of Black Americans. Kaiser Family Foundation (October 2020). *https://files.kff.org/attachment/Report-Race-Health-and-COVID-19-The-Views-and-Experiences-of-Black-Americans.pdf; and* Shen M.J., Peterson E.B., Costas-Muñiz R. *et al.* The Effects of Race and Racial Concordance on Patient-Physician Communication: A Systematic Review of the Literature. *J. Racial and Ethnic Health Disparities* 5, 117–140 (2018). *https://doi.org/10.1007/s40615-017-0350-4.*

[103] Taylor, J., Racism, inequality, and health care for African Americans. The Century Foundation: Report (December 19, 2019). *https://tcf.org/content/report/racism-inequality-health-care-african-americans/; and* Chavis, B., Op-Ed: Big insurance must help end surprise medical billing. blackpressUSA (February 24, 2020). *https://blackpressusa.com/op-ed-big-insurance-must-help-end-surprise-medical-billing/.*

[104] Pérez-Stable E.J., El-Toukhy S., Communicating with diverse patients: How patient and clinician factors affect disparities. *Patient Educ Couns.* 2018;101(12):2186–2194. doi:10.1016/j.pec.2018.08.021; McNally, M., Confronting disparities in access to health care for underserved populations. MedCity News (February 22, 2021). *https://medcitynews.com/2021/02/confronting-disparities-in-access-to-healthcare-for-underserved-populations-in-2021/.*

[105] Greaney, Thomas. ''Surprise Billing: a Window into the U.S. Health Care System.'' American Bar Association. (September 2020). *https://www.americanbar.org/groups/crsj/publications/human_rights_magazine_home/health-matters-in-elections/surprise-billing/#:~:text=The%20%E2%80%9Csurprise%E2%80%9D%20typically%20occurs%20when,the%20difference%20between%20what%20the.*

[106] Cooper, Z. et al. ''Surprise! Out-of-Network Billing for Emergency Care in the United States.'' National Bureau of Economic Research: Working Paper 23623 (July 2017). *https://www.nber.org/papers/w23623.*

[107] Greaney, Thomas. ''Surprise Billing: a Window into the U.S. Health Care System.'' American Bar Association. (September 2020). *https://www.americanbar.org/groups/crsj/publications/human_rights_magazine_home/health-matters-in-elections/surprise-billing/#:~:text=The%20%E2%80%9Csurprise%E2%80%9D%20typically%20occurs%20when,the%20difference%20between%20what%20the.*

[108] Sun EC, Mello MM, Moshfegh J, Baker LC, Assessment of Out-of-Network Billing for Privately Insured Patients Receiving Care in In-Network Hospitals. JAMA Intern Med. 2019; 179(11):1543–1550 (2019). doi:10.1001/jamainternmed.2019.3451.

[109] Centers for Medicare and Medicaid Services. ''Emergency Medical Treatment & Labor Act (EMTALA).'' (March 2021). *https://www.cms.gov/Regulations-and-Guidance/Legislation/EMTALA#:~:text=In%201986%2C%20Congress%20enacted%20the,regardless%20of%20ability%20to%20pay.*

[110] Brannon, Ike and David Kemp. ''The Potential Pitfalls of Combatting Surprise Billing.'' CATO Institute. (Fall 2019). *https://www.cato.org/sites/cato.org/files/2019-10/regulation-v42n3-1-updated.pdf.*

[111] Brannon, Ike and David Kemp. ''The Potential Pitfalls of Combatting Surprise Billing.'' CATO Institute. (Fall 2019). *https://www.cato.org/sites/cato.org/files/2019-10/regulation-v42n3-1-updated.pdf.* See also Polsky, D, Cidav Z., Swanson A. ''Marketplace Plans With Narrow Physician Networks Feature Lower Monthly Premiums Than Plans With Larger Networks.'' Health Affairs. (October 2016). *https://www.healthaffairs.org/doi/10.1377/hlthaff.2016.0693.*

[112] Zhu, Jane M., Lynn M. Hua, and Daniel Polsky. ''Private Equity Acquisitions of Physician Medical Groups across Specialties, 2013–2016.'' 323 *JAMA* 7 (2020): 663–665.

[113] Zhu, Jane M., Lynn M. Hua, and Daniel Polsky. ''Private Equity Acquisitions of Physician Medical Groups across Specialties, 2013–2016.'' 323 *JAMA* 7 (2020): 663–665.

[114] Konda S, Francis J, Motaparthi K, Grant-Kels JMGroup for Research of Corporatization and Private Equity in Dermatology. ''Future Considerations for Clinical Dermatology in the Setting of 21st Century American Policy Reform: Corporatization and the Rise of Private Equity in Dermatology.'' *Journal of the American Academy of Dermatology,* 2019;81(1):287–296.e8. *https://www.jaad.org/article/S0190-9622(18)32667-7/fulltext.*

[115] Appelbaum E, Batt R. ''Private Equity Buyouts in Healthcare: Who Wins, Who Loses?'' Institute for New Economic Thinking. (March 2020). *https://www.ineteconomics.org/research/research-papers/private-equity-buyouts-in-healthcare-who-wins-who-loses.*

[116] Appelbaum E, Batt R. ''Private Equity Buyouts in Healthcare: Who Wins, Who Loses?'' Institute for New Economic Thinking. (March 2020). *https://www.ineteconomics.org/research/research-papers/private-equity-buyouts-in-healthcare-who-wins-who-loses.*

[117] Offodile II, Anaeze C., et al. ''Private Equity Investments in Health Care: An Overview of Hospital and Health System Leveraged Buyouts, 2003–17.'' *Health Affairs,* Vol. 40(5), (May 2021). *https://www.healthaffairs.org/doi/10.1377/hlthaff.2020.01535.*

largest air ambulance transport companies were owned by private equity firms.[118]

In addition, some private equity firms may choose not to participate in plans' and issuers' networks in order to reap higher payments.[119] Private equity-owned hospitals have been found to charge higher prices.[120] According to one study, 204 private equity-owned hospitals had an annual net income averaging $8.5 million prior to their acquisition. After private equity groups purchased the hospitals, their net income rose to $12.9 million.[121] This represents a 52 percent increase in net income, on average. Another study found that the entry of two private equity firms into the hospital sector increased out-of-network billing rates by more than 30 and 80 percentage points, respectively, from 2011 to 2015.[122] The study also found that the payments that one private equity firm received for emergency department physicians from insurers increased by 122 percent and patient cost-sharing payments to emergency department (ED) physicians increased by 83 percent. Furthermore, some hospitals and providers do not accept private health insurance coverage. For example, one study found that 5 percent of physicians participated in cash-only practices in 2020.[123] When billing out-of-network, these providers who choose to remain out-of-network can charge much higher fees than what public or private payers typically allow.[124]

The Departments and OPM seek comment on how private equity ownership structures may be affected by the Federal IDR process.

Surprise billing represents a market failure, as often patients either do not have the option to seek care elsewhere or must make decisions based on incomplete information about the network status of providers and associated costs.[125] This market failure is exacerbated by the fact that patients must rely on the guidance of the provider, insurer, or plan, which have financial incentives that can be contrary to the patient's financial interests.[126]

As of February 28, 2021, 18 states had implemented comprehensive legislation [127] regulating surprise billing, 15 states had implemented limited legislation, and 14 states had implemented an IDR system regarding out-of-network payments.[128] However, even in states that have passed legislation, states cannot regulate health plans that are self-insured by employers.[129]

On December 27, 2020, the Consolidated Appropriations Act, 2021 (CAA), which includes the No Surprises Act, was enacted.[130] 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 No Surprises Act added new provisions applicable to group health plans and health insurance issuers offering group or individual health insurance coverage in Subchapter B of chapter 100 of the Code, Part 7 of ERISA, and Part D of title XXVII of the PHS Act. Section 102 of the No Surprises Act added Code section 9816, ERISA section 716, and PHS Act section 2799A–1, which contain limitations on cost sharing and requirements regarding the timing of initial payments for emergency services furnished by nonparticipating providers and emergency facilities, and for nonemergency services furnished by nonparticipating providers at certain participating health care facilities. Section 102 of the No Surprises Act also added 5 U.S.C. 8902(p) requiring FEHB carriers, facilities, and providers to comply with requirements described in applicable provisions with respect to FEHB covered individuals. Section 103 of the No Surprises Act amended Code section 9816, ERISA section 716, and PHS Act section 2799A–1 to establish a Federal IDR process that allows plans and issuers and nonparticipating providers and facilities to resolve disputes regarding out-of-network rates. 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 the timing of initial payments for nonparticipating providers of air ambulance services and allow plans and issuers and providers of air ambulance services to access the Federal IDR process described in Code section 9816, ERISA section 716, and PHS Act section 2799A–1. The No Surprises Act provisions that apply to health care providers and facilities, and providers of air ambulance services, such as prohibitions on balance billing for certain items and services and requirements related to disclosures about balance billing protections, were added to title XXVII of the PHS Act in a new part E.

On July 13, 2021, the Departments and OPM published the July 2021 interim final rules.[131] The July 2021 interim final rules implemented provisions of the No Surprises Act to protect participants, beneficiaries, and enrollees in group health plans and group and individual health insurance coverage from surprise medical bills when they receive emergency services, non-emergency services from nonparticipating providers at certain participating facilities, and air ambulance services, under certain circumstances.

These interim final rules build upon the protections in the July 2021 interim

[118] Appelbaum E, Batt R. ''Private equity buyouts in healthcare: Who wins, who loses?'' Institute for New Economic Thinking. (March 2020). *https://www.ineteconomics.org/research/research-papers/private-equity-buyouts-in-healthcare-who-wins-who-loses.*

[119] Cooper, Zack, Fiona Scott Morton, and Nathan Shekita. ''Surprise! Out-Of-Network Billing for Emergency Care in the United States.'' 128 Journal of Political Economy 9. (2020).

[120] Bruch, Joseph D., Suhas Gondi, and Zirui Song. ''Changes in Hospital Income, Use, and Quality Associated with Private Equity Acquisition.'' 180 JAMA Internal Medicine 11 (2020): 1428–1435.

[121] Bruch, Joseph D., Suhas Gondi, and Zirui Song. ''Changes in Hospital Income, Use, and Quality Associated with Private Equity Acquisition.'' 180 *JAMA Internal Medicine* 11 (2020): 1428–1435.

[122] Cooper, Zack, Fiona Scott Morton, and Nathan Shekita. ''Surprise! Out-Of-Network Billing for Emergency Care in the United States.'' 128 Journal of Political Economy 9. (2020).

[123] Oliver, Eric. ''What Percent Of Physicians are in a Cash-Only Practice?—9 Stats.'' *Becker's ASC Review* (2021). *https://www.beckersasc.com/benchmarking/what-percent-of-physicians-are-in-a-cash-only-practice-9-stats.html.*

[124] Cooper, Zack, Fiona Scott Morton, and Nathan Shekita. ''Surprise! Out-Of-Network Billing for Emergency Care in the United States.'' 128 Journal of Political Economy 9. (2020).

[125] Assistant Secretary for Planning and Evaluation. ''HHS Secretary's Report on: Addressing Surprise Medical Billing.'' Office of Health Policy. (July 2020). *https://aspe.hhs.gov/system/files/pdf/263871/Surprise-Medical-Billing.pdf.*

[126] Assistant Secretary for Planning and Evaluation. ''HHS Secretary's Report on: Addressing Surprise Medical Billing.'' Office of Health Policy. (July 2020). *https://aspe.hhs.gov/system/files/pdf/263871/Surprise-Medical-Billing.pdf.*

[127] The states that have passed comprehensive legislation include California, Colorado, Connecticut, Florida, Georgia, Illinois, Maine, Maryland, Michigan, New Hampshire, New Jersey, New Mexico, New York, Ohio, Oregon, Texas, Virginia, and Washington. The Commonwealth Fund. ''State Balance-Billing Protections.'' (February 2021). *https://www.commonwealthfund.org/sites/default/files/2021-03/Hoadley_state_balance_billing_protections_table_02052021.pdf.*

[128] The states that have passed limited legislation include Arizona, Delaware, Indiana, Iowa, Massachusetts, Minnesota, Mississippi, Missouri, Nebraska, Nevada, North Carolina, Pennsylvania, Rhode Island, Vermont, and West Virginia. The Commonwealth Fund. ''State Balance-Billing Protections.'' (February 2021). *https://www.commonwealthfund.org/sites/default/files/2021-03/Hoadley_state_balance_billing_protections_table_02052021.pdf.*

[129] The Commonwealth Fund. ''State Balance-Billing Protections.'' (November 2020). *https://www.commonwealthfund.org/sites/default/files/2020-12/Hoadley_state_balance-billing_protections_11302020.pdf.*

[130] Public Law 116–260 (December 27, 2020).

[131] 86 FR 36872 (July 13, 2021).

final rules and implement the Federal IDR provisions under Code sections 9816(c) and 9817(b), ERISA sections 716(c) and 717(b), PHS Act sections 2799A–1(c) and 2799A–2(b), and 5 U.S.C. 8902(p). The Federal IDR process will permit group health plans, health insurance issuers offering group or individual health insurance coverage, FEHB carriers, and nonparticipating providers, facilities, and providers of air ambulance services to determine the out-of-network rate for items and services that are emergency services, nonemergency services furnished by nonparticipating providers at participating facilities, and air ambulance services furnished by nonparticipating providers of air ambulance services, under certain circumstances.

Furthermore, these interim final rules extend the balance billing protections related to external reviews to grandfathered plans, including non-Federal governmental plans and individual market plans. The definitions of group health plan and health insurance issuer that are cited in section 110 of the No Surprises Act include both grandfathered and non-grandfathered plans and coverage. Accordingly, the practical effect of section 110 of the No Surprises Act is that grandfathered health plans must provide external review for adverse benefit determinations involving benefits subject to these surprise billing protections. Grandfathered and non-grandfathered plans must comply either with a state external review process or the Federal external review process. The disclosure requirements of the Federal external review process require: (1) A preliminary review by plans of requests for external reviews; (2) Independent Review Organizations (IROs) to notify claimants of eligibility and acceptance for external review; (3) the plan or issuer to provide IROs with documentation and other information considered in making adverse benefit determination; (4) the IRO to forward to the plan or issuer any information submitted by the claimant; (5) plans to notify the claimant and IRO if it reverses its decision; (6) the IRO to notify the claimant and plan of the result of the final external review; and (7) the IRO to maintain records for 6 years.

Additionally, these interim final rules implement provisions of the No Surprises Act that require health care providers and health care facilities to furnish good faith estimates upon request or upon the scheduling of items or services for uninsured (or self-pay) individuals. In order to implement these good faith estimate provisions under PHS Act section 2799B–6(1) and 2799B–6(2)(B), as added by section 112 of the No Surprises Act, HHS is adding 45 CFR 149.610 to establish requirements for providers and facilities to specifically inquire about an individual's health coverage status and establish requirements for providing a good faith estimate to uninsured (or self-pay) individuals.

PHS Act section 2799B–6(2) and these interim final rules specify that a provider or facility must provide a notification (in clear and understandable language) of the good faith estimate of the expected charges for furnishing such items or services (including any items or services that are reasonably expected to be provided in conjunction with such scheduled items or services and such items or services reasonably expected to be so provided by another health care provider or health care facility), with the expected billing and diagnostic codes (*i.e.,* ICD, CPT, HCPCS, DRG and/or NDC codes) for any such items or services. These interim final rules include definitions of certain terms, requirements for the providers and facilities, content requirements, and methods and manner requirements for issuing good faith estimates consistent with the provisions of PHS Act sections 2799B–6, 2799B–6(1), and 2799B–6(2)(B).

PHS Act section 2799B–7, as added by section 112 of the No Surprises Act, provides further protections for uninsured (or self-pay) individuals by requiring the Secretary of HHS to establish a process (in this section referred to as patient-provider dispute resolution) under which an uninsured (or self-pay) individual who received a good faith estimate of expected charges from a provider or facility, and who, after being furnished the item or service, is billed for charges that are substantially in excess of the estimate, may seek a determination from a SDR entity of the amount to be paid. HHS is adding new 45 CFR 149.620 to implement this patient-provider dispute resolution process including specific definitions related to the patient-provider dispute resolution process. HHS is also codifying provisions related to the eligibility of an item or service for the patient-provider dispute resolution process, certification and selection of SDR entities, fees associated with the patient-provider dispute resolution process, and deferral to state patient-provider dispute resolution processes.

Consistent with Executive Orders 13985 and 13988, and all civil rights laws and protections cited previously, these interim final rules include provisions designed to address and increase the HHS' understanding of barriers underserved and minority communities face in accessing the protections established in the No Surprises Act, including the provision of good faith estimates for uninsured (or self-pay) individuals, and the process for patient-provider dispute resolution.

The Departments seek comment from individuals from racial/ethnic minority and underserved communities, including individuals with vision, hearing, or language limitations, individuals with limited English proficiency, lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons, and individuals with health literacy needs, and providers who serve these individuals, to help identify emerging, persistent, or perceived barriers to individuals accessing and understanding these processes, rights, and protections, and other provisions of the No Surprises Act included in this rule, and policies to address and remove these barriers.

1.2. Summary of Impacts

Plans, issuers, FEHB carriers, health care providers, facilities, and providers of air ambulance services will incur costs to comply with the requirements in these interim final rules, as discussed later in this section of this preamble. However, the Departments and OPM have determined that the benefits of these interim final rules justify the costs.

The provisions in these interim final rules will help ensure that participants, beneficiaries, and enrollees with health coverage are protected from surprise medical bills. When plans, issuers, and FEHB carriers participate in the Federal IDR process, individuals with health coverage will gain peace of mind, experience a reduction in out-of-pocket expenses, be able to meet their deductible and out-of-pocket maximum limits sooner, and may experience increased access to care. One study found that surprise billing decreased by 34 percent in New York State between 2015 and 2018, when the state implemented an IDR process.[132] The study also found that New York's Out-of-Network Law [133] saved consumers over $400 million from the date of implementation with respect to emergency services alone.[134]

[132] Marion Mass. ''Surprise Billing Legislation Should Put Independent Dispute Resolution at Its Heart.'' *Morning Consult.* (March 2020). *https://morningconsult.com/opinions/surprise-billing-legislation-should-put-independent-dispute-resolution-at-its-heart/.*

[133] NY Fin Serv L § 605 (2014).

[134] New York State Department of Financial Services. ''New York's Surprise Out-Of-Network

The information regarding the good faith estimates furnished by providers and facilities will allow uninsured (or self-pay) individuals to have access to information about health care pricing before receiving care. This information will allow uninsured (or self-pay) individuals to evaluate options for receiving health care, make cost-conscious health care purchasing decisions, and reduce surprises in relation to their health care costs for those items and services. Additionally, uninsured (or self-pay) individuals may use the good faith estimate for comparison with actual billed charges received after items or services are furnished. If the billed charges are substantially in excess of the good faith estimate, an uninsured (or self-pay) individual may seek a determination from an SDR entity under the patient-provider dispute resolution process.

HHS will request information from uninsured (or self-pay) individuals in order to initiate the patient-provider dispute resolution process. This information will be used to help determine eligibility for the patient-provider dispute resolution process and is necessary for determining which provider or facility should be contacted for dispute resolution. Providers and facilities are required to submit information to an SDR entity to inform the SDR entity's payment determination decisions.

In accordance with OMB Circular A–4, Table 1 depicts an accounting statement summarizing the Departments' assessment of the benefits, costs, and transfers associated with this regulatory action. The Departments are unable to quantify all benefits, costs, and transfers of these interim final rules but have sought, where possible, to describe these non-quantified impacts. The effects in Table 1 reflect non-quantified impacts and estimated direct monetary costs resulting from the provisions of these interim final rules.

TABLE 1: Accounting Statement

Benefits:

Non-quantified benefits of the Federal IDR process for the population with health coverage:

- Increased protection for participants, beneficiaries, and enrollees from surprise bills from out-of-network providers by creating a process for plans, issuers, FEHB carriers, and nonparticipating providers and facilities to resolve disputes regarding certain out-of-network rates. Note that, unless specified otherwise, providers include providers of air ambulance services.
- Increased awareness of expected charges for items or services, reduction in financial anxiety and out-of-pocket expenses for individuals with health coverage because individuals will be able to meet their deductibles and out-of-pocket maximum limits sooner.
- Increased access to care for individuals with health coverage that may have otherwise forgone or delayed needed treatment due to concerns over the potential for high out-of-pocket expenses.

Non-quantified benefits of the patient-provider dispute resolution process for uninsured (or self-pay) individuals:

- Increased awareness of expected charges for items or services, reduction in financial anxiety, more informed health care decisions, and protection for uninsured (or self-pay) individuals by requiring providers and facilities to furnish good faith estimates for scheduled or requested items and services.
- Improved access to care for uninsured (or self-pay) individuals that may have otherwise forgone or delayed needed treatment due to concerns over receiving unexpected large bills.
- Protection for uninsured (or self-pay) individuals from excessive surprise bills from providers or facilities by establishing a patient-provider dispute resolution process that may result in lower payments if the SDR entity determines the amount to be paid by the uninsured (or self-pay) individual to the provider or facility are lower than the billed charges.

Non-quantified benefits regarding external review:

- Increased access to benefits for some individuals.
- Reduced incidence of excessive delays and inappropriate denials, averting serious, avoidable lapses in access to quality health care and resultant injuries and losses to participants, beneficiaries, enrollees, and FEHB covered individuals.
- Potential increase in confidence and satisfaction among participants, beneficiaries, and enrollees in their health care benefits.
- Improved awareness among plans, issuers, and FEHB carriers of participant, beneficiary, enrollee, FEHB covered individuals, and provider concerns.

COSTS TO PLANS, ISSUERS, AND FEHB CARRIERS

Costs (in millions)	Estimate	Year dollar	Discount rate	Period covered
Annualized	$517.12	2021	7 percent	2022–2031
Monetized ($/Year)	491.44	2021	3 percent	2022–2031

The annualized cost estimates reflect estimated costs associated with the Federal IDR process for nonparticipating providers or nonparticipating emergency facilities, the Federal IDR process for providers of air ambulance services, IDR entity certification and reporting requirements, the Federal IDR process for the uninsured, SDR entity certification, and the extension of the external review to grandfathered plans and claims under certain provisions of the No Surprises Act. The Departments estimate a total cost of $760.95 million in the first year and $440.67 million going forward.

Costs to the Government:

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 maintenance costs for the Federal IDR portal are split between the Federal IDR process and the patient-provider dispute resolution process, based on anticipated volume for each program. The costs associated with the Federal IDR portal are estimated to be a one-time cost of $6 million in fiscal year 2021 and annual costs of $1 million going forward. The costs associated with the patient provider dispute resolution process are estimated to be a one-time cost of $10 million in fiscal year 2021 and an annual cost of $12 million going forward. Additionally, the costs associated with the Federal external review costs are estimated to be $1.16

Protection Law Report on the Independent Dispute Resolution Process.'' (September 2019).

million in fiscal year 2021 and $567,000 annually going forward.

Transfers:

Non-quantified transfers associated with the Federal IDR process for the population with health coverage:

- Potential transfers from providers who had previously balance billed for out-of-network claims to individuals who are no longer responsible for paying these balance bills.
- Potential transfers from plans, issuers, and FEHB carriers who were previously not responsible for out-of-network balance bills to providers and facilities that will submit out-of-network balance bills to plans, issuers, and FEHB carriers as a result of the interim final rules.
- Potential transfers from plans, issuers, and FEHB carriers to participants, enrollees, and beneficiaries if the Federal IDR process results in lower premiums.
- Potential transfers from participants, enrollees, and beneficiaries to plans, issuers, and FEHB carriers if the Federal IDR process results in higher premiums.
- Potential transfers to the Federal Government in the form of reduced Premium Tax Credits if the Federal IDR process results in the lower premiums.
- Potential transfers from the Federal Government to eligible enrollees, in the form of increased Premium Tax Credits payments if the Federal IDR process results in an increase in premiums.
- Potential transfers from individuals with health coverage who pay premiums to individuals with large out-of-network bills and uninsured individuals if the Federal IDR process results in an increase in premiums.
- Potential transfers from providers, facilities, and providers of air ambulance services to plans, issuers, and FEHB carriers if some providers, facilities, and providers of air ambulance services collect lower out-of-network payments.
- Potential transfers between providers, facilities, and providers of air ambulance services and individuals with health coverage, depending on the weight place on the QPA in payment determinations under the Federal IDR process. The presumption in favor of the QPA in the Federal IDR process may result in transfers from providers and facilities to participants, beneficiaries, and enrollees.

Non-quantified transfers associated with the patient-provider dispute resolution process for uninsured (or self-pay) individuals:

- Potential transfer of the patient-provider dispute resolution administrative fee from the provider or facility to the uninsured (or self-pay) individuals if the SDR entity makes a payment determination in favor of the uninsured (or self-pay) individual.
- Potential transfer from uninsured (or self-pay) individuals to providers or facilities if the SDR entity makes a payment determination that is higher than the good faith estimate.

Non-quantified transfers associated with external review:

- Potential transfer from plans, issuers, and FEHB carriers to participants, beneficiaries, and enrollees now receiving payment for denied benefits.

1.3. Affected Entities

These interim final rules will affect health care patients, health care providers, health care facilities, providers of air ambulance services, self-insured plans, issuers, and FEHB carriers.

In 2019, there were 1,553 issuers in the U.S. health insurance market, of which 1,298 issuers serve the individual market, 586 issuers serve the small group market, and 788 issuers serve the large group market.[135] Additionally, the Departments and OPM estimate that 46 issuers are FEHB carriers. While there is a significant amount of research that demonstrates the prevalence of surprise billing, as discussed in the July 2021 interim final rules, the Departments do not have data on what percentage of health insurance issuers cover individuals who experience surprise billing. However, given the size and scope of insurance companies, the Departments assume that all health insurance issuers will be affected by these interim final rules. The Departments estimate that 8.5 percent, or approximately 132 issuers are considered small under the Small Business Administration's (SBA) size standards.[136]

Of the plans that filed a Form 5500 in 2018, 25,500 plans were self-insured.[137] The Departments do not have data on what percentage of self-insured group health plans cover individuals who have received a surprise bill. The Departments request comment on how many group health plans will be affected by these interim final rules.

In 2018, 296.2 million individuals had health insurance. Of the 213.2 million individuals with private insurance, 178.4 million had employer-sponsored insurance and 34.8 million had other private insurance, including individual market coverage.[138] One study looked at claims data from a large commercial issuer for the period 2010–2016 and found that over 39 percent of emergency department visits to in-network hospitals resulted in an out-of-network bill, and 37 percent of inpatient admissions to in-network hospitals resulted in at least one out-of-network bill.[139] The Departments estimate that these interim final rules will directly affect individuals with private health coverage who visit an emergency room, visit a hospital, or are transported by an air ambulance.

The Departments expect that the Federal IDR process will have overflow effects of decreasing the incidence of surprise medical bills in general, even for patients who do not have a claim that goes to the Federal IDR process. The Federal IDR process relies on a ''baseball-style'' arbitration, in which each party submits their desired amount, and the certified IDR entity selects one of the two offers submitted. This differs from other types of arbitration, in which the arbitrator would often select a value between the two submissions. Accordingly, this process encourages each party to submit a reasonable offer. Further, the parties involved will need to weigh the costs associated with the Federal IDR process, including payment of the administrative fee and the certified IDR entity fee if their offer is not chosen. The Departments are of the view this may serve as an incentive to not only submit reasonable offers once the Federal IDR

[135] Centers for Medicare and Medicaid Services. ''Medical Loss Ratio Data and System Resources'' (2019). *https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.*

[136] The issuers affected by these interim final rules are expected to fall under the industry of Direct Health and Medical Insurer Carries, NAICS 524114. According to the SBA Table of Size Standards, an issuer is considered small if its annual receipts are less than $41.5 million. (*See* Small Business Administration. ''Table of Size Standards.'' (August 2019). *https://www.sba.gov/document/support--table-size-standards.*) Applying this standard to the 2017 County Business Patterns and Economic Census uniformly across establishments, the Departments estimate that 132, or 8.5 percent of issuers are small. (*See* Census Bureau. ''2017 SUSB Annual Data Tables by Establishment Industry, Data by Enterprise Receipt Size.'' (May 2021). *https://www.census.gov/data/tables/2017/econ/susb/2017-susb-annual.html.*)

[137] Stewart, Al. ''Report to Congress: Annual Report on Self-Insured Group Health Plans.'' (March 2021). *https://www.dol.gov/sites/dolgov/files/EBSA/researchers/statistics/retirement-bulletins/annual-report-on-self-insured-group-health-plans-2021.pdf.*

[138] 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.*

[139] Sun EC, Mello MM, Moshfegh J, Baker LC, Assessment of Out-of-Network Billing for Privately Insured Patients Receiving Care in In-Network Hospitals. JAMA Intern Med. 2019; 179(11):1543–1550 (2019). doi:10.1001/jamainternmed.2019.3451.

process has been initiated, but also to conduct business in a way to avoid ending up in the Federal IDR process altogether. The Departments cannot estimate how large these overflow effects will be on a national basis; however, the experience in New York State provides a point of reference. In 2018, in New York State, surprise billing decreased by 34 percent after the IDR process was implemented.[140]

Surprise billing occurs more often in specialties that are not shopped.[141] A recent survey looked at 13.8 million visits to 35,000 unique providers in six specialties in 2017 to estimate the percent of providers with at least one out-of-network claim by specialty and whether the procedure was inpatient or outpatient. The survey found that less than half of specialist providers surveyed billed at least once on an out-of-network basis. Their findings are shown in the last four columns in Table 2.[142] The second column provides the number of active physicians in each specialty from the American Association of Medical Colleges.[143] As set forth in Table 2, the prevalence of providers who bill on an out-of-network basis and the average frequency of visits that are billed out-of-network among providers who do bill on an out-of-network basis varies by specialty.

The Departments estimate that 16,992 emergency and other health care facilities will be affected by these interim final rules, including 6,090 hospitals,[144] 29,227 diagnostic and medical laboratories,[145] 270 independent freestanding emergency departments,[146] 9,280 ambulatory surgical centers,[147] and 1,352 critical access hospitals. The Departments acknowledge that this estimate double counts some entities, particularly with regard to facilities that have laboratories in-house.

TABLE 2—PHYSICIANS WITH OUT-OF-NETWORK CLAIMS

	Number of active physicians [148]	Percent of providers with at least one out-of-network claim, 2017 [149] (%)		Mean percent of visits with services billed out-of-network for providers who billed out-of-network at least once [150] (%)	
		Inpatient	Outpatient	Inpatient	Outpatient
Emergency	45,134	44.1	49.3	14.7	34.3
Pathology	12,640	44.0	33.0	44.3	31.4
Radiology	28,017	27.7	32.5	11.0	17.9
Anesthesiology	42,249	57.0	31.8	11.3	28.4
Behavioral Health/Psychiatry	38,778	29.8	14.9	21.4	24.4
Cardiovascular	22,514	17.9	17.0	6.8	8.3

As seen in Table 2, among the specialist providers considered, emergency physicians were most likely to bill on an out-of-network basis at least once; however, emergency physicians account for less than 5 percent of total physicians.[151] The Departments estimate that 15 percent, or 140,270, of physicians, [152] on average, bill on an out-of-network basis and will be affected by these interim final rules. The Departments estimate that 44.1 percent, or approximately 61,890 physicians, practice in a small business under the SBA size standards.[153] The Departments seek comment on these estimates.

Physician staffing companies, which allow for medical facilities to hire the services of a medical professional without hiring the medical professional

[140] Marion Mass. ''Surprise Billing Legislation Should Put Independent Dispute Resolution at Its Heart.'' *Morning Consult.* (March 2020). *https://morningconsult.com/opinions/surprise-billing-legislation-should-put-independent-dispute-resolution-at-its-heart/.*

[141] Greaney, Thomas. ''Surprise Billing: A Window into the U.S. Health Care System.'' American Bar Association. (September 2020). *https://www.americanbar.org/groups/crsj/publications/human_rights_magazine_home/health-matters-in-elections/surprise-billing/.*

[142] Fugelsten Biniek, Jean, et al. ''How Often Do Providers Bill Out of Network?'' Health Care Cost Institute. (May 2020). *https://healthcostinstitute.org/out-of-network-billing/how-often-do-providers-bill-out-of-network.*

[143] American Association of Medical Colleges. ''Active Physicians by Age and Specialty. *Physician Specialty Data Report.* (December 2019). *https://www.aamc.org/data-reports/workforce/interactive-data/active-physicians-age-and-specialty-2019.*

[144] American Hospital Association. ''Fast Facts on U.S. Hospitals, 2021.'' (January 2021). *https://www.aha.org/statistics/fast-facts-us-hospitals.*

[145] IBIS World. Definitive Healthcare. ''Diagnostic & Medical Laboratories Industry in the US—Market Research Report?'' (May 2021). *https://www.ibisworld.com/industry-statistics/number-of-businesses/diagnostic-medical-laboratories-united-states/.*

[146] Emergency Medicine Network. ''2018 National Emergency Department Inventory.'' (2021). *https://www.emnet-usa.org/research/studies/nedi/nedi2018/.*

[147] Definitive Healthcare. ''How Many Ambulatory Surgery Centers are in the US?'' (April 2019). *https://www.definitivehc.com/blog/how-many-ascs-are-in-the-us.*

[148] *See* American Association of Medical Colleges. ''Active Physicians by Age and Specialty. *Physician Specialty Data Report.* (December 2019). *https://www.aamc.org/data-reports/workforce/interactive-data/active-physicians-age-and-specialty-2019.*

[149] *See* Fugelsten Biniek, Jean, et al. ''How Often Do Providers Bill Out of Network?'' Health Care Cost Institute. (May 2020). *https://healthcostinstitute.org/out-of-network-billing/how-often-do-providers-bill-out-of-network.*

[150] *Id.*

[151] American Association of Medical Colleges. ''Active Physicians by Age and Specialty.'' Physician Specialty Data Report. (December 2019). *https://www.aamc.org/data-reports/workforce/interactive-data/active-physicians-age-and-specialty-2019.* The American Association of Medical Colleges estimated that among the 935,136 active physicians in the U.S. in 2019, 45,134 were emergency physicians (4.8 percent).

[152] The Departments do not have data on the percentage of physicians who bill out of network across all specialties; however, it is likely lower than the percentage of physicians who bill out of network across the six specialties cited in the cited study. The six specialties cited account for approximately 20 percent of physicians. Based on the information presented in Table 2, the Departments estimate that on average, just over 30 percent of physicians in these specialties had at least one out-of-network claim. The Departments assumes that the other 80 percent of physicians bill on an out-of-network basis just 10 percent of the time. The Departments approximate the percent of physicians who bill on an out-of-network basis to be: (20 percent × 32 percent) + (10 percent × 80 percent) = 14.4 percent. As an approximation, the Departments round this to 15 percent.

[153] The physicians affected by these interim final rules are expected to fall under the industry of Offices of Physicians, NAICS 62111. According to the SBA Table of Size Standards, an office of physicians is considered small if its annual receipts are less than $12.0 million. (*See* Small Business Administration. ''Table of Size Standards.'' (August 2019). *https://www.sba.gov/document/support--table-size-standards.*) Applying this standard to the 2017 County Business Patterns and Economic Census uniformly across employees, the Departments estimate that 61,890, or 44.1 percent of physicians work in an office considered a small business. (*See* Census Bureau. ''2017 SUSB Annual Data Tables by Establishment Industry, Data by Enterprise Receipt Size.'' (May 2021). *https://www.census.gov/data/tables/2017/econ/susb/2017-susb-annual.html.*

themselves, may also be affected by these interim final rules, as they provide services in medical specialties that are not shopped, including emergency, radiology, and anesthesiology.[154] Physician staffing companies often bill patients directly for services rendered.[155] Within recent years, the growth of the health care staffing industry has accelerated, driven by staffing shortages in health care facilities as the population ages.[156] A survey of 200 health care executives found that 85 percent of surveyed health care facility managers used temporary physicians within the last year, and 72 percent were seeking more temporary physicians.[157] There are approximately 40 health care staffing firms providing these services.[158]

Furthermore, in 2014, it was estimated that there were 1,073 businesses in the air ambulance service industry.[159] One study estimated that between 2014 and 2017, 77 percent of air ambulance claims were out-of-network.[160] The Departments do not have data on the number of providers of air ambulance services that submit out-of-network claims; however, given the prevalence of out-of-network billing among providers of air ambulance services, the Departments assume that all businesses in the industry will be affected by these interim final rules. The Departments estimate that 59.2 percent, or approximately 635 providers of air ambulance services, are considered small under the SBA size standards.[161]

IDR entities must be certified under the standards and procedures set forth in guidance by the Departments. In order to be certified, an entity must have sufficient expertise in arbitration and claims administration, managed care, billing and coding, medical, and legal matters, with sufficient staffing to make determinations within 30 business days allowed for such payment determinations. Additionally, IDR entities must meet appropriate indicators of fiscal integrity and stability and maintain a current accreditation from a nationally recognized and relevant accrediting organization, such as URAC, or ensure that it otherwise possesses the requisite training to conduct payment determinations (for example, providing documentation that personnel employed by the IDR entity have completed arbitration training by the AAA, the AHLA, or a similar organization), among other requirements.

The National Association of Independent Review Organizations is an association of URAC-accredited independent review organizations, and in 2021, they had 29 members.[162] While this does not represent the entire pool of independent review organizations, this offers insight into the number of potential entities that may seek certification as IDR entities. In 2019, New York had certified three IDR entities to handle the state's IDR process.[163] In 2018, the state of New York accounted for 5.8 percent of the private insurance market.[164] The Departments recognize that the health care and surprise billing experiences across states are heterogeneous; however, if this proportion were uniform across the country, there would be approximately 52 IDR entities. Based on these two benchmarks, the Departments estimate that there will be 50 IDR entities that will seek certification by the Departments. Within these 50 entities, HHS estimates that there will be between one and three contracted SDR entities, depending on the anticipated volume of patient-provider dispute resolution cases and other factors necessary for administering an efficient program.

Health care providers and health care facilities are required to furnish a good faith estimate of expected charges to uninsured (or self-pay) individuals for scheduled items and services and upon request. In 2019, there were approximately 938,966 active physicians,[165] 6,090 hospitals,[166] 9,280 ambulatory surgical centers,[167] and 1,352 critical access hospitals.[168] As of 2019, there were approximately 29,349,300 uninsured individuals in the United States.[169] HHS estimates that approximately 3,498,942 uninsured (or self-pay) individuals will be impacted by this rule requirement [170] based on the

[154] Appelbaum, Eileen and Rosemary Batt. ''Private Equity and Surprise Medical Billing.'' (2021). Institute for New Economic Thinking. *https://www.ineteconomics.org/perspectives/blog/private-equity-and-surprise-medical-billing.*

[155] Moody's Investor Service. ''Surprise Billing Ban to Constrain Physician Firms' Cash Flow, Curb Negotiating Clout for Air Ambulances.'' (2021). *https://www.moodys.com/research/Moodys-Surprise-billing-ban-to-constrain-physician-staffing-firms-cash--PBC_1263184.*

[156] Schwartz, Chris. ''Overview of the Temporary Healthcare Staffing Sector.'' Blue Pencil Strategies. *https://healthywork.uic.edu/wp-content/uploads/sites/452/2019/08/Temporary-Healthcare-Staffing-Fact-Sheet.pdf.*

[157] Gooch, Kelly. ''Temporary Physicians Staffing: Why and How Often It Occurs.'' Becker's Hospital Review. (2020). *https://www.beckershospitalreview.com/workforce/temporary-physician-staffing-why-and-how-often-it-occurs.html.*

[158] Schwartz, Chris. ''Overview of the Temporary Healthcare Staffing Sector.'' Blue Pencil Strategies. *https://healthywork.uic.edu/wp-content/uploads/sites/452/2019/08/Temporary-Healthcare-Staffing-Fact-Sheet.pdf.*

[159] IBIS World. ''Air Ambulance Service Industry in the US—Market Research Report.'' (December 2020). *https://www.ibisworld.com/united-states/market-research-reports/air-ambulance-services-industry/.*

[160] Brown, Erin, et al. ''The Unfinished Business of Air Ambulance Bills.'' Health Affairs Blog, March 26, 2021. *https://www.healthaffairs.org/do/10.1377/hblog20210323.911379/full/.*

[161] The providers of air ambulance services affected by these interim final rules are expected to fall under the industry of Ambulance Services, NAICS 621910. According to the SBA Table of Size Standards, an air ambulance service provider is considered small if its annual receipts are less than $16.5 million. (*See* Small Business Administration. ''Table of Size Standards.'' (August 2019). *https://www.sba.gov/document/support--table-size-standards.*) Applying this standard to the 2017 County Business Patterns and Economic Census uniformly across establishments, the Departments estimate that 635, or 59.2 percent of providers of air ambulance services are small. *See* Census Bureau. ''2017 SUSB Annual Data Tables by Establishment Industry, Data by Enterprise Receipt Size.'' (May 2021). *https://www.census.gov/data/tables/2017/econ/susb/2017-susb-annual.html.*

[162] Lacewell, Linda. ''New York's Surprise Out-of-Network Protection Law.'' Patient Choice Coalition.'' (September 2019). *http://www.patientchoicecoalition.com/blog/2019/11/22/report-on-the-independent-dispute-resolution-process/.*

[163] *Id.*

[164] In 2018, 10.5 million individuals had employer-sponsored insurance and 1.8 million individuals had other private insurance in New York State, while 178.4 million individuals had employer-sponsored insurance and 34.8 million individuals had other private insurance nationally. The Departments estimates New York accounts for 5.8 percent of the private insurance market ((10.5 + 1.8)/(178.4 + 34.8) = 5.8 percent). *See* 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.*

[165] *https://www.aamc.org/data-reports/workforce/interactive-data/active-physicians-us-doctor-medicine-us-md-degree-specialty-2019.*

[166] *https://www.aha.org/statistics/fast-facts-us-hospitals.*

[167] *https://blog.definitivehc.com/how-many-ascs-are-in-the-us#:~:text=Currently%2C%20there%20are%20more%20than,Healthcare's%20platform%20on%20surgery%20centers.*

[168] *https://www.flexmonitoring.org/historical-cah-data-0*).

[169] This figure includes those without health insurance and those who have coverage under the Indian Health Service only. Source: *https://www.kff.org/other/state-indicator/total-population/?dataView=1&currentTimeframe=0&selectedDistributions=uninsured&selectedRows=%7B%22wrapups%22:%7B%22united-states%22:%7B%7D%7D%7D&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.*

[170] The number is estimated as follows: 51,744,200 nonemergency elective procedures (surgical and non-surgical) performed annually × 9.2% uninsured rate = 4,760,466. HHS assumes that some uninsured populations will forego elective procedures because of costs. Therefore, a 30% decrease adjustment was included resulting in 3,332,326. HHS also assumes a 5% adjustment for good faith estimate inquires only resulting in a final value of 3,498,942. *See* Squitieri, Lee et al. ''Resuming Elective Surgery during Covid–19: Can Inpatient Hospitals Collaborate with Ambulatory Surgery Centers?.'' *Plastic and reconstructive*

number of nonemergency elective procedures (surgical and non-surgical) performed annually multiplied by the percentage of uninsured (or self-pay) individuals (9.2%), and HHS assumes that some uninsured individuals will forego elective procedures because of cost. HHS also assumes that a certain number of good faith estimates will be furnished only upon request, increasing the number of good faith estimates from that of the total for scheduled items and services.

These interim final rules also implement a patient-provider dispute resolution process that applies to uninsured (or self-pay) individuals whose billed charges exceed the expected charges in the good faith estimate for a provider or facility by $400 or greater. HHS does not have data on the percentage of how many uninsured (or self-pay) individuals will initiate the patient-provider dispute resolution process. For the purposes of the estimates in this section, HHS relied on the experience of New York State. From 2015 to 2018, New York State had a total of 1,486 disputes involving surprise bills submitted to the state IDR process, and 31% of these disputes (457 in all) were found ineligible for IDR for various reasons including 8% (approximately 36 cases) due to being self-insured.[171] For the purposes of this analysis, HHS assumes that, going forward, New York State will continue to see 40 IDR adjudications each year involving surprise medical bills for self-insured individuals. Accordingly, HHS estimates that there will be 26,659 claims that result in patient-provider dispute resolution cases each year. [172] These interim final rules establish requirements that an SDR entity must meet the same certification standards as a certified IDR entity. HHS estimates that there will be between one and three contracted SDR entities depending on the anticipated volume of patient-provider dispute resolution cases and other factors necessary for administering an efficient program. HHS will assess if a potential SDR entity meets the certification standards as part of the contracting process.

Furthermore, the interim final rules extend the balance billing protections related to external review to grandfathered plans. Prior to the interim final rules, the Departments estimate that there are approximately 8.1 million participants in ERISA-covered plans in states that have no external review laws or whose laws do not meet the Federal minimum requirements.[173] These estimates lead to a total of 92.5 million participants not having access to external review. Among the 92.5 million participants, 80.5 million participants in non-grandfathered plans and 12 million participants in grandfathered plans will be required to be covered by the external review requirement.

The Departments estimate that there are approximately 1.3 external reviews for every 10,000 participants [174] and that there will be approximately 12,304 external reviews annually. Experience from North Carolina indicates that about 75 percent of requests for external reviews are actually eligible to proceed to an external review.[175] Therefore, the Departments expect that there will be about 15,942 requests for external review.[176]

1.4. Benefits

Federal IDR Process

In the past, information asymmetries regarding health care costs and provider or facility network status between individuals and plans, issuers, and providers have left individuals vulnerable to surprise billing. These interim final rules will provide a structure to guide the resolution of pricing disparities in a way that will prevent a patient's information asymmetry from resulting in a surprise bill, thus alleviating the market failure.

As a result of these interim final rules, individuals with health coverage will only be liable for their in-network cost-sharing amounts when receiving care from nonparticipating providers at participating facilities (in certain circumstances), nonparticipating emergency facilities, and nonparticipating providers of air ambulance services. Accordingly, these individuals are likely to see lower out-of-pockets costs, reduced anxiety, reduced financial stress, and lower medical debt. Further, these payments will now count towards their deductible and maximum out-of-pocket limits, allowing individuals to reach those limits sooner. A significant number of individuals forgo or delay care due to the cost of care.[177] A reduction in out-of-pocket expenses is likely to improve access to care and allow individuals to obtain needed treatment that they may otherwise have neglected or foregone due to concerns about the cost of care.

Further, these interim final rules create a system in which disputes may be resolved in a consistent and efficient manner. These interim final rules are intended to minimize reliance on the Federal IDR process and encourage parties to submit reasonable offers and allow for more efficient price discovery. By requiring the non-prevailing party to pay the certified IDR entity fees, these interim final rules increase the financial stakes for parties that submit an offer that is unreasonably high or low. However, if the parties agree upon a settlement, after initiation, but prior to determination by the certified IDR entity, each party must pay half of the certified IDR entity's fees, unless the parties agree otherwise on a method for allocating the fees. Thus, parties have an incentive to choose a settlement compared to the Federal IDR process. During negotiations, providers may be more willing to accept a lower price and similarly, plans, issuers, and FEHB carriers may be more willing to offer a higher price.

Similarly, these interim final rules are intended to encourage the settlement of multiple claims. Under these interim final rules, the party that initiates the Federal IDR process is suspended from taking the same party to arbitration for an item or service that is the same or similar item or service as the qualified

surgery. Global open vol. 9,2 e3442. 18 Feb. 2021, doi:10.1097/GOX.0000000000003442 (The study estimates 4,297,850 nonemergency elective procedures (surgical and non-surgical) are performed each month. This value was multiplied by 12 months = 51,574,200. HHS adjusted by approximately one-third of one percent to account annual increase in volume since study publication resulting in 51,744,200). See also KFF Health Insurance Coverage of the Total Population.

[171] *https://www.dfs.ny.gov/system/files/documents/2019/09/dfs_oon_idr.pdf.*

[172] The number is estimated as follows: 51,744,200 nonemergency elective procedures (surgical and non-surgical) performed annually × 9.2% uninsured rate = 4,760,466. HHS assumes that some uninsured (or self-pay) individuals will forego elective procedures because of costs. Therefore, a 30% decrease adjustment was included resulting in 3,332,326. HHS assumes that 10% of uninsured (or self-pay) individuals who undergo a nonemergency elective procedure will receive a billed charge that is $400 or more than the total expected charges in the good faith estimate for the provider or facility, therefore 3,332,326 × 10% = 333,232. HHS assumes that 8% will engage the provider-patient dispute resolution process, therefore 333,232 × 8% = 26,659.

[173] These states are Alabama, Florida, Georgia, Pennsylvania, Texas, and Wisconsin. See Affordable Care Act: Working with States to Protect Consumers, available at *https://www.cms.gov/CCIIO/Resources/Files/external_appeals.html.*

[174] AHIP Center for Policy and Research, ''An Update on State External Review Programs, 2006,'' July 2008.

[175] North Carolina Department of Insurance. ''Health Insurance Smart NC: Annual Report on External Review Activity 2013.'' *https://digital.ncdcr.gov/digital/collection/p249901coll22/id/730531.*

[176] 12,304/0.75 = 15,942.

[177] According to a Kaiser Family Foundation analysis of National Health Interview Survey data, in 2019, 10.5 percent of adults reported forgoing or delaying medical care due to costs. Reference: Krutika, Amin, Gary Claxton, Giorlando Ramirez, and Cynthia Cox (2021). ''How Does Cost Affect Access to Care?'' Peterson-KFF Health System Tracker. Available at *https://www.healthsystemtracker.org/chart-collection/cost-affect-access-care/.*

IDR item or service already subject to a certified IDR entity's determination for 90 calendar days following a payment determination. Furthermore, these interim final rules permit multiple qualified IDR items and services to be batched together in a single payment determination proceeding to encourage efficiency; however, the batched items and services must involve the same provider or group of providers, the same facility, the same provider of air ambulance services, the same plan or issuer, treatments involving the same or similar items or services (as determined by service codes), and have to occur within a single 30-business-day period (or during the 90-calendar-day suspension period). By batching similar qualified IDR items and services, these interim final rules may reduce the per-service cost of the Federal IDR process and potentially the aggregate administrative costs, since the Federal IDR process is likely to exhibit at least some economies of scale.[178] For example, the per-service cost of a payment determination involving ten services is likely to be lower than the per-service cost of a payment determination involving five services. Thus, these interim final rules may result in cost savings for plans, issuers, and providers. The Departments do not have data or a way to estimate how prevalent batching will be, and thus the potential cost savings that may result, in comparison to a hypothetical IDR process without batching. The Departments seek comment and data on this topic, if available.

In addition, these interim final rules prohibit conflicts of interest in the selection of certified IDR entities. The selected certified IDR entity cannot be a group health plan; a health insurance issuer offering group health insurance coverage, individual health insurance coverage or short-term, limited-duration insurance; an FEHB carrier; or a provider, a facility or a provider of air ambulance services. Additionally, the selected certified IDR entity cannot be an affiliate of a group health plan; a health insurance issuer offering group health insurance coverage, individual health insurance coverage or short-term, limited-duration insurance; an FEHB carrier; or a provider, a facility or a provider of air ambulance services. The selected certified IDR entity cannot be an affiliate or subsidiary of a professional or trade association representing group health plans; health insurance issuers; FEHB carriers; or providers, facilities, or providers of air ambulance services. Also, the selected certified IDR entity and its personnel cannot have a material familial, financial, or professional relationship with a party to the payment determination being disputed. By prohibiting conflicts of interest, these interim final rules will help ensure that the selected certified IDR entity will take both parties into full consideration during arbitration and ensure that the resolution of the dispute is conducted fairly.

Furthermore, these interim final rules dictate what factors the certified IDR entities may consider for their decisions. Specifically, these interim final rules require that certified IDR entities consider the QPA and requires them to consider other relevant factors, to the extent credible information is provided by the parties, while not allowing for the consideration of usual and customary rates, billed charges of the provider, or public payor rates, such as those of Medicare, Medicaid, the Children's Health Insurance Program, TRICARE, chapter 17 of title 38, United States Code, or demonstration projects under title XI of the Social Security Act.

The Departments seek comment addressing the benefits that will be associated with these interim final rules. The Departments also seek comment on how the interim final rules will affect individuals from minority and underserved communities and providers who serve these individuals.

Protections for the Uninsured

Health insurance and health care costs are critical determinants of access to health care and are central reasons for existing health inequities.[179] In the past decade, while overall rates of health insurance coverage have increased, the rates of health insurance coverage among most minority groups continue to be disproportionately lower than among non-minority groups. Estimates from the Centers for Disease Control and Prevention (CDC) National Health Interview Survey (NHIS), suggest that approximately 30 million U.S. residents lacked health insurance in the first half of 2020.[180] Prior to the COVID–19 pandemic, according to information collected in the Current Population Survey Annual Social and Economic Supplement (CPS ASEC) and the American Community Survey (ACS), in 2019, 8.0% of people, or 26.1 million individuals, did not have health insurance at any point during the year.[181] Additionally, the most recent ACS data documents the largest annual increase in the number of uninsured children from 2018 to 2019 since the survey began asking about health insurance in 2008. The child uninsured rate increased from 5.2% in 2018 to 5.7% in 2019.[182]

The provisions in these interim final rules will protect uninsured (or self-pay) individuals by allowing them to obtain a good faith estimate of expected charges from providers and facilities prior to receiving scheduled items and services and upon request. With this information, uninsured (or self-pay) individuals may be more likely to consider and compare costs across providers or facilities prior to or upon scheduling an item or service to help inform decisions regarding costs for an item or service. Additionally, these interim final rules protect these uninsured (or self-pay) individuals from receiving excessive surprise bills from providers and facilities, and allow an uninsured (or self-pay) individual to seek a determination through the patient-provider dispute resolution process if billed charges for items or services from a provider or facility are substantially in excess of the expected charges listed on the good faith estimate.

The patient-provider dispute resolution process further protects uninsured (or self-pay) individuals as the process may result in lower payments. During the dispute resolution process, the SDR entity must review any documentation submitted by the uninsured (or self-pay) individual or their authorized representative, or a provider or facility, and must make a determination as to whether the health care provider or health care facility has provided credible information for each billed item or service, including an item or service that did not originally appear on the good faith estimate, to demonstrate that the difference between the billed charge and the expected

[178] Fielder, Matthew, Loren Adler, and Benedic, Ippolito. ''Recommendations for Implementing the No Surprises Act.'' U.S.C.-Brookings Schaeffer on Health Policy. (March 2021). *https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2021/03/16/recommendations-for-implementing-the-no-surprises-act/.*

[179] ''Mirror, Mirror 2021: Reflecting Poorly.'' The Commonwealth Fund (2021). *https://www.commonwealthfund.org/publications/fund-reports/2021/aug/mirror-mirror-2021-reflecting-poorly.*

[180] ''Trends in the US Uninsured Population 2010–2020.'' APSE Office of Health Policy (2020). *https://aspe.hhs.gov/system/files/pdf/265041/trends-in-the-us-uninsured.pdf.*

[181] Keisler-Starkey, Katherine and Lisa N. Bunch. ''Health Insurance Coverage in the United States: 2019.'' (2020) *https://www.census.gov/library/publications/2020/demo/p60-271.html.*

[182] ''Census Data Show Largest Annual Increase in Number of Uninsured Children in More Than a Decade.'' *https://ccf.georgetown.edu/2020/09/15/census-data-show-decades-largest-annual-increase-in-number-of-uninsured-children/.*

charge in the good faith estimate reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided. HHS is of the view that this helps ensure that the SDR entity review is comprehensive and that the facts and circumstances for the billed charge for each item or service are considered by the SDR entity. HHS is also of the view that this approach ensures that the uninsured (or self-pay) individual is only billed charges that reflect medically necessary items or services and are based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided. This dispute resolution process protects the uninsured (or self-pay) individual from unexpected charges in cases where there are extra charges based on items or services that are not medically necessary, or could have been reasonably foreseen and thus included on the good faith estimate.

These provisions also provide protections when an uninsured (or self-pay) individual receives a bill that includes providers or facilities that were not included in the good faith estimate, specifically if a co-provider or co-facility is replaced at the last moment by a different co-provider or co-facility. These interim final rules provide important consumer protections that are aimed to protect uninsured (or self-pay) individuals from unexpected medical bills by not allowing a provider or facility to essentially circumvent these protections simply due to not being directly represented on the good faith estimate. Therefore, HHS is of the view that it is necessary and appropriate for billed items or services of providers or facilities to be eligible for dispute resolution if the billed charge is substantially in excess of the total expected charges included in the good faith estimate for the original co-provider or co-facility. If the replacement provider or facility provides the uninsured (or self-pay) individual with an updated good faith estimate in accordance with 45 CFR 149.610(b)(2) then the determination of whether an item or service billed by the replacement co-provider or co-facility is eligible for dispute resolution is based on whether the total billed charges for the replacement co-provider or co-facility is substantially in excess of the total expected charges included in the good faith estimate provided by the replacement co-provider or co-facility. HHS recognizes that these particular situations may be more complex for an uninsured (or self-pay) individual to determine eligibility for dispute resolution since the provider or facility may not be reflected in the good faith estimate.

HHS is of the view that requiring an uninsured (or self-pay) individual to pay the entire cost of dispute resolution in cases where the provider or facility prevails in dispute resolution could be prohibitive for such an uninsured (or self-pay) individual to access the dispute resolution process. HHS is also concerned that requiring a provider or facility to pay dispute resolution costs when they do not prevail could impose a burden on the provider or facility and potentially provide an incentive for the provider or facility to raise prices on uninsured (or self-pay) individuals to account for potential dispute resolution costs or avoid treating uninsured (or self-pay) individuals altogether. Therefore, HHS is adopting an approach in which HHS will cover dispute resolution costs through contracts with SDR entities for the patient-provider dispute-resolution process. HHS estimates that the total costs to be paid for patient-provider dispute resolution to SDR entities to be $10,633,600.[183] Such an approach ensures that the uninsured (or self-pay) individual would not be required to pay dispute resolution costs and as a result would not face a barrier to accessing the dispute resolution process. Additionally, as the provider or facility would not be required to pay dispute resolution costs, such approach would reduce the provider's or facility's incentives to increase prices or restrict an uninsured (or self-pay) individual's access to needed care.

In addition, PHS Act section 2799B–7 requires that the Secretary of HHS establish an administrative fee to participate in the patient-provider dispute resolution process in such a manner as to not create a barrier to an uninsured (or self-pay) individual to participate in such process. HHS intends to establish an administrative fee in guidance in a manner that will not create a barrier to an uninsured (or self-pay) individual's access to the patient-provider dispute resolution process. For the first year, HHS expects the fee to be no more than $25.

Although HHS is of the view that requiring all parties to the dispute resolution to pay an administrative fee to offset some of the Federal costs for administering the patient-provider dispute resolution program is appropriate, only the non-prevailing party will be required to pay the administrative fee (either as a payment made directly to the SDR entity in the case of the uninsured (or self-pay) individual, or in a reduction in the final payment determination amount as in the case of the provider or facility). In cases where the SDR entity determines the payment amount the uninsured (or self-pay) individual pays is less than the billed charge, the SDR entity would apply a reduction equal to the administrative fee amount paid by the uninsured (or self-pay) individual to the payment amount to calculate the final payment determination amount to be paid by the uninsured (or self-pay) individual for the items or services. HHS is of the view that requiring the SDR entity to apply a reduction equal to the administrative fee paid by the uninsured (or self-pay) individual to the payment amount is the appropriate approach as it simplifies the number of transactions. HHS anticipates collecting $666,475 [184] in administrative fees from an anticipated 26,659 cases, which will offset some of the costs of the patient-provider dispute resolution process, which is estimated to be $12.6 million (which includes IDR portal system maintenance and contracting fees for SDRs) beginning in 2022, resulting in a total cost to the Federal Government of approximately $12 million.

External Review Requirements

These interim final rules will help transform the external review process

[183] The number is estimated as follows: 51,744,200 nonemergency elective procedures (surgical and non-surgical) performed annually × 9.2% uninsured rate = 4,760,466. HHS assumes that some uninsured (or self-pay) individuals will forgo elective procedures because of costs. HHS assumes that 333,232 of uninsured (or self-pay) individuals who undergo a nonemergency elective procedure will receive a billed amount that is $400 or greater more than the total expected charges listed in the good faith estimate for the provider or facility, therefore 3,332,326 × 10% = 333,232. The Department assumes that 8% of these individuals will engage the provider-patient dispute resolution process, therefore 333,232 × 8% = 26,659. For the first year, HHS expects the SDR fee per arbitration to be about $400 therefore $400 × 26,659 = $10,633,600.

[184] The number is estimated as follows: 51,744,200 nonemergency elective procedures (surgical and non-surgical) performed annually × 9.2% uninsured rate = 4,760,466. HHS assumes that some uninsured (or self-pay) individuals will forego elective procedures because of costs. HHS assumes that 333,232 of uninsured (or self-pay) individuals who undergo a nonemergency elective procedure will receive a billed charge that is at least $400 more than the total expected charges listed in the good faith estimate for the provider or facility, therefore 3,332,326 × 10% = 333,232. The Department assumes that 8% will engage the provider-patient dispute resolution process, therefore 333,232 × 8% = 26,659. For the first year, HHS expects the SDR fee per arbitration to be $25 therefore $25 × 26,659 = $666,475.

into a more uniform and structured process. As stated earlier in this preamble, these interim final rules extend the balance billing protections related to external review to grandfathered plans. Grandfathered health plans must provide external review for adverse benefit determinations involving benefits subject to these surprise billing protections. Additionally, for non-grandfathered health plans these interim final rules clarify that, to the extent not already covered, that any adverse determination that involves consideration of whether a plan or issuer is complying with PHS Act section 2799A–1 or 2799A–2, ERISA section 716 or 717, or Code section 9816 or 9817 is eligible for external review. Grandfathered and non-grandfathered plans must comply either with a state external review process or the Federal external review process. A more uniform external review process will provide a broad range of direct and indirect benefits that will accrue to varying degrees to all affected parties. In general, the Departments expect that these interim final rules will improve the extent to which group health plans, issuers, and FEHB carriers provide benefits consistent with the established terms of individual plans or coverages. This change will cause some participants to receive benefits that they might otherwise have been denied. Furthermore, expenditures by plans may be reduced as a fuller system of claims and appeals processing helps facilitate enrollee acceptance of cost management efforts.

Furthermore, the more uniform standards for handling appeals and external review provided by these interim final rules will reduce the incidence of inappropriate denials, averting serious, avoidable lapses in access to health care and resultant injuries and losses to participants, beneficiaries, and enrollees. These changes also will enhance participants', beneficiaries', and enrollees' level of confidence in and satisfaction with their health care benefits and improve plans' awareness of participant, beneficiary, enrollee, and provider concerns. These changes could prompt plan and issuer responses that improve health care quality.

1.5. Costs

These interim final rules seek to protect patients from surprise billing, while also seeking to minimize the costs to providers, facilities, plans, issuers, and individuals.

The ultimate effect of the Federal IDR process on health care costs is uncertain. Discussions of the uncertainty and potential transfers that the Departments expect are included in the Transfers and Uncertainty sections.

1.5.1. Federal IDR Process for Nonparticipating Providers or Nonparticipating Emergency Facilities

The Departments and OPM do not have data on how many claims will be submitted to the Federal IDR process. For the purposes of the estimates in this section, the Departments and OPM rely on the experience of New York State. In 2018, New York State had 1,014 IDR decisions, up from 650 in 2017 and 396 in 2016.[185] The Departments do not know what is causing the increasing trend or whether the trend is likely to continue to increase. The Departments seek comments on this trend for analytic purposes. In 2018, the state of New York accounted for 5.8 percent of the private insurance market.[186] For purposes of this analysis, the Departments assume that, going forward, New York State will continue to see 1,000 IDR cases each year and that the number of Federal IDR cases will be proportional to that in New York State by share of covered individuals in the private health coverage market. Accordingly, the Departments estimate that there will be approximately 17,000 claims that are submitted to the Federal IDR process each year.[187] The Departments seek comment on this estimate.

Surprise billing decreased by 34 percent in New York State between 2015 and 2018 when the state implemented an IDR process.[188] While the number of IDR cases has been trending up, the decline in surprise billing is likely to result in a decline in IDR cases. Additionally, the usage and cost of certified IDR entities is likely to decrease when certified IDR entities use the QPA as the rebuttable presumption in payment determination, particularly after the first instance of using the QPA. The Departments do not have any data or experiences on which to base an estimate of how much use of the Federal IDR process will decline over time. Accordingly, in these estimates, prevalence of the use of the Federal IDR process is assumed to be constant; however, the Departments recognize that this is likely an overestimate.

The Departments estimate that the cost associated with the Federal IDR process for nonparticipating providers or nonparticipating emergency facilities will be $38.4 million. This includes an estimated cost of $21.1 million for paperwork requirements. For more details, please refer to the Paperwork Reduction Act section of this preamble.

In addition to the paperwork costs for the Federal IDR process, the Departments estimate that it will take, a medical and health services manager 2 hours and a clerical worker 15 minutes on average to prepare materials for open negotiation for each plan, issuer, or FEHB carrier and provider or facility. 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.[189] This results in a cost of $10.3 million.[190]

If the plan, issuer, or FEHB carrier and the provider or facility fail to select a certified IDR entity, the Departments will select a certified IDR entity through a random selection method. The Departments assume that in 25 percent of IDR payment determinations, a certified IDR entity will not be selected by the parties. The Departments request comment on this assumption.

Furthermore, the party whose offer was not chosen by the certified IDR entity must pay the certified IDR entity fee, in addition to the administrative fee (required to be paid by both parties upon initiation of the IDR process). However, if the parties agreed upon an out-of-network rate, the certified IDR entity fee must be divided equally

[185] Adler, Loren. ''Experience with New York's Arbitration Process for Surprise Out-of-Network Bills.'' U.S.C.-Brookings Schaeffer on Health Policy. (October 2019). *https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2019/10/24/experience-with-new-yorks-arbitration-process-for-surprise-out-of-network-bills/.*

[186] In 2018, 10.5 million individuals had employer-sponsored insurance and 1.8 million individuals had other private coverage in New York State, while 178.4 million individuals had employer-sponsored coverage and 34.8 million individuals had other private coverage nationally. The Departments estimate that New York accounts for 5.8 percent of the private insurance market ((10.5 + 1.8)/(178.4 + 34.8) = 5.8 percent). *See* 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.*

[187] This is calculated as: 1,000/0.058 = 17,333.

[188] Marion Mass. ''Surprise Billing Legislation Should Put Independent Dispute Resolution at Its Heart.'' Morning Consult. (March 2020). *https://morningconsult.com/opinions/surprise-billing-legislation-should-put-independent-dispute-resolution-at-its-heart/.*

[189] This is calculated 17,333/(1 − 0.25) = 23,111.

[190] The burden is estimated as follows: 23,111 claims × 2 hours + 23,111 claims × 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 × 2 hours × $105.01 + 23,111 claims × 0.5 hour × $55.23 = $5,172,803. 2 × $5,172,803 = $10,345,605. Labor rates are EBSA estimates.

between the parties, unless otherwise agreed to by the parties. In New York, IDR entities included independent review organizations who contracted with board certified physicians and other insurance contract experts.[191] The fees charged by IDR entities in New York ranged from $300 to $600.[192] In Texas, the state contracted with individual attorneys to provide IDR entities. In Texas, fixed fees ranged from $270 to $6,000.[193] Based on these ranges, the Departments estimate that on average the certified IDR entity fees will be approximately $400. This results in a cost of $6.9 million.[194]

1.5.2. IDR Process for Air Ambulances

In 2018, 178.4 million individuals had employer-sponsored health insurance and 34.8 million individuals had other private insurance, including individual market coverage.[195] In 2017, the Health Cost Institute (HCCI) estimated that, on average, there were 33.3 air ambulance uses per 100,000 people,[196] and the Government Accountability Office (GAO) estimated that approximately 69 percent of air transports resulted in an out-of-network bill.[197] 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 ambulances services, the Departments assume that it will be substantially higher than for hospital or emergency department claims. The Departments assume that 10 percent of out-of-network claims for air ambulance services will be submitted to the Federal IDR process,[198] which would result in nearly 4,900 air transport payment determinations in the Federal IDR process each year.[199] The Departments seek comment on this estimate.

The Departments estimate that the cost associated with the Federal IDR process for nonparticipating providers or nonparticipating providers of air ambulance services will be $11.1 million. This includes an estimated cost of $5.3 million for paperwork requirements. For more details, please refer to the Paperwork Reduction Act section.

In addition to the paperwork costs, the Departments estimate that it will take, a medical and health services manager 2 hours and a clerical worker 15 minutes on average to prepare materials for open negotiation for each plan, issuer, or FEHB carrier and provider of air ambulance services. 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 6,532 claims will go through open negotiation.[200] This results in a cost of $3.8 million.[201]

As stated above, 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 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.

Furthermore, the party whose offer was not chosen by the certified IDR entity must pay the certified IDR entity fee, in addition to the administrative fee (initially required to be paid by both parties upon initiation of the Federal IDR process). However, if the parties agree upon an out-of-network rate, the costs must be divided equally between the parties, unless otherwise agreed to by the parties. In New York, IDR entities included independent review organizations that contracted with board certified physicians and other insurance contract experts.[202] The fees charged by IDR entities in New York ranged from $300 to $600.[203] In Texas, the state contracted with individual attorneys to provide IDR entities. In Texas, fixed fees per case ranged from $270 to $6,000.[204] Based on these ranges, the Departments estimate that on average the certified IDR entity fees will be approximately $400. This results in a cost of approximately $2 million.[205] This results in a cost of approximately $2 million.[206]

1.5.3. Requests Extension of Time Periods for Extenuating Circumstances

A plan, issuer, FEHB carrier, provider, facility, or provider of air ambulance services may request an extension regarding the time periods set forth in these interim final rules, other than for the timing of the payments, including payments to the provider, facility, or air ambulance services, under extenuating circumstances. To request an extension, entities will need to submit the Request for Extension due to Extenuating Circumstances form through the Federal IDR portal, if the extension is necessary to address delays due to matters beyond the control of the parties or for good cause. Additionally, they must attest that prompt action will be taken to ensure that the required action is made as soon as administratively practicable. The Departments estimate that the costs associated with requests for the extension of time periods will be $1,381 annually. For more details, please refer to the Paperwork Reduction Act section of this preamble.

[191] Kaiser Family Foundation. ''Surprise Medical Bills: New Protections for Consumers Take Effect in 2022.'' (2019). *https://www.kff.org/private-insurance/fact-sheet/surprise-medical-bills-new-protections-for-consumers-take-effect-in-2022/.*

[192] The Commonwealth Fund. ''How States are Using Independent Dispute Resolution to Resolve Out-of-Network Payments in Surprise Billing.'' (February 2020). *https://www.commonwealthfund.org/blog/2020/how-states-are-using-independent-dispute-resolution-resolve-out-network-payments-surprise.*

[193] Kaiser Family Foundation. ''Surprise Medical Bills: New Protections for Consumers Take Effect in 2022.'' (2019). *https://www.kff.org/private-insurance/fact-sheet/surprise-medical-bills-new-protections-for-consumers-take-effect-in-2022/.*

[194] The cost is estimated as follows: (17,333 × $400) = $6,933,200.

[195] 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.*

[196] 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.*

[197] 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.*

[198] The Departments utilize 10 percent as an assumption to estimate the overall number of physicians billing out-of-network at least once in a year.

[199] The Departments estimate that of the 213.2 million individuals with employer-sponsored and other private health insurance (178.4 million individuals with employer-sponsored health insurance and 34.8 million individuals with other private 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 × 0.000333 × 0.69 × 0.1= 4,899).

[200] This is calculated 4,899/(1 − 0.25) = 6,532.

[201] The burden is estimated as follows: 6,532 claims × 2 hours + 6,532 claims × 0.25 hour = 39,190 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 claims × 2 hours × $105.01 + 6,532 claims × 0.5 hour × $55.23 = $1,895,077. 2 × $1,895,077 = $3,790,154. Labor rates are EBSA estimates.

[202] Kaiser Family Foundation. ''Surprise Medical Bills: New Protections for Consumers Take Effect in 2022.'' (2019). *https://www.kff.org/private-insurance/fact-sheet/surprise-medical-bills-new-protections-for-consumers-take-effect-in-2022/.*

[203] The Commonwealth Fund. ''How States are Using Independent Dispute Resolution to Resolve Out-of-Network Payments in Surprise Billing.'' (February 2020). *https://www.commonwealthfund.org/blog/2020/how-states-are-using-independent-dispute-resolution-resolve-out-network-payments-surprise.*

[204] Kaiser Family Foundation. ''Surprise Medical Bills: New Protections for Consumers Take Effect in 2022.'' (2019). *https://www.kff.org/private-insurance/fact-sheet/surprise-medical-bills-new-protections-for-consumers-take-effect-in-2022/.*

[205] The cost is estimated as follows: (4,899 × $400) = $1,959,600.

[206] The cost is estimated as follows: (4,899 × $400) = $1,959,600.

1.5.4. Requirements for Certified IDR Entities

An IDR entity must be certified under standards and procedures set forth in these interim final rules and in guidance promulgated by the Departments. For each month, certified IDR entities will be required to report information on their activity to the Departments. The Departments estimate that there will be 50 entities seeking IDR certification, as discussed earlier in this analysis of economic and paperwork burdens.

The Departments estimate that the cost associated with the IDR entity certification process and reporting requirements will be $149,616 in the first year and $124,491 in the subsequent years. For more details, please refer to the Paperwork Reduction Act section.

1.5.5. External Review Requirements

The interim final rules require grandfathered health plans to provide external review for adverse benefit determinations involving benefits subject to these surprise billing protections.

The Departments estimate that there are approximately 84.4 million participants in self-insured ERISA-covered plans. Prior to the interim final rules, the Departments estimate that there were approximately 8.1 million participants in ERISA-covered plans in the states which currently have no external review laws or whose laws do not meet the Federal minimum requirements. These estimates lead to a total of 92.5 million participants. Among the 92.5 million participants, 80.5 million participants in non-grandfathered plans and 12 million participants in grandfathered plans will be required to be covered by the external review requirement.

The Departments estimate that there are approximately 1.3 external reviews for every 10,000 participants and that there will be approximately 12,304 external reviews annually. Experience from North Carolina indicates that about 75 percent of requests for external review are actually eligible to proceed to an external review.[207] Therefore, the Departments expect that there will be about 15,942 requests for external review. The Departments estimate that the cost associated with the external review requirements for ERISA-covered plans will be $3.3 million.

Additionally, HHS estimates that there are approximately 13.5 million individual market enrollees and 19.3 million non-Federal governmental plans enrollees.[208] These estimates lead to a total of 32.8 million total enrollees in individual market and non-Federal Government plans. Among the 32.8 million participants, 2.6 million are in grandfathered plans and 30.1 million are in non-grandfathered plans. HHS also added a 2 percent increase in the number of out-of-networks claims to capture the increase in burden on non-grandfathered plans resulting from the surprise billing and cost sharing protections of the external review requirements, resulting in an adjusted total of 30.7 million participants for non-grandfathered plans and an adjusted total of 33.3 million participants for all individual market and non-Federal Government plans.

HHS also estimates there are an estimated 1.3 external reviews for every 10,000 participants and that there will be approximately 4,337 total external reviews annually for individual market and non-Federal Government plans. This amount includes 3,994 reviews for non-grandfathered plans and 343 for grandfathered plans. Experience from North Carolina indicates that about 75 percent of requests for external reviews are actually eligible to proceed to an external review, therefore it is expected that there will be about 5,783 requests for external review. This amount includes 5,326 requests for non-grandfathered plans and 457 requests for grandfathered plans. HHS estimates that the cost associated with the external review requirements for individual market and non-Federal Government plans will be $241,850.

In summary, the Departments estimate that the total annual cost associated with the External Review for DOL will be $3.3 million and the total annual cost associated with the External Review for HHS will be will be $0.2 million. For more details, see the Paperwork Reduction Act section.

1.5.6. Protections for the Uninsured

These interim final rules seek to protect uninsured (or self-pay) individuals from surprise billing through two mechanisms: The provision of good faith estimates from providers and facilities and the patient-provider dispute resolution process to resolve billing disputes when an uninsured (or self-pay) individual receives a bill for charges that are substantially in excess of the expected charges listed in the good faith estimates.

1.5.7. Good Faith Estimates

As discussed in the Paperwork Reduction Act section of this preamble, HHS estimates the total annual burden to convening providers or facilities to notify uninsured (or self-pay) individuals of the availability of good faith estimates to be approximately 2,743,283 hours with an equivalent cost of $320,250,167. HHS estimates the annual cost to a convening provider or facility to provide a good faith estimate of expected charges to uninsured (or self-pay) individuals for scheduled items and services and upon requests between 2022 and 2024 to be $356,727,765 and total burden hours of 3,538,305.

1.5.8. Patient-Provider Dispute Resolution Process

As discussed in the Paperwork Reduction Act section of this preamble, HHS estimates the total annual burden associated with the patient-provider dispute resolution process for uninsured (or self-pay) individuals and health care providers and health care facilities to be approximately 255,524 hours with an equivalent cost of $29,764,646.

1.5.9. Patient-Provider SDR Entity Certification

As discussed in the Paperwork Reduction Act section of this preamble, HHS estimates the total annual burden associated with the SDR entity certification to be 16 hours with an equivalent cost of $1,873 in the first year. In subsequent years, the total hour burden associated with the SDR entity certification or recertification is 2.25 hours with an equivalent cost of $257. HHS seeks comment on the assumptions and calculations made in the corresponding Information Collection Request (ICR). The Departments also seek comment on the estimates presented in this section and on any additional costs incurred by patients, providers, providers of air ambulance services, facilities and uninsured (or self-pay) individuals.

1.5.10. Summary

The Departments estimate the total cost burden associated with these interim final rules to be $760.95 million in the first year, with $38.43 million attributable to the Federal IDR process for nonparticipating providers or nonparticipating emergency facilities or

[207] North Carolina Department of Insurance. ''Health Insurance Smart NC: Annual Report on External Review Activity 2013.'' *https://digital.ncdcr.gov/digital/collection/p249901coll22/id/730531.*

[208] Individual market based on data from MLR annual report for the 2019 MLR reporting year, available at *https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.* Non-federal government plans data from Agency for Healthcare Research and Quality, Center for Financing, Access and Cost Trends. 2019 Medical Expenditure Panel Survey-Insurance Component.

group health plans or health insurance issuers offering health insurance coverage, $11.08 million attributable to the Federal IDR process for air ambulance services; $149,616 attributable to costs associated with certification and recordkeeping requirements for certified IDR entities, $4.02 million attributable to the external review process, and $706.7 million attributable to the patient-provider dispute resolution process.

The Departments seek comment addressing the costs that will be associated with these interim final rules. The Departments also seek comment on how these interim final rules will affect individuals from minority and underserved communities, and providers and facilities who serve these individuals.

1.6. Transfers

These interim final rules will protect patients from surprise bills for emergency and nonemergency medical services and air ambulance services. The Departments and OPM recognize this as transfers between individuals, plans, issuers, FEHB carriers, and providers, facilities, and providers of air ambulance services. The Departments and OPM expect that these interim final rules will result in some transfers from providers, facilities, and providers of air ambulance services to individuals, some transfers from plans, issuers, and FEHB carriers to providers, facilities, and providers of air ambulance services, and some transfers from individuals to plans, issuers, and FEHB carriers and providers, facilities, and providers of air ambulance services. The magnitude of each of these transfers is uncertain, and as such, the ultimate effect of the Federal IDR process on each of entity is largely uncertain.

These interim final rules may result in lower out-of-pocket spending by individuals, as these interim final rules are expected to decrease surprise billing. This result would follow from two types of transfers: Transfers from providers, facilities, and providers of air ambulance services who had previously balance billed individuals for out-of-network claims to individuals who would have received those balance bills, and transfers from plans, issuers, and FEHB carriers who were previously not responsible for out-of-network bills to providers who would submit out-of-network bills to plans, issuer, and FEHB carriers as a result of these interim final rules. The Departments request comment or data on how large each of these transfers might be.

As shown in Table 3, the mean provider charges relative to Medicare payment rates differ across physician specialties, and the ratios for specialties in which surprise billing is more common have a higher ratio of mean provider charges relative to Medicare payments rates than those specialties for which surprise billing is less common. These higher rates have been linked to the fact that patients are not able to select providers in these specialties, leaving patients more vulnerable to surprise billing.[209] The Departments expect that the proposed interim final rules will lead to the ratio of mean provider charges to Medicare payment rates to converge with specialties with comparatively infrequent surprise billing.

TABLE 3—RATIO OF MEAN PROVIDER CHARGES TO MEDICARE PAYMENT RATES BY SPECIALTY

Specialty	Mean ratios, 2018[210]
Specialties with infrequent surprise billing	
Family Practice	2.1
Internal Medicine	2.2
Primary Care	2.2
Dermatology	2.1
Specialties with frequent surprise billing	
Anesthesiology	7.0
Emergency Medicine	5.7
Diagnostic Radiology	4.0
Pathology	2.7

Further, research finds that New York's Out-of-Network Law[211] has saved consumers over $400 million from the date of implementation, March 2015, through the end of 2018 with respect to emergency services alone.[212] These savings have been realized in part through a reduction in costs associated with emergency services and an increased incentive for network participation. By establishing an IDR process for out-of-network emergency services, the Out-of-Network Law reduced out-of-network billing by 34 percent and lowered in-network emergency physician payments by 9 percent.[213]

The interim final rules are expected to have an effect on premiums, although there is uncertainty around how premiums will ultimately be affected. The Congressional Budget Office estimated the provisions in the No Surprises Act are likely to reduce premiums by 0.5 percent to 1 percent in most years.[214] In comparison, the CMS's Office of the Actuary (OACT) estimated the provisions are likely to increase premiums by 0.00 percent to 0.35 percent.[215] Neither of these estimates isolate the effect attributable to the Federal IDR process.

The ultimate effect on premiums will depend on how much plans, issuers, FEHB carriers, and providers, facilities, and providers of air ambulance services will use the Federal IDR process and how the Federal IDR process affects plan, issuer, and FEHB carrier liability. If payments to providers decrease, this change may result in a decrease in premiums. This decrease in premiums will result in a transfer from providers and facilities to participants, enrollees, or beneficiaries through plans, issuers, and FEHB carriers. Additionally, this could result in a transfer from eligible enrollees to the Federal Government in the form of reduced payment of the Premium Tax Credits (PTC). Conversely, if payments to providers increase, the expenditures for plans, issuers, and FEHB carriers may be passed on to consumers in the form of increased premiums. This could result in three types of transfers: (1) From the participants, enrollees, and beneficiaries to the plans, issuers, and FEHB carriers; (2) from the Federal Government to

[209] *See* Hannick, Kathleen and Loren Adler. ''Provider Charges Relative to Medicare Rates, 2012–2018.'' USC-Brookings Schaeffer on Health Policy. (May 2021). *https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2021/05/03/provider-charges-relative-to-medicare-rates-2012-2018/.*

[210] *See* Hannick, Kathleen and Loren Adler. ''Provider Charges Relative to Medicare Rates, 2012–2018.'' USC-Brookings Schaeffer on Health Policy. (May 2021). *https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2021/05/03/provider-charges-relative-to-medicare-rates-2012-2018/.*

[211] NY Fin Serv L § 605 (2014).

[212] New York State Department of Financial Services. ''New York's Surprise Out-Of-Network Protection Law Report on the Independent Dispute Resolution Process.'' (September 2019). *https://www.pacep.net/assets/documents/NYReportontheIDRProcess.pdf.*

[213] Cooper, Zack, Fiona Scott Morton, and Nathan Shekita. ''Surprise! Out-Of-Network Billing for Emergency Care in the United States.'' 128 Journal of Political Economy 9. (2020).

[214] Congressional Budget Office. ''Estimate for Divisions O Through FF. H.R. 133, Consolidated Appropriations Act, 2021. Public Law 116–260.'' *https://www.cbo.gov/system/files/2021-01/PL_116-260_div%20O-FF.pdf.*

[215] The OACT analysis assumed that an individuals' cost-sharing is limited to their in-network cost-sharing amounts and that plans and issuers are responsible for any excess of the allowed amounts for nonparticipating providers over in-network reimbursement rates. OACT assumed that that the average allowed amounts for services provided by nonparticipating providers will remain higher than in-network reimbursement rates after the No Surprises Act takes effect. OACT estimated a range of values for out-of-network allowed charges between 125 percent and 150 percent of average network rates. OACT assumed that these estimated levels reflected the Federal IDR process but did not make any explicit assumptions about the separate impact of the Federal IDR process.

eligible enrollees in the form of increased PTC; and (3) from insured individuals who pay premiums to individuals with large out-of-network bills.

In addition, these interim final rules may affect in-network and out-of-network rates received by physicians. It is possible that the out-of-network rates collected by some providers, facilities, and providers of air ambulance services will be lower than they would have been if not for the provisions in these interim final rules. There is also uncertainty around how these interim final rules will affect the negotiation dynamics between providers, facilities, plans, issuers, and FEHB carriers regarding health care costs.

As evidenced in states where arbitrators are directed to base their determinations on billed charges, there have been increased health care costs as a result of the out-of-network payment standard being higher than that in-network rate.[216] However, as noted in an analysis by the USC.-Brookings Schaeffer Initiative for Health Policy, if certified IDR entities base their determinations on median in-network rates, which are typically lower than billed charges, the IDR process could place downward pressure on health care costs and premiums. If certified IDR entities choose amounts that are above median in-network rates, this could result in a potential increase in costs and premiums.[217] For example, in New York, providers prevailed in IDR at nearly twice the rate that issuers prevailed. In the state, arbiters are told to consider the 80th percentile of billed charges in their decision process. A study found that even when deciding in favor of health plans, arbitrations averaged just 11 percent below the 80th percentile of charges, which is consistently above the typical in-network or out-of-network rates. This result implies that plans, issuers, and FEHB carriers only won in arbitration when paying above-market rates.[218]

Further, in the Federal IDR process, certified IDR entities are required to consider credible information about additional factors such as providers' expertise and patient characteristics after beginning with a presumption in favor of the QPA, making it beneficial for a provider or facility to initiate the process when they expect to be paid more than the median in-network rate. A report from the Congressional Budget Office noted that some providers, particularly those with more specialized services, may be able to negotiate for larger payments from insurers by threatening to initiate the Federal IDR process.[219] This outcome could result in a transfer from plans, issuers, and FEHB carriers to providers. Furthermore, this outcome could also result in higher premiums, which could ultimately result in a transfer from patients to providers.[220]

In addition, these interim final rules may affect provider and facility payments and revenue. It is possible that the payments collected by some providers and facilities will be lower than they would have been if not for the provisions in these interim final rules. These interim final rules set standards requiring certified IDR entities to consider the QPA (typically the median in-network rate) when making payment determinations; the Departments expect this approach to have a downward impact on health care costs, potentially resulting in transfers from providers and facilities to individuals with health coverage.

Furthermore, the external review requirements of these interim final rules may result in a transfer from plans, or issuers to participants and beneficiaries now receiving payment for denied benefits. These transfers will improve equity, because incorrectly denied benefits will be paid.

These interim final rules also establish requirements for the uninsured (or self-pay) individual to submit an administrative fee payment when initiating the patient-provider dispute resolution process as provided in 45 CFR 149.620(g) and described in section IV.B.8 of this preamble. This requirement may result in a transfer to the uninsured (or self-pay) individual from the provider or issuer if the uninsured (or self-pay) individual prevails in the dispute resolution process. Under such circumstances, the SDR entity must apply a reduction equal to the administrative fee amount paid by the individual to the final determination amount for charges to be paid by the individual for the items or services.

1.7. Regulatory Alternatives

Section 6(a)(3)(C)(iii) of Executive Order 12866 requires an economically significant regulation to include an assessment of the costs and benefits of potentially effective and reasonable alternatives to the planned regulation. The Departments considered whether the certified IDR entity was required to consider the QPA and permitted to consider other statutory factors only when a party presents clear and convincing evidence that the value of the qualified IDR item or service materially differs from the QPA due to those factors, or whether the certified IDR entity should be required to consider all factors equally.

The Departments are of the view, however, that applying a clear and convincing evidence standard does not afford enough weight to the statutory requirement that certified IDR entities consider the additional permissible factors. Such a standard could result in a certified IDR entity failing to consider credible information a party provides, even where it clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate. On the other hand, permitting consideration of all permissible factors equally disregards the weight that the No Surprises Act places on the QPA. For example, Code section 9816(c)(7)(B)(iii)–(iv), ERISA section 716(c)(7)(B)(iii)–(iv), and PHS Act section 2799A–1(c)(7)(B)(iii)–(iv) require the Departments to report the offers as a percentage of the QPA and the amount of the offer selected, expressed as a percentage of the QPA. The statute also provides strict rules for calculating the QPA and creates disclosure and audit requirements regarding the QPA.

The Departments, therefore, are of the view that starting with a rebuttable presumption that the QPA is the appropriate payment amount properly emphasizes the QPA while requiring the consideration of the permissible additional factors when appropriate. The QPA generally is based on the median of contracted rates, which are the product of contract negotiations between providers and facilities and plans (and their service providers) and issuers, and therefore generally reflect market rates. The statute sets out detailed rules for calculating the QPA, including a requirement that when

[216] Ollove, Michael. Laws to Curb Surprise Medical Bills Might Be Inflating Health Care Costs. PEW. (2021. *https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2021/05/20/laws-to-curb-surprise-medical-bills-might-be-inflating-health-care-costs.*

[217] Adler, Loren, et al. ''Understanding the No Surprises Act.'' USC-Brookings Schaeffer on Health Policy. (2021). *https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2021/02/04/understanding-the-no-surprises-act/.*

[218] Adler, Loren. ''Experience with New York's Arbitration Process for Surprise Out-of-Network Bills.'' USC-Brookings Schaeffer on Health Policy. (October 2019). *https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2019/10/24/experience-with-new-yorks-arbitration-process-for-surprise-out-of-network-bills/.*

[219] Congressional Budget Office Cost Estimate. ''H.R. 2328, Reauthorizing and Extending America's Community Health Act.'' (September 2019). *https://www.cbo.gov/system/files/2019-09/hr2328.pdf.*

[220] Congressional Budget Office Cost Estimate. ''H.R. 2328, Reauthorizing and Extending America's Community Health Act.'' (September 2019). *https://www.cbo.gov/system/files/2019-09/hr2328.pdf.*

plans, issuers, and FEHB carriers do not have sufficient information to calculate their own median contracted rates, they utilize a database free of conflicts of interests.[221] Plans, issuers, and FEHB carriers must provide specific information on how the QPA is calculated to nonparticipating providers and facilities, ensuring that they are aware of how this rate was calculated.[222] Plans, issuers, and FEHB carriers are also subject to audit requirements that will be enforced by the Departments and OPM to ensure that they follow these standards.[223] The Departments are also required to report how the out-of-network rates compare to the QPA, suggesting that Congress saw it as an appropriate analogue for the out-of-network rate.[224] Moreover, starting with the QPA as the rebuttable presumption for the appropriate payment amount will increase the predictability of dispute resolution outcomes which may encourage parties to reach an agreement outside of the Federal IDR process to avoid the administrative costs and will aid in reducing prices that may have been inflated due to the practice of surprise billing prior to the No Surprises Act. Finally, the Departments are of the view that this approach will protect participants, beneficiaries, and enrollees from excessive costs, either through reduced costs for items and services or through decreased premiums. Therefore, in determining which offer to select, these interim final rules provide that the certified IDR entity must begin with the presumption that the QPA for the applicable year is the appropriate payment amount for the qualified IDR items or services. The certified IDR entity must, however, consider the other factors when a party provides credible information, and must choose the offer closest to the QPA, unless the credible evidence submitted by the parties clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate.

As noted previously, emphasizing the QPA will allow for predictability. As mentioned earlier in this preamble, when the recognized amount is the QPA, plans, issuers, and FEHB carriers must provide the QPA to providers and facilities when submitting an initial payment amount or denial of payment, and must provide additional information regarding the QPA upon request. Thus, even before beginning negotiations, all parties involved will know that the QPA is the primary factor that the certified IDR entity will always consider (while other factors may be considered, depending on the circumstances). This certainty will encourage plans, issuers, providers, and facilities to make offers that are closer to the QPA, and to the extent another factor could support deviation from the QPA, to focus on evidence concerning that factor. This certainty may also encourage parties to avoid the Federal IDR process altogether and reach an agreement during the open negotiation period. Finally, it is anticipated that focusing on the QPA will help mitigate costs and reduce government expenditures once the Federal IDR process is fully implemented, as projected by the Congressional Budget Office.[225] Therefore, after carefully considering both interpretations, the Departments chose to emphasize the QPA.

Furthermore, as discussed earlier in this preamble, the Departments considered how to select a certified IDR entity if the parties fail to do so. Academic literature is inconclusive regarding whether the selection process of an arbitrator has an effect on the arbitration results. One study found significant consistency between factors affecting an arbitrator's decision,[226] suggesting that the selection of a certified IDR entity by parties to the IDR, or the selection process of a certified IDR entity by the government if the parties fail to select a certified IDR entity, should not have a significant effect on the outcome. Contrarily, another study found large differences among arbitrator decisions; however, the authors attributed these differences to information disparities between parties.[227] As the parties in the Federal IDR process under these interim final rules are all professionals with specialized knowledge in health care, these information disparities are expected to be minimal in the context of the Federal IDR process.

Although the academic literature suggests that the selection of an IDR entity is unlikely to have a significant effect on the IDR entity's determination, the Departments explored options to minimize this risk. The Departments considered alternative approaches, including whether the Departments should consider the specific fee of the certified IDR entity, or look to other factors, such as how often the certified IDR entity chooses the amount closest to the QPA. However, looking to how often the certified IDR entity chooses the amount closest to the QPA could unfairly penalize certified IDR entities that have correctly handled decisions when there is credible information clearly demonstrating that the QPA is materially different from the appropriate out-of-network rate. Using this as a factor in assigning certified IDR entities could incentivize decisions that do not adequately take into account the other factors set forth in the statute and these interim final rules, even when there is credible information clearly demonstrating that the QPA is materially different from the appropriate out-of-network rate. Moreover, the consideration of other factors may encourage plans, issuers, FEHB carriers, or providers and facilities, to decline to agree to a particular certified IDR entity, thinking that the Departments will favor certain criteria. Given the cost controls applicable to the certification process, it is unlikely that the cost of a specific certified IDR entity will be a significant factor in the inability of the parties to choose a certified IDR entity.

Thus, after carefully considering the alternatives, the Departments have chosen to use a random selection method to select a certified IDR entity with a fee within the allowed range. If there is an insufficient number of certified IDR entities with a fee within the allowed range available to arbitrate the case, the Departments will use a random selection method to select a certified IDR entity that has received approval from the Departments to charge a fee outside of the allowed range.

External Review

The Departments considered different amendments to the regulations for external review to address the scope for non-grandfathered plans and issuers in light of section 110 of the No Surprises Act. Under the existing rules, a claim is eligible for external review under the Federal external review process if it involves medical judgement. The Departments note that the scope of

[221] Code section 9816(a)(2), (3)(E); ERISA section 716(a)(2), (3)(E) and PHS Act section 2799A–1(a)92), (3)(E); 26 CFR 54.9816–6T, 29 CFR 2590.716–6, and 45 CFR 149.140.

[222] Id.

[223] 86 FR 36872, 36899 (July 13, 2021).

[224] Code section 9816(c)(7)(A)(v), (B)(iii) and (iv); ERISA section 716(c)(7)(A)(v), (B)(iii) and (iv); and PHS Act section 2799A–1(c)(7)(A)(v), (B)(iii) and (iv).

[225] Congressional Budget Office, Estimate for Divisions O Through FF, H.R. 133, Consolidated Appropriations Act, 2021, Public Law 116–260, Enacted on December 27, 2020. *https://www.cbo.gov/publication/56962.*

[226] Farber, Henry and Max Bazerman. ''The General Basis of Arbitrator Behavior: An Empirical Analysis of Conventional and Final-Offer Arbitration.'' *The Econometric Society.* Vol. 54(4) (July 1986). *https://www.jstor.org/stable/1912838.*

[227] Egan, Mark, Gregor Matvos, and Amit Seru. ''Arbitration with Uniformed Consumers.'' National Bureau of Economic Research. (October 2018). *https://www.nber.org/system/files/working_papers/w25150/w25150.pdf.*

claims that are eligible for external review in general is broad, as many adverse benefit determinations involve medical judgment. The examples the Departments have provided of questions involving medical judgement (described in more detail earlier in the preamble) include questions involving health care setting, level of care, or effectiveness of a covered benefit, whether treatment involved ''emergency care'' or ''urgent care,'' affecting coverage, and how a claim is coded. The Departments note that the state external review process also extends to questions involving the requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit. The Departments are of the view that many claims that result in an adverse benefit determination involving items and services subject to the surprise billing and cost-sharing protections under the No Surprises Act generally would be eligible for external review under the current scope as specified in the 2015 final regulations. However, as stated above, section 110 of the No Surprises Act directs the Departments to require the external review process under PHS Act section 2719 to apply with respect to *any* adverse determination by a plan or issuer under PHS Act section 2799A–1 or 2799A–2, ERISA section 716 or 717, or Code section 9816 or 9817, including with respect to whether an item or service that is subject to such a determination is an item or service to which the respective section applies. The Departments are of the view that it is important to ensure that consumers can avail themselves of external review in these situations and ensure that they are afforded full protection against surprise medical costs (including cost sharing), as intended by the No Surprises Act. Accordingly, these interim final rules amend the 2015 final rules to broaden the scope of external review requirements and explicitly require, to the extent not already covered, that any adverse determination that involves consideration of whether a plan or issuer is complying with PHS Act section 2799A–1 or 2799A–2, ERISA section 716 or 717, or Code section 9816 or 9817 is eligible for external review.

HHS considered certain other approaches to furnishing good faith estimates to uninsured (or self-pay) individuals. HHS considered notification of the availability of good faith estimates using only broad outreach efforts and not, in addition to, specifically requiring that providers or facilities inform uninsured (or self-pay) individuals of the availability of good faith estimates. However, HHS is of the view that uninsured (or self-pay) individuals are more acutely aware of and concerned about health care costs when engaging with providers and facilities. Not requiring providers or facilities to notify uninsured (or self-pay) individuals of the availability of good faith estimates would potentially deprive uninsured (or self-pay) individuals of the ability to avail themselves of these important consumer protections under the No Surprises Act.

HHS considered requiring good faith estimates for each instance of a recurring item or service with the same expected charges. HHS is of the view that to do so would unnecessarily increase the burden on providers and facilities, particularly for those items and services furnished weekly or more than once per week, without adding additional informational value for the uninsured (or self-pay) individual. HHS is of the view that, while a single good faith estimate for certain recurring items and services is sufficient, establishing certain limitations is necessary in order to confirm and periodically evaluate the accuracy of the information included in the good faith estimate. For instance, HHS includes requirements that limit the applicability of a good faith estimate for recurring items and services to no longer than 12 months. If additional recurrences of furnishing such items or services are expected beyond 12 months, a convening provider or convening facility must provide an uninsured (or self-pay) individual with a new good faith estimate.

HHS also considered requiring the use of standardized notices for good faith estimates issued to uninsured (or self-pay) individuals. However, HHS is of the view that requiring the use of such model notices for good faith estimates would not allow providers or facilities necessary flexibilities to develop notices that would be most effective for their patient populations.

HHS also considered basing the substantially in excess threshold as equal to only a percentage of the expected charges in the good faith estimate; however HHS has concerns that such an approach could make dispute resolution easier to access for items or services where the expected charges are small, which would include circumstances where the difference between the billed charge and the expected charges in the good faith estimate is too small to justify the costs of dispute resolution. Alternatively, when the total expected charges in the good faith estimate are very high, few items or services could be subject to dispute resolution, despite significant unexpected charges. HHS also considered other approaches to defining the ''substantially in excess'' standard, including setting it as the lesser of a specific percentage of the total expected charges in the good faith estimate or a flat maximum dollar amount, or based on a percentage of the expected charges in the good faith estimate that varies depending on the expected costs of the items or service. Although these approaches would mitigate some of the concerns discussed previously and would make it easier for higher cost items or services to meet the substantially in excess threshold, these approaches would increase concerns that dispute resolution for lower cost services could be overused, thus potentially increasing costs for providers and facilities and potentially increasing costs for such items or services. As an alternative, HHS also considered an approach for determining ''substantially in excess'' based on an amount that is the greater of either a percentage of the total amount of expected charges in the good faith estimate or a flat minimum dollar amount. However, HHS remains concerned that such an approach could effectively put dispute resolution out of reach for uninsured (or self-pay) individuals in situations where the expected charges for the item or service are high, particularly for those who need to undergo more complex procedures. Finally, HHS considered a tiered approach, either a flat dollar amount that would increase as the total expected charges in the good faith estimate increases or a percentage that would decrease as the total of expected charges in the good faith estimate increases, but HHS is of the view that such an approach would add undue complexity and could be confusing for uninsured (or self-pay) individuals, providers, facilities, and other stakeholders.

Lastly, HHS considered basing the definition of ''substantially in excess'' on billed charges that exceed a certain percentage for the same or similar services using an independent database. However, HHS is of the view that such a mechanism is inconsistent with the statute which contemplates items or services to be determined to be ''substantially in excess'' based on the good faith estimate provided, rather than being based on a specific benchmark, such as that provided by an independent database.

As HHS obtains additional experience with the patient-provider dispute resolution process, HHS intends to review data on the use of the dispute

resolution process and may propose adjustments to the definition of ''substantially in excess'' in the future.

HHS considered whether to base eligibility for patient-provider dispute resolution on whether an individual item or service listed on a good faith estimate is billed an amount substantially in excess to the expected charge in the good faith estimate. However, HHS is concerned that such an approach would add complexity as each item or service on the good faith estimate would need to be assessed separately for eligibility. HHS also considered basing the eligibility on the total of all billed charges for all items or services and all providers or facilities listed on the good faith estimate, however such an approach would be significantly more complex given that the good faith estimate could consist of estimates of multiple providers and facilities who would bill the uninsured (or self-pay) individual separately. This approach could also potentially increase the burden on the uninsured (or-self pay) individual who would likely need to submit multiple bills from multiple providers or facilities for dispute resolution. Additionally, such an approach could require a provider or facility to respond to a notice requesting additional documentation from an SDR entity due to the billing of other providers, even when the provider or facility did not bill an uninsured (or self-pay) individual an amount substantially in excess of the good faith estimate. As a result, HHS is of the view that it is appropriate to base eligibility for dispute resolution on each provider or facility listed on the good faith estimate.

HHS considered not requiring co-providers or co-facilities that are not represented on a good faith estimate due to replacing an original co-provider or co-facility that was represented in a good faith estimate to be subject to the patient-provider dispute resolution process due to not having provided estimates of expected charges with which to base whether the billed charges substantially exceed the estimate. However, HHS is of the view that such requirements should still apply in these circumstances as they provide important consumer protections that are aimed to protect uninsured (or self-pay) individuals from unexpected medical bills, and allowing a replacement co-provider or co-facility to essentially circumvent these protections simply due to not being directly represented on the good faith estimate would weaken these consumer protections.

HHS considered requiring the Federal IDR portal be used by an uninsured (or self-pay) individual to initiate a patient-provider dispute resolution process rather than making the use of the Federal IDR portal optional. However, HHS was concerned that such a requirement could pose an unreasonable barrier for uninsured (or self-pay) individuals, particularly those with limited or no access to the internet.

HHS considered not providing a mechanism for the uninsured (or self-pay) individual to settle on a payment amount for an item or service prior to an SDR entity issuing a payment determination. However, HHS is of the view that providing an opportunity for the uninsured (or self-pay) individual and the provider or facility to come to terms on a payment amount that is mutually agreeable for the parties involved is appropriate as it can help resolve payment disputes quickly without the need for a determination by an SDR entity. Such a process can also incentivize a provider or facility to accept a lower payment amount or to provide financial assistance to the uninsured (or self-pay) individual.

HHS considered whether to allow the SDR entity to have discretion to determine a payment amount lower than the expected charges listed in the good faith estimate. However, HHS is of the view that such an approach would result in less transparency and predictability for the uninsured (or self-pay) individuals, providers and facilities regarding the outcomes of the patient-provider dispute resolution process. Therefore, HHS is of the view that the good faith estimate represents charges the uninsured (or self-pay) individual would likely expect to pay for the items or services, and as a result the consumer protections established in the patient-provider dispute resolution process serve as an important backstop that protects an uninsured (or self-pay) individual from unexpected billed charges that substantially exceed the good faith estimate.

HHS considered allowing an SDR entity to use a different standard for conducting determinations, other than that the information submitted by the provider must provide credible information that the difference between the billed charge and the expected charge for the item or service in the good faith estimate reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided. However, HHS is of the view is that such an approach would not align with the standard utilized in the Federal IDR processes discussed in section III of this preamble. This approach would result in adding undue complexity to the patient-provider dispute resolution process and the use of a different standard from the Federal IDR process could potentially lead to confusion for uninsured (or self-pay) individuals, providers and facilities.

When an SDR entity determines that the provider or facility has provided credible information that the difference between the billed charge and the expected charge for the item or service in the good faith estimate reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, HHS considered requiring that the SDR determine that the payment amount be equal to the billed charge, rather than the lesser of the billed charge or the payment amount for the same or similar services contained on an independent database (or if applicable, the good faith estimate). However, HHS is concerned that such an approach may increase the incentive for providers and facilities to inflate their billed charges, particularly in cases where the provider or facility believes they can justify the billed charges.

HHS considered not requiring an SDR entity determination to be binding upon the parties involved, in the absence of a fraudulent claim or evidence of misrepresentation of facts presented to the IDR entity involved. However, HHS was concerned that not having the process be binding could lead to a provider or facility not abiding by the SDR entity determination and holding the uninsured (or self-pay) individual liable for the entire billed charge even if the SDR entity determined that the uninsured (or self-pay) individual pay a lower amount. HHS is of the view that without making the determination binding, the consumer protections established in PHS Act section 2799B–7 would be significantly diminished and that the cost for administering the program may outweigh the benefit.

HHS considered various approaches to paying for the costs of the patient-provider dispute resolution process. HHS considered requiring the uninsured (or self-pay) individual to pay the patient-provider dispute resolution costs (*e.g.,* SDR entity costs) in cases where the individual does not prevail in dispute resolution. However, such an approach could place a significant burden on the uninsured (or

self-pay) individuals, especially low-income individuals. Such a requirement would also not be in alignment with the requirements in PHS Act section 2799B–7 that the administrative fee be set so as not to create a burden to participation. HHS also considered requiring the provider or facility to pay for dispute resolution costs when the provider or facility does not prevail. However, HHS has concerns that such an approach would impose a burden on the providers and facilities and could potentially provide an incentive for the providers and facilities to increase the prices on uninsured (or self-pay) individuals to account for potential patient-provider dispute resolution costs or avoid treating uninsured (or self-pay) individuals altogether.

HHS considered using an open certification process for SDR entities rather than contracting with a limited number of SDR entities that meet the certification requirements outlined in 45 CFR 149.620(d). However, HHS is of the view that an open certification process would increase the administrative burden associated with certifying SDR entities and would not allow for the same level of administrative oversight, monitoring, and audit potential as opposed to contracting with the SDR entities directly.

HHS considered not providing a mechanism to defer to a state that implements a parallel patient-provider dispute resolution process that meets certain minimum Federal requirements. However, such an approach would not allow for states to establish processes which meet Federal minimum standards that are specifically tailored for the state's residents and providers and facilities in the state. Allowing a state to establish a process that meets or exceeds the Federal minimum standards is also consistent with other provisions of the No Surprises Act such as allowing the application of a state law to determine the total amount payable to out-of-network providers and facilities.

1.8. Uncertainty

It is unclear what percentage of participants, beneficiaries, and enrollees experience surprise billing. The frequency of surprise billing may differ among small and large health issuers.

Furthermore, among individuals who experience surprise billing, the percentage of claims that would be resolved by the Federal IDR process is unclear. It is possible that some claims would be resolved through early settlement before they proceed to the Federal IDR process. It is also possible that some claims would be determined to be ineligible for the Federal IDR process. While there is some data from New York regarding these questions, it is uncertain whether other states' trends will be similar to New York's or whether New York's experience can be extrapolated to other states.

Additionally, these interim final rules permit multiple qualified IDR items and services to be batched in a single payment determination to encourage efficiency. In order for qualified IDR items or services to be batched, they must involve the same service code or comparable code under different procedural systems. Batching by service code will allow parties to group together qualified IDR items and services that are medically similar, promoting efficiency by allowing the certified IDR entity to consider similar qualified IDR items and services, and more efficiently focus on where the value of the qualified IDR items or services is consistently materially different from the QPA. Additionally, the Departments require batching to be done by provider or group of providers, the same facility, or the same provider of air ambulance services sharing the same NPI or TIN. By allowing groupings of providers with the same TIN, this will allow group practices to batch together qualified IDR items or services. Due to the uncertainty surrounding how often and how many payment determinations will consider batched items and services, the Departments acknowledge the high degree of uncertainty around the estimates of how many disputes will result in the Federal IDR process each year.

Additionally, it is unclear how these interim final rules will alter the experiences of everyone involved in the health care system, beyond the individuals and entities that are involved in the Federal IDR process. For example, research finds that New York's Out-of-Network law [228] reduced surprise billing by 34 percent and lowered in-network emergency physician payments by 9 percent via shifting the billing costs to emergency department physicians who bill on an out-of-network basis.[229] Research also finds that New York's Out-of-Network law increased the incentive for physicians providing emergency services to participate in health plan networks.[230]

It is unclear to what degree providers and facilities may adjust their pricing for items and services in order to pay for the anticipated costs of providing a good faith estimate. It also is unclear if providers and facilities will provide higher estimates than the amounts they intend to charge in order to avoid the patient-provider dispute resolution process, and what impact this practice might have on an individual's decision to seek necessary care. For example, some providers and facilities may overestimate the costs for items or services, up-code to a more expensive service, or add additional unnecessary services, which could circumvent the intended consumer protections. These actions could impact whether some patients defer or delay needed care on the basis of perceived costs or have a pathway to dispute bills through the patient-provider dispute resolution process.

Among uninsured (or self-pay) individuals who receive billed charges that are substantially in excess of the expected charges in the good faith estimate, it is unclear to what extent such bills will be resolved using the patient-provider dispute resolution process, or to what extent such bills will be resolved in other ways such as a settlement where the provider or facility would offer a lower bill, discount, or an offer of financial assistance.≤

Last, the Departments are uncertain whether the policies adopted in these interim final rules could ultimately lead to inflation of health care costs or could result in a reduction in uninsured (or self-pay) individuals' access to needed care. One study, which examined the arbitration decisions in New Jersey, where billed charges or usual and customary rates are taken into consideration in the IDR process, found that the median payments awarded were 5.7 times higher than the median in-network rates for the same services. The study concluded that basing arbitration decisions on provider-billed charges would likely increase health care costs.[231] In New York State, state guidance directs arbiters to consider the 80th percentile of billed charges and the New York Department of Financial Services has found that arbitration decisions resulted in, on average, charges 8 percent higher than the

[228] NY Fin Serv L § 605 (2014).

[229] Cooper, Z. et al., Surprise! Out-Of-Network Billing for Emergency Care in the United States, NBER Working Paper 23623, 2017, available at *https://www.nber.org/papers/w23623.*

[230] New York State Department of Financial Services. ''New York's Surprise Out-Of-Network Protection Law Report on the Independent Dispute Resolution Process.'' (September 2019). *https://www.pacep.net/assets/documents/NYReportontheIDRProcess.pdf.*

[231] Chartock, B.L., Adler, L., Ly, B., Duffy, E., & Trish, E. (2021). Arbitration over Out-Of-Network Medical Bills: Evidence from New Jersey Payment Disputes: Study Examines Arbitration Decisions to Resolve Payment Disputes Between Issuers and Out-Of-Network Providers in New Jersey. 40 *Health Affairs* 1, 130–137. *https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2020.00217.*

eightieth percentile of billed charges.[232] By considering the offer closest to the QPA and prohibiting certified IDR entities from considering billed charges, these interim final rules will likely limit potential inflationary effects even if arbitration leads to payment determinations that are above the amounts plans and issuers typically pay to in-network providers.[233] Thus, these interim final rules may constrain inflationary effects, but the degree to which they may do so is uncertain.

1.9. Conclusion and Summary of Economic Impacts

The Departments are of the view that these interim final rules will help ensure that consumers are protected from unexpected out-of-network medical costs by creating a process for plans, issuers, FEHB carriers and nonparticipating providers, facilities, and providers of air ambulance services to resolve disputes regarding out-of-network rates. These interim final rules provide a market-based approach that will allow these entities to agree upon reasonable payment rates.

The Departments expect a significant reduction in the incidence of surprise billing, potentially resulting in significant savings for consumers. There may be a potential transfer from providers, facilities, and providers of air ambulance services to the participant, beneficiary, or enrollee if the out-of-network rate collected is lower than what would have been collected had the provider or facility balance billed the participant, beneficiary, or enrollee. Overall, these interim final rules provide a mechanism to effectively resolve disputes between plans, issuers, and FEHB carriers and providers and facilities, while protecting patients.

HHS is of the view that the provisions in these interim final rules will protect uninsured (or self-pay) individuals from surprise medical costs by allowing them to obtain a good faith estimate of expected charges from providers and facilities prior to receiving scheduled items and services and upon request. With this information, uninsured (or self-pay) individuals may be more likely to consider and compare costs across providers or facilities prior to or upon scheduling an item or service to help inform decisions regarding costs for an item or service. These benefits, however, are predicated on the good faith estimate being a reasonably predictive and accurate document that can be understood by patients and their representatives. Additionally, these interim final rules protect these uninsured (or self-pay) individuals by allowing an uninsured (or self-pay) individual to seek a determination through the patient-provider dispute resolution process if actual billed charges for items or services from a provider or facility are substantially in excess of the expected charges listed in the good faith estimate. Moreover, HHS is of the view that uninsured (or self-pay consumers) will also benefit from being able to take advantage of the patient-provider dispute resolution process as an intermediary step in resolving outstanding medical bills, which will delay providers sending these outstanding bills to collection agencies.

The patient-provider dispute resolution process further protects uninsured (or self-pay) individuals as the process may result in lower payments if an SDR entity determines that information submitted by a provider or facility does not provide credible information that the billed charge for an item or service reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, in which case the SDR entity must determine as the payment amount the expected charge for the item or service (or in the case of a new item or service, $0) to be paid by the uninsured (or self-pay) individual to the provider or facility.

The Departments estimate that these interim final rules will impose incremental costs of approximately $760.95 million in the first year and $440.67 million in subsequent years. Over 10 years, the associated costs will be approximately $3.62 billion with an annualized cost of $517.12 million, using a 7 percent discount rate.[234]

C. Paperwork Reduction Act

Contemporaneously with the publication of these interim final rules, the Departments are each submitting a request for a new ICR containing the information collection requirements for the Federal IDR process, and the patient-provider dispute resolution process for HHS, created by the No Surprises Act be processed as an Emergency Clearance Request in accordance with section 5 CFR 1320.13 of the Paperwork Reduction Act, Emergency Processing. 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. To obtain a copy of the ICR go to *https://www.RegInfo.gov.*

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 of the ICRs for 180 days, the maximum allowed for an ICR approved using an emergency 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 and OPM will open a 60-day and 30-day comment period for each ICR.

The Departments are particularly interested in comments that:

- Evaluate whether the collection of information is necessary for the functions of the Departments, including whether the information will have practical utility;
- Evaluate the accuracy of the Departments' estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology (for example permitting electronically delivered responses).

[232] Adler, Loren. ''Experience with New York's Arbitration Process for Surprise Out-of-Network Bills.'' U.S.C.-Brookings Schaeffer on Health Policy. (October 2019). *https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2019/10/24/experience-with-new-yorks-arbitration-process-for-surprise-out-of-network-bills/.*

[233] Fielder, Matthew, Loren Adler, and Benedic Ippolito. ''Recommendations for Implementing the No Surprises Act.'' U.S.C.-Brookings Schaeffer on Health Policy. (March 2021). *https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2021/03/16/recommendations-for-implementing-the-no-surprises-act/.*

[234] The costs would be $4.19 billion over 10-year period with an annualized cost of $491.44 million, applying a 3 percent discount rate.

Comments on these topics may also be submitted to the Departments during the open comment period for these interim final rules. See the **ADDRESSES** section in this rule on where to send comments.

1. Labor Cost Estimates

1. Labor Cost Estimates

TABLE 4—WAGE ESTIMATES

Occupation title	Occupational code	Hourly total compensation ($/hour)	Overhead cost ($/hour)	Total hourly labor costs ($/hour)
Secretaries and Administrative Assistants, Except Legal, Medical, and Executive	43–6014	$28.96	$26.27	$55.23
Lawyer	23–1011	105.28	35.68	140.96
Computer Programmers	15–1251	67.62	46.15	113.77
Medical Secretaries and Administrative Assistants	43–6013	27.94	18.13	46.07
Human Resources Specialists	13–1071	49.09	42.74	91.83
Business Operations Specialist	13–1198	59.60	41.72	101.32
General and Operations Manager	11–1021	88.25	34.30	122.55
Compensation and Benefits Manager	11–3111	96.97	24.81	121.78
Computer and Information Systems Managers	11–3021	113.52	53.38	166.90
Medical and Health Services Manager	11–9110	83.39	21.62	105.01
Physician (all other)	29–1228	154.74	14.66	169.40
All occupations	00–0000	39.40	24.92	64.32

Group health plans, health insurance issuers, and FEHB carries are responsible for ensuring compliance with these interim final rules. Accordingly, in the following ICR sections, the Departments refer to costs on plans, issuers, and FEHB carriers. However, it is expected that most self-insured group health plans will work with a TPA to meet the requirements of these interim 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.

2. ICRs Regarding IDR Process for Nonparticipating Providers or Nonparticipating Emergency Facilities (26 CFR 54.9816–8T, 29 CFR 2590.716–8, and 45 CFR 149.510)

As discussed in the Regulatory Impact Analysis, 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.[235] 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 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. As shown in Table 5, for all 23,111 payment determinations 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.[236] 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. The Departments assume that 5 percent of these notices would be mailed and will incur a printing cost of $0.05 per page and $0.55 for postage. Thus, the mailing cost is estimated to be $693.[237]

TABLE 5—ANNUAL BURDEN AND COSTS TO PREPARE AND SEND THE NOTICE OF OPEN NEGOTIATION PROCESS FOR NONPARTICIPATING PROVIDERS OR NONPARTICIPATING EMERGENCY FACILITIES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing costs	Total estimated cost
23,111	51,999	$5,172,803	$693	$5,173,496

[235] This is calculated 17,333/(1 − 0.25) = 23,111.

[236] The burden is estimated as follows: 23,111 claims × 2 hours + 23,111 claims × 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 × 2 hours × $105.01 + 23,111 claims × 0.5 hour × $55.23 = $5,172,803. Labor rates are EBSA estimates.

[237] This is calculated 23,111 × 0.05 × ($0.05 + $0.55) = $693.

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. As shown in Table 6, 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.[238] 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 these notices 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 $520.[239]

TABLE 6—ANNUAL BURDEN AND COST TO PREPARE AND SEND THE NOTICE OF IDR INITIATION FOR NONPARTICIPATING PROVIDERS OR NONPARTICIPATING EMERGENCY FACILITIES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing and printing costs	Total estimated cost
17,333	38,999	$3,879,602	$520	$3,880,122

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 request comment on this assumption. 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. As shown in Table 7, for the 173 payment determinations resolved in this manner, the annual burden would be 130 hours, with an associated equivalent cost of $11,472.[240]

TABLE 7—ANNUAL BURDEN AND COST TO PREPARE AND SEND THE NOTICE OF AGREEMENT ON AN OUT-OF-NETWORK RATE STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing and printing costs	Total estimated cost
173	130	$11,472	$0	$11,472

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. The Departments request comments on this assumption. 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. As shown in Table 8, 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.[241] 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 $390.[242]

[238] The burden is estimated as follows: 17,333 claims × 2 hours + 17,333 claims × 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 × 0.25 hours × $105.01 + 17,333 claims × 2 hours × $55.23 = $3,879,602. Labor rates are EBSA estimates.

[239] This is calculated 17,333 × 0.05 × ($0.05 + $0.55) = $520.

[240] The burden is estimated as follows: 17,300 claims × 1 percent × 0.5 hours + 17,300 claims × 1 percent × 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 × 1 percent × 0.5 hours × $105.01 + 17,300 claims × 1 percent × 0.25 hours × $55.23 = $11,472. Labor rates are EBSA estimates.

[241] The burden is estimated as follows: (13,000 claims × 75 percent × 1 hour) + (13,000 claims × 75 percent × 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 × 75 percent × 0.25 hours × $105.01) +13,000 claims × 75 percent × 1 hours × $55.23) = $1,544,628. Labor rates are EBSA estimates.

[242] This is calculated 13,000 × 0.05 × ($0.05 + $0.55) = $390.

TABLE 8—ANNUAL BURDEN AND COST TO SELECT A CERTIFIED IDR ENTITY AND NOTIFY THE DEPARTMENTS OF SELECTION FOR NONPARTICIPATING PROVIDERS OR NONPARTICIPATING EMERGENCY FACILITIES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing and printing costs	Total estimated cost
13,000	16,250	$1,544,628	$390	$1,545,018

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 for a payment amount for the qualified IDR item or service furnished by such provider or facility though 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. As shown in Table 9, 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.[243] 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 $1,040.[244]

TABLE 9—ANNUAL BURDEN AND COST TO PREPARE AND SUBMIT OFFER FOR NONPARTICIPATING PROVIDERS OR NONPARTICIPATING EMERGENCY FACILITIES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing and printing costs	Total estimated cost
17,333	103,998	$10,057,993	$1,040	$10,059,033

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.[245] 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.[246]

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. The Departments assume it will take 30 minutes for a clerical worker to establish the records for each IDR payment determinations. The burden for each certified IDR entity would be 30 minutes, with an equivalent cost of approximately $28. As shown in Table 10, for the maintenance and recordkeeping of 17,333 claims, the annual burden would be 8,667 hours, with an annual

[243] The burden is estimated as follows: (17,333 claims × 2.5 hours + 17,333 claims × 0.5 hours) + (17,333 claims × 2.5 hours + 17,333 claims × 0.5 hours) = 103,998 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 claims × 2.5 hours × $105.01 + 17,333 claims × 0.5 hours × $55.23) + (17,333 claims × 2.5 hours × $105.01 + 17,333 claims × 0.5 hours × $55.23) = $10,057,993. Labor rates are EBSA estimates.

[244] This is calculated (17,333 × 0.05 × ($0.05 + $0.55) + (17,333 × 0.05 × ($0.05 + $0.55) = $1,040.

[245] IDR Payment Determination Notification (ERISA 716(c)(5)(A)).

[246] 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.

equivalent cost burden estimate of $0.5 million.[247]

TABLE 10—ANNUAL BURDEN AND COST FOR THE CERTIFIED IDR ENTITY TO MAINTAIN RECORDS FOR NONPARTICIPATING PROVIDERS OR NONPARTICIPATING EMERGENCY FACILITIES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
17,333	0	$0	$478,651	$478,651

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. As shown in Tables 11 through 13, HHS, DOL, the Department of the Treasury, and OPM share jurisdiction, HHS will account for 45 percent of the burden, or approximately, 95,119 hours at an equivalent cost of $9,299,924 and a cost burden of $216,582. DOL and the Department of the Treasury will each account for 25 percent of the burden, or approximately 52,844 hours at an equivalent cost of $5,166,624 and a cost burden of $120,324. OPM will account for 5 percent of the burden or approximately 10,569 hours at an equivalent cost of $1,033,325 and a cost burden of $24,065.

TABLE 11—HHS SUMMARY ANNUAL COST AND BURDEN OF IDR PROCESS FOR NONPARTICIPATING PROVIDERS OR NONPARTICIPATING EMERGENCY FACILITIES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing and printing cost	Other costs	Total estimated cost
49,477	95,119	$9,299,924	$1,189	$215,393	$9,516,506

TABLE 12—DOL AND DEPARTMENT OF THE TREASURY'S SUMMARY ANNUAL COST AND BURDEN OF IDR PROCESS FOR NONPARTICIPATING PROVIDERS OR NONPARTICIPATING EMERGENCY FACILITIES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing and printing cost	Other costs	Total estimated cost
27,487	52,844	$5,166,624	$661	$119,663	$5,286,948

TABLE 13—OPM'S SUMMARY ANNUAL COST AND BURDEN OF IDR PROCESS FOR NONPARTICIPATING PROVIDERS OR NONPARTICIPATING EMERGENCY FACILITIES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing and printing cost	Other costs	Total estimated cost
5,497	10,569	$1,033,325	$132	$23,933	$1,057,390

3. ICRs Regarding Federal IDR Process for Air Ambulance (26 CFR 54.9817–2T, 29 CFR 2590.717–2, and 45 CFR 149.520)

According to the March 2019 Health Insurance Coverage Bulletin, in 2018, 213.2 million individuals had private health insurance.[248] In 2017, HCCI estimated that, on average, there were 33.3 air ambulance uses per 100,000 people,[249] and the GAO estimated that approximately 69 percent of air transports resulted in an out-of-network bill.[250] 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.

Accordingly, the government estimates there will be 4,899 air

[247] The burden is estimated as follows: (17,333 claims × 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 × 30 minutes × $55.23) = $478,651. Labor rates are EBSA estimates.

[248] 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.*

[249] 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.*

[250] 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.*

ambulance service claims submitted to the Federal IDR process each year.[251]

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.[252] The Departments estimate that it will take an average of 2 hours for a medical and health services manager to write each notice of open negotiation 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. As shown in Table 14, 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.[253] 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 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 $196.[254]

TABLE 14—ANNUAL BURDEN AND COSTS TO PREPARE AND SEND THE NOTICE OF OPEN NEGOTIATION PERIOD FOR PROVIDERS OF AIR AMBULANCE SERVICES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing and printing cost	Total estimated cost
6,532	14,696	$1,461,951	$196	$1,462,147

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. As shown in Table 15, 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.[255] The initiating party may furnish the Notice of IDR Initiation to the other party electronically if the initiating party has a good faith belief that the electronic method is readily accessible by the other party and the notice is provided in paper form free of charge upon request. The Departments assume that 5 percent of 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.[256]

TABLE 15—ANNUAL BURDEN AND COST TO PREPARE AND SEND THE NOTICE OF IDR INITIATION FOR PROVIDERS OF AIR AMBULANCE SERVICES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing and printing cost	Total estimated cost
4,899	11,022	$1,096,463	$147	$1,096,610

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 request comment on this assumption. 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

[251] 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 × 0.000333 × 0.69 × 0.1= 4,899).

[252] This is calculated as 4,899/(1 − 0.25) = 6,532.

[253] The burden is estimated as follows: 6,532 claims × 2 hours + 6,532 claims × 0.25 hours = 14,696 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 claims × 0.25 hours × $105.01 + 6,532 claims × 2 hours × $55.23 = $1,461,951. Labor rates are EBSA estimates.

[254] This is calculated 6,532 × 0.05 × ($0.05 + $0.55) = $196.

[255] The burden is estimated as follows: 4,899 claims × 2 hours + 4,899 claims × 0.25 hours = 11,022 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 claims × 0.25 hours × $105.01 + 4,899 claims × 2 hours × $55.23 = $1,096,463. Labor rates are EBSA estimates.

[256] This is calculated 4,899 × 0.05 × ($0.05 + $0.55) = $147.

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. As shown in Table 16, for the 49 payment determinations resolved in this manner, the annual burden would be 37 hours, with an associated equivalent cost of $3,249.[257]

TABLE 16—ANNUAL BURDEN AND COST TO PREPARE AND SEND THE NOTICE OF AGREEMENT ON AN OUT-OF-NETWORK RATE STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing and printing cost	Total estimated cost
49	37	$3,249	$0	$3,249

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. The Departments request comment on this assumption. 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. As shown in Table 17, 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.[258] 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 $110.[259]

TABLE 17—ANNUAL BURDEN AND COST TO SELECT CERTIFIED IDR ENTITY AND NOTIFY THE DEPARTMENTS OF SELECTION FOR PROVIDERS OF AIR AMBULANCE SERVICES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing and printing cost	Total estimated cost
3,674	4,593	$436,535	$110	$436,646

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 if there are an insufficient number of certified IDR entities) 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 or fully or partially self-insured), 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. As shown in Table 18, 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.[260] The Departments assume

[257] The burden is estimated as follows: 4,899 claims × 1 percent × 0.5 hours + 4,899 claims × 1 percent × 0.25 hours = 37 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 claims × 1 percent × 0.5 hours × $105.01 + 4,899 claims × 1 percent × 0.25 hours × $55.23 = $3,249. Labor rates are EBSA estimates.

[258] The burden is estimated as follows: (4,899 claims × 75 percent × 1 hour) + (4,899 claims × 75 percent × 0.25 hours) = 4,593 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 claims × 75 percent × 0.25 hours × $105.01) + (4,899 claims × 75 percent × 1 hours × $55.23) = $436,535. Labor rates are EBSA estimates.

[259] This is calculated 3,674 × 0.05 × ($0.05 + $0.55) = $110.

[260] The burden is estimated as follows: (4,899 claims × 2 hours + 4,899 claims × 0.25 hours) + (4,899 claims × 2 hours + 4,899 claims × 0.25 hours) = 22,044 hours for providers and issuers. A labor rate of $105.01 is used for a medical and health

Continued

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 $294.[261]

TABLE 18—ANNUAL BURDEN AND COST TO PREPARE AND SUBMIT OFFER FOR PROVIDERS OF AIR AMBULANCE SERVICES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing and printing cost	Total estimated cost
4,899	22,044	$2,192,926	$294	$2,193,220

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.[262] 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. As shown in Table 19, for the maintenance and recordkeeping of 4,899 claims, the annual burden would be 2,449 hours, with an estimated annual equivalent cost burden of $0.1 million.[263]

TABLE 19—ANNUAL BURDEN AND COST FOR THE CERTIFIED IDR ENTITY TO MAINTAIN RECORDS FOR PROVIDERS OF AIR AMBULANCE SERVICES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
4,899	2,499	$0	$135,278	$135,278

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. 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 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. As shown in Table 20, the hour burden associated with HHS requirements is estimated to be approximately 23,576 hours at an equivalent cost of $2,336,006. The total cost burden associated with HHS requirement is estimated to be $61,211. As shown in Table 21, the hour burden associated with DOL and the Department of the Treasury requirements is estimated to be approximately 13,089 hours at an equivalent cost of $1,297,781 each. The total cost burden associated with DOL and the Department of the Treasury requirement is estimated to be $34,006. As shown in Table 22, the hour burden associated with OPM requirements is estimated to be approximately 2,620 hours at an equivalent cost of $259,556 each. The total cost burden associated with OPM requirement is estimated to be $6,801.

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 × 2 hours × $105.01 + 4,899 claims × 0.25 hours × $55.23) + (4,899 claims × 2 hours × $105.01 + 4,899 claims × 0.25 hours × $105.01) = $2,192,926. Labor rates are EBSA estimates.

[261] This is calculated (4,899 × 0.05 × ($0.05 + $0.55)) + (4,899 × 0.05 × ($0.05 + $0.55)) = $294.

[262] IDR Payment Determination Notification (ERISA 716(c)(5)(A)).

[263] The burden is estimated as follows: (4,899 claims × 30 minutes) = 2,449 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 claims × 30 minutes × $55.23) = $135,278. Labor rates are EBSA estimates.

TABLE 20—HHS SUMMARY COST AND BURDEN OF FEDERAL IDR PROCESS FOR PROVIDERS OF AIR AMBULANCE SERVICES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing and printing cost	Other costs	Total estimated cost
16,188	23,576	$2,336,006	$336	$60,875	$2,397,217

TABLE 21—DOL AND DEPARTMENT OF THE TREASURY'S SUMMARY COST AND BURDEN OF FEDERAL IDR PROCESS FOR PROVIDERS OF AIR AMBULANCE SERVICES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing and printing cost	Other costs	Total estimated cost
8,993	13,098	$1,297,781	$187	$33,819	$1,331,787

TABLE 22—OPM'S SUMMARY COST AND BURDEN OF FEDERAL IDR PROCESS FOR PROVIDERS OF AIR AMBULANCE SERVICES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing and printing cost	Other costs	Total estimated cost
450	2,620	$259,556	$37	$6,734	$266,357

3. ICRs Regarding the Request of Extension of Time Periods for Extenuating Circumstances (26 CFR 54.9816–8T, 29 CFR 2590.716–8, and 45 CFR 149.510)

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 and 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 request comment on how many entities are likely to make such a request. The Departments estimate that it will take a clerical worker 15 minutes to prepare and send the notice. As shown in Table 23, the annual burden would be 25 hours, with an associated equivalent cost of $1,381.[264] The Departments expect these requests to be submitted through the Federal IDR portal, and therefore have not estimated an associated mailing cost.

TABLE 23—ANNUAL BURDEN AND COSTS TO REQUEST AN EXTENSION OF TIMES PERIODS FOR EXTENUATING CIRCUMSTANCES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing cost	Total estimated cost
100	25	$1,381	$0	$1,381

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 be allocated to health care providers. 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. As shown in Table 24, the hour burden associated with HHS requirements is estimated to be approximately 11 hours at an equivalent cost of $621. As shown in Table 25, the hour burden associated with DOL and the Department of the Treasury requirements is estimated to be approximately 6 hours at an equivalent cost of $345 each. As shown in Table 26, the hour burden associated with OPM requirements is estimated to be approximately 1 hour at an equivalent cost of $69.

[264] The burden is estimated as follows: 100 requests × 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 × 0.25 hours × $55.23 = $1,381. Labor rates are EBSA estimates.

TABLE 24—HHS'S ANNUAL BURDEN AND COSTS REQUEST AN EXTENSION OF TIMES PERIODS FOR EXTENUATING CIRCUMSTANCES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing cost	Total estimated cost
45	11	$621	$0	$621

TABLE 25—DOL AND DEPARTMENT OF THE TREASURY'S ANNUAL BURDEN AND COSTS TO REQUEST AN EXTENSION OF TIMES PERIODS FOR EXTENUATING CIRCUMSTANCES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing cost	Total estimated cost
25	6	$345	$0	$345

TABLE 26—OPM'S ANNUAL BURDEN AND COSTS TO REQUEST AN EXTENSION OF TIMES PERIODS FOR EXTENUATING CIRCUMSTANCES STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Mailing cost	Total estimated cost
5	1.25	$69	$0	$69

5. ICRs Regarding IDR Entity Certification and IDR Entity Monthly Reporting (26 CFR 54.9816–8T, 29 CFR 2590.716–8, and 45 CFR 149.510)

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 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 specified provisions encompassed by these interim final rules, including, but not limited to, the requirements applicable to certified IDR entities when making payment determinations as well as the requirements for certification and revocation (such as specifications for wind down activities and reallocation of certified IDR entity fees, where warranted).

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. As shown in Table 27, for the 50 IDR entities that will go through certification, this results in a cost burden of $27,468 in the first year.[265]

TABLE 27—ONE TIME AND ANNUAL BURDEN AND COSTS TO CERTIFY AND RECERTIFY

Year	Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
2022	50	0	$0	$27,468	$27,468
2033	10	0	0	2,343	2,343
2024	10	0	0	2,343	2,343
3 Year Average	23.33	0	0	10,718	10,718

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,

[265] The burden is estimated as follows: (50 IDR entities × 5.10 hours) + (50 IDR entities × 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 × 5.10 hours × $105.01) + (50 IDR entities × 0.25 hours × $55.23) = $27,468.

including the time to review instructions, search existing data resources, gather required data, and complete and review information collection. As shown in Table 28, this results in a cost burden of $49,707.[266]

TABLE 28—ANNUAL BURDEN AND COSTS TO SUBMIT ADMINISTRATIVE FEE STARTING IN 2022

Estimated number of IDR entities participating	Total annual burden (hours)	Total estimated labor cost	Other cost	Total estimated cost
50	0	$0	$49,707	$49,707

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. As shown in Table 30, for the 10 certified IDR entities that will go through recertification, this results in a cost burden of $2,238 in subsequent years.[267] Table 29 summarizes these costs over time.

TABLE 29—ONE TIME AND ANNUAL BURDEN AND COSTS TO CERTIFY AND RECERTIFY

Year	Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
2022	50	0	$0	$27,468	$27,468
2023	10	0	0	3,343	2,343
2024	10	0	0	2,343	2,343
3 Year Average	23.33	0	0	10,718	10,718

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. As shown in Table 30, for the three petitions, this results in a cost burden of $560.[268]

TABLE 30—ANNUAL BURDEN AND COSTS ASSOCIATED WITH THE PETITION FOR DENIAL OR WITHDRAWAL OF IDR ENTITY CERTIFICATION STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
3	0	$0	$560	$560

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

[266] The burden is estimated as follows: (18 hours × $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 × 18 hours × $55.23) = $49,707. Labor rates are EBSA estimates.

[267] The burden is estimated as follows: (50 IDR entities × ⅕ × 2.1 hours) + (50 IDR entities × ⅕ × 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 × ⅕ × 2.1 hours × $105.01) + (50 IDR entities × ⅕ × 0.25 hours × $55.23) = $2,343.

[268] The burden is estimated as follows: (3 IDR entities × 2 hours) + (3 IDR entities × 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 × 2 hours × $105.01) + (3 IDR entities × 0.25 hours × $55.23) = $560.

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.

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.[269]

TABLE 31—ANNUAL BURDEN AND COST FOR THE IDR MONTHLY REPORT STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
600	0	0	$71,291	$71,291

The certified IDR entities are required, following the discovery of a breach of unsecured IIHI, to notify of the breach the provider, facility, or provider of air ambulance services; the plan or issuer; the Departments; and each individual whose unsecured IIHI has been, or is reasonably believed to have been, subject to the breach, to the extent possible. The Departments estimate that three certified IDR entities will have a breach each year. In addition, the Departments estimate that it will take a medical and health services manager 1 hour, on average, to handle the initial breach and follow the required protocols, and that it will take a general and operations manager 45 minutes, on average, to ensure the protocol is executed and adapt policies accordingly. 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.[270] 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.[271] The Departments seek comment addressing the costs that will be associated with these interim final rules.

TABLE 32—ANNUAL BURDEN AND COST FOR BREACH NOTIFICATION STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
3	0	$0.09	$591	$591.09

[269] The burden is estimated as follows: (50 IDR entities × 1 hour × 12 reports annually) + (50 IDR entities × 0.25 hours × 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 × 1 hour × 12 reports × $105.01) + (200 IDR entities × 0.25 hours × 12 reports × $55.23) = $71,291.

[270] The burden is estimated as follows: (3 certified IDR entities × 1 hour) + (3 certified IDR entities × 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 × 1 hour × $105.01) + (3 certified IDR entities × 0.75 hour × $122.55) = $591.

[271] This is calculated 3 × 0.05 × ($0.05 + $0.55) = $0.09.

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. As shown in Tables 33 through 35, 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. Therefore, the cost burden associated with HHS requirements is $67,327 in the first year and $56,021 in subsequent years. The three-year average cost burden associated with HHS requirements is $59,790. The cost burden associated with each of the DOL and the Department of the Treasury requirements is $37,404 in the first year and $31,123 in subsequent years. The three-year average cost burden associated with DOL and the Department of the Treasury is $33,217 each. The cost burden associated with OPM requirements is $7,481 in the first year and $6,225 in subsequent years. The three-year average cost burden associated with OPM requirements is $6,643. The Departments seek comment on the assumptions and calculations made in this ICR.

TABLE 33—HHS SUMMARY COST AND BURDEN OF IDR ENTITY CERTIFICATION STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
305	$0	$0	$59,790	$59,790

TABLE 34—DOL AND THE DEPARTMENT OF THE TREASURY'S SUMMARY COST AND BURDEN OF IDR ENTITY CERTIFICATION STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
170	0	$0	$33,217	$33,217

TABLE 35—OPM'S SUMMARY COST AND BURDEN OF IDR ENTITY CERTIFICATION STARTING IN 2022

Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
34	0	$0	$6,643	$6,643

ICRs Regarding Notice of the Right to Good Faith Estimates for Uninsured (or Self-Pay) Individuals (45 CFR 149.610)

Convening providers and facilities are required under 45 CFR 149.610(b) to inform uninsured (or self-pay) individuals of the availability of good faith estimates of expected charges. The notice regarding the availability of good faith estimates for uninsured (or self-pay) individuals must be written in a clear and understandable manner and made available in accessible formats and in the language(s) spoken by individual(s) seeking items and services with such convening provider or convening facility. Additionally, the notice must be prominently displayed (and easily searchable from a public search engine), on the convening provider's or convening facility's website, in the convening provider's or convening facility's office, and on-site where scheduling or questions about the cost of items and services occur. These ICRs estimate the information collection burdens for three groups of provider types: (1) Providers associated with health care facilities, (2) individual physician practitioners, and (3) wholly physician-owned private practices. For all three groups of providers, the ICRs apply the same methodology to estimate the burden, consisting of the following steps:

- Drafting notices informing uninsured (or self-pay) individuals of their right to receive a good faith estimate of expected charges.
- Displaying the notices on the provider's website, in the provider's office, and on-site where scheduling or questions about the cost of items or services occur.
- Posting a single page notice in at least two prominent locations.
- Printing and materials costs for posting notices.

Details about the requirements of the steps that apply to all 3 provider groups are described once for providers associated with health care facilities and apply equally to the other two provider groups. Any specific differences in estimating the burden to comply with these requirements are detailed for the specific provider group below. HHS invites comment on the assumptions and calculations made in these ICRs.

Providers Associated With Health Care Facilities

Unique to providers associated with health care facilities, HHS assumes that such providers will enter into agreements with their associated health care facility to provide notice of the availability of good faith estimates of expected charges to uninsured (or self-pay) individuals on their behalf. HHS estimates that for each health care facility it will take an average of 2 hours for a lawyer to draft an agreement and a medical secretary and administrative assistant 2 hours to provide electronic copies to all associated convening providers to sign. As shown in Table 36, this results in an equivalent cost estimate of approximately $91,770,384 to be incurred as one-time cost in 2021.[272] HHS cannot estimate how

[272] The burden is estimated as follows: 245,336 health care facilities × 2 hours = 490,672 hours. A

Continued

many providers will incur burden to sign the agreement, but assumes the burden to providers will be minimal; the use of electronic signature portals may reduce the burden to the convening provider. In future years, this agreement can be included in the contract between the facilities and providers at no additional cost.

TABLE 36—ESTIMATED ONE-TIME AND HOUR BURDEN FOR PROVIDERS ASSOCIATED WITH FACILITIES TO ENTER INTO AGREEMENTS TO PROVIDE NOTICE OF RIGHT TO A GOOD FAITH ESTIMATE

Year	Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Total burden (hours)	Total estimated cost
2021	245,336	245,336	4	981,344	$91,770,384

HHS assumes that the associated facility will draft the notices informing uninsured (or self-pay) individuals of their right to receive a good faith estimate of expected charges. Information regarding the availability of good faith estimates for uninsured (or self-pay) individuals must be written in a clear and understandable manner and made available in accessible formats and in the language(s) spoken by individual(s) seeking items and services with such convening provider. Additionally, the notices must be prominently displayed on the convening provider's website, and in the convening provider's office, and on-site where scheduling or questions about the cost of items or services occur. Providers may satisfy this requirement by utilizing the language in the standard notice anticipated to be issued by HHS. HHS estimates that for each health care facility, it will take an average of two hours for a lawyer to read and understand the anticipated notice and draft any additions in clear and understandable language, a medical secretary and administrative assistant 30 minutes to prepare the document for posting within the facility, and a computer programmer 1 hour to post the information on each providers' website on behalf of the facility. As shown in Table 37, this results in an equivalent cost of approximately $102,754,069 to be incurred as a one-time cost in 2021.[273]

TABLE 37—ESTIMATED ONE-TIME COST AND HOUR BURDEN FOR HEALTH CARE FACILITIES (INCLUDING ON BEHALF OF HEALTH CARE PROVIDERS ASSOCIATED WITH HEALTH CARE FACILITIES) TO DRAFT AND POST NOTICE OF GOOD FAITH ESTIMATE

Year	Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Total burden (hours)	Printing and materials costs	Total estimated cost
2021	245,336	245,336	2.5	858,676	$25,752	$102,754,069

HHS assumes that each health care facility will post a single page document in at least 2 prominent locations so uninsured (or self-pay) individuals are provided reasonable notice of their right to a good faith estimate of expected charges. A prominent location in the health care facility may include patient appointment check-in kiosks, reception front-desks, patient appointment scheduling locations, and where patients pay bills. The notices should be drafted in clear and understandable language, shorter in length, and printed in legible font size. HHS assumes that each facility will incur a printing cost of $0.05 per page and materials for a total equivalent cost of $0.10. Hospitals may have a greater number of posting locations because of building size, therefore, HHS anticipates that hospitals will post four additional notices on average and incur an additional cost of $0.20 each. This results in a one-time equivalent cost of approximately $24,534 to all non-hospital health care facilities and an overall one-time cost of approximately $25,752 when including hospitals.

HHS estimates that the one-time burden for providers and facilities to enter into agreements and for facilities to develop, prepare, print, and post the notices and update their respective websites will be approximately 1,840,020 total burden hours with an associated equivalent cost of approximately $194,524,453, as shown in Table 38.

labor rate of $140.96 is used for a lawyer. The labor rate is applied in the following calculation: 245,336 health care facilities × 2 hours × $140.96 = $69,165,125. 245,336 health care facilities × 2 hours = 490,672 hours. A labor rate of $46.07 is used for a medical secretary and administrative assistant. The labor rate is applied in the following calculation: 245,336 health care facilities × 2 hours × $46.07 = $22,605,259. Therefore, 490,672 hours + 490,672 hours = 981,344 total burden hours and $69,165,125 + $22,605,259 = $91,770,381 total annual respondent time cost.

[273] The burden is estimated as follows: 245,336 health care facilities × 2 hours = 490,672 hours. A labor rate of $140.96 is used for a lawyer. The labor rate is applied in the following calculation: 245,336 health care facilities × 2 hours × $140.96 = $69,165,125. 245,336 health care facilities × 0.5 hours = 122,668 hours. A labor rate of $46.07 is used for a medical secretary and administrative assistant. The labor rate is applied in the following calculation: 245,336 health care facilities × 0.5 hours × $46.07 = $5,651,315. 245,336 health care facilities × 1 hours = 245,336 hours. A labor rate of $113.77 is used for a computer programmer. The labor rate is applied to the following calculation: 245,336 health care facilities × 1 hour × $113.77= $27,911,877. Therefore, 490,672 hours + 122,668 hours + 245,336 hours = 858,676 total burden hours. Additionally, one-time printing and material costs are estimated using the following calculation: .05 × 2 pages × 245,336 impacted health care facilities = 25, 752 total one-time cost for printing and materials. The total respondent time costs are $69,165,125 + $5,651,315 + $27,911,877 + $25,752 = $102,754,069.

TABLE 38—TOTAL ESTIMATED ONE-TIME COST AND HOUR BURDEN FOR HEALTH CARE FACILITIES (INCLUDING ON BEHALF OF HEALTH CARE PROVIDERS ASSOCIATED WITH HEALTH CARE FACILITIES) TO PROVIDE NOTICE OF RIGHT TO A GOOD FAITH ESTIMATE [274]

Year	Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Total annual burden (hours)	Printing and materials costs	Total estimated cost
2021	245,336	245,336	7.5	1,840,020	$25,752	$194,524,453

Individual Physician Practitioners

HHS estimates that 145,887 individual physician practitioners will incur burden and cost to comply with this provision.[275] HHS estimates an average of 2 hours and 30 minutes for the individual physician practitioner to read and understand the provided notice and draft any additions in clear and understandable language and (for 80% of individual physician practitioners) a computer programmer one hour to post the information in the provider's website. HHS estimates that the one-time burden for individual physician practitioners to develop, prepare, print, post the notices, and make website updates will be approximately 481,426 total burden hours. This results in an equivalent cost of approximately $75,075,712.[276]

HHS assumes that each individual physician practitioner will incur a printing cost of $0.05 per page and materials for a total equivalent cost of $0.10. This results in an annual one-time equivalent cost of approximately $14,589 to all individual physician practitioners.

HHS estimates that the annual one-time burden for individual physician practitioners to develop, prepare, print, post the notices, and make website updates will be approximately 481,426 total burden hours with an associated equivalent cost of approximately $75,075,712, as shown in Table 39.

TABLE 39—ESTIMATED ONE-TIME COST AND HOUR BURDEN FOR INDIVIDUAL PHYSICIAN PRACTITIONERS TO DRAFT AND POST NOTICE OF GOOD FAITH ESTIMATE NOTICE [277]

Year	Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Total annual burden (hours)	Printing and material costs	Total estimated cost
2021	145,887 (All Physicians)	145,887	2.5	364,717		$61,797,674
2021	116,709* (Additional burden for Subset of Physicians with Websites).	*116,709	1	116,709		13,278,038
Total			3.5	481,426		**75,075,712

*This is calculated as the sum of $61,797,674 (cost for all individual physician practitioners to draft notice of right to GFE) + $13,278,038 (cost for computer programmers to post notice of right to GFE on 80% of practitioners' websites). Total estimated cost of $75,075,712 includes burden for all individual physician practitioners to draft the notice of right to GFE plus the additional burden for computer programmers to add the notice to the website for the subset (80 percent) of total physicians that have websites, (80 percent of 145,887 = 116,709).

Wholly-Physician-Owned Private Practices

HHS estimates that 120,525 wholly physician-owned private practices will incur burden and cost to comply with this provision.[278] For each practice, HHS estimates an average of 2 hours and 30 minutes for a general and operations manager to read and understand the provided notice and draft any additions in clear and understandable language and a computer programmer one hour to post the information in the provider's website. This results in an equivalent cost of approximately $50,650,005 to be incurred as a one-time cost in 2021.[279]

[274] Estimated cost includes the sum of Table 28 and 29. It also includes computer programming cost to update health care facility websites with uninsured (or self-pay) individuals' right to the good faith estimate. Total printing and material costs for all health care facilities of $24,534 to all non-hospital health care facilities and an overall one-time cost of approximately $25,752 for hospitals.

[275] In generating these estimates, HHS reviewed data from the American Medical Association (AMA) and Kaiser Family Foundation. See Kane C. Policy Research Perspectives Recent Changes in Physician Practice Arrangements: Private Practice Dropped to Less than 50 Percent of Physicians in 2020. Accessed July 15, 2021. *https://www.ama-assn.org/system/files/2021-05/2020-prp-physician-practice-arrangements.pdf;* Professionally Active Physicians. KFF. Published May 20, 2020. *https://www.kff.org/other/state-indicator/total-active-physicians/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22.*

[276] The burden is estimated as follows: 145,887 individual physician practitioners × 2.5 hours = 364,717 hours. A labor rate of $169.40 is used for a physician. The labor rate is applied to the following calculation: 145,887 individual physician practitioners × 2.5 hours × $169.40 = $61,783,085. HHS assumes that 80 percent of individual physician practitioners have a website resulting in 116,709 websites needed to be updated with good faith estimate notices. HHS assumes that the physician will pay a computer programmer to make the website update. The burden is estimated as follows: 116,709 websites needing updates × 1 hour = 116,709 hours. A labor rate of $113.77 is used for a computer programmer. The labor rate is applied to the following calculation: 116,709 websites needing updates × 1 hour × $113.77 = $13,278,038. Therefore, 364,717 hours + 116,709 hours = 481,426 total burden hours. The total annual respondent time cost is $61,783,085 + $13,276,038 = $75,061,124. Total printing and material costs are of $14,589. Therefore, $75,061,124 + $14,589 = $75,075,712.

[277] HHS estimates that 80 percent (116,709) of individual physician practitioners have a website. Therefore, estimated cost includes computer programming cost to update individual physician practitioners' websites with uninsured (or self-pay) individuals' right to good faith estimate. HHS assumes that each individual physician practitioner will incur a printing cost of $0.05 per page and materials for a total equivalent cost of $0.10. Total printing and material costs of $14,589 are included.

[278] In generating these estimates, HHS reviewed data from the American Medical Association (AMA) and Kaiser Family Foundation. See Kane C. Policy Research Perspectives Recent Changes in Physician Practice Arrangements: Private Practice Dropped to Less than 50 Percent of Physicians in 2020. Accessed July 15, 2021. *https://www.ama-assn.org/system/files/2021-05/2020-prp-physician-practice-arrangements.pdf;* Professionally Active Physicians. KFF. Published May 20, 2020. *https://www.kff.org/other/state-indicator/total-active-physicians/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22.*

[279] The burden is estimated as follows: 125,525 wholly physician-owned private practices × 2.5 hours = 301,312 hours. A labor rate of $122,55 is used for a general and operations manager. The labor rate is applied to the following calculation: 120,525 wholly physician-owned private practices

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HHS assumes that each the wholly physician-owned private practice will incur a printing cost of $0.05 per page and materials for a total equivalent cost of $0.10. This results in a one-time equivalent cost of approximately $12,052 to all wholly physician-owned private practices.

HHS estimates that the annual one-time burden for wholly physician-owned private practices to develop, prepare, print, and post the notices, and make website updates will be approximately 421,837 total burden hours with an associated equivalent cost of approximately $50,650,005, as shown in Table 40.

TABLE 40—ESTIMATED ONE-TIME COST AND HOUR BURDEN FOR WHOLLY PHYSICIAN-OWNED PRIVATE PRACTICES TO DRAFT AND POST NOTICE OF GOOD FAITH ESTIMATE NOTICE *

Year	Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Total annual burden (hours)	Material and printing costs	Total estimated cost
2021	120,525	120,525	3.5	421,837	$12,052	[280] $50,650,005

* Estimated cost includes computer programming cost to update wholly physician-owned private practice website with uninsured (or self-pay) individuals' right to a good faith estimate. HHS assumes that each the wholly physician-owned private practice will incur a printing cost of $0.05 per page and materials for a total equivalent cost of $0.10. Total printing and material costs of $12,052 are included.

Summary

HHS estimates that the one-time burden for health care providers (including providers associated with health care facilities, individual physician practitioners, and wholly physician-owned private practices) and health care facilities to provide notice of the right to a good faith estimate of expected charges to uninsured (self-pay) individuals will be approximately 2,743,283 total burden hours with an associated equivalent cost of approximately $320,250,169.

TABLE 41—ESTIMATED TOTAL ONE-TIME COST RELATED TO NOTICE OF RIGHT TO GOOD FAITH ESTIMATE *

Year	Estimated number of respondents	Estimated number of responses	Burden per response (hours) [281]	Total annual labor burden (hours)	Total printing and material costs	Total estimated cost
2021	511,748	511,748	15.5	2,743,283	$52,393	$320,250,169

* Tables 38 through 40 are combined to estimate total amounts. This table presents a cumulative 15.5 hours of burden per response for summary purposes.

7. ICRs Regarding Requirements for Provision of Good Faith Estimate of Expected Charges Upon Request of Uninsured (or Self-Pay) Individuals and for Scheduled Items and Services (45 CFR 149.610)

These interim final rules require a convening provider or facility to provide a good faith estimate of expected charges to uninsured (or self-pay) individuals for scheduled items and services and upon request (45 CFR 149.610) including those items or services furnished by a co-provider or co-facility in conjunction with the primary items or services. HHS estimates that approximately 3,498,942 uninsured (or self-pay) individuals will be impacted by this rule requirement.[282] A total of 511,748 providers associated with health care facilities, individual physician practitioners, and wholly physician-owned private practices will incur the burden and costs associated with generating a good faith estimate.[283] HHS welcomes comments on this estimate.

HHS estimates that it will take an average of 30 minutes for a business operations specialist to determine a patient's insurance status, orally inform the patient of their right to receive a good faith estimate of expected charges, and provide an oral good faith estimate, if no additional items and services are needed. HHS assumes 1,749,471 (50 percent) of uninsured (or self-pay) individuals fall in this category. Therefore, the annual equivalent cost estimate for provision of good faith estimates where no additional items and services are needed is of $88,628,201.[284]

HHS estimates that it will take an average of 30 minutes for a business operations specialist to generate a good faith estimate of expected charges furnished by a co-provider and co-facility for items and services to the convening provider. Given that 1,749,471 (50 percent) of uninsured (or

× 2.5 hours × $122.55 = $36,925,829. 120,525 wholly physician-owned private practices × 1 hour = 120,525 hours. A labor rate of $113.77 is used for a computer programmer. The labor rate is applied to the following calculation: 120,525 wholly physician-owned private practices × 1 hour × $113.77 = $13,712,123. Therefore, the total burden hours are 301,312 + 120,525 = 421,837 and the total equivalent costs are $36,925,829 + $13,712,123 = $50,637,952. The printing and material costs are $12,052. Therefore, $50,637,952 + $12,052 = $50,650,005.

[280] 301,312 + 120,525 = 421,837 and the total equivalent costs are $36,925,829 + $13,712,123 = $50,637,952. The printing and material costs are $12,052. Therefore, $50,637,952 + $12,052 = $50,650,005.

[281] This includes the time for providers associated with health care facilities to enter into agreements with health care facilities to provide good faith estimates on their behalf.

[282] The number is estimated as follows: 51,744,200 nonemergency elective procedures (surgical and non-surgical) performed annually × 9.2% uninsured rate = 4,760,466. HHS assumes that some uninsured populations will forego elective procedures because of costs. Therefore, a 30% decrease adjustment was included resulting in 3,332,326. HHS also assumes a 5% adjustment for good faith estimate inquires only resulting in a final value of 3,498,942. See Squitieri, Lee *et al.* ''Resuming Elective Surgery during Covid–19: Can Inpatient Hospitals Collaborate with Ambulatory Surgery Centers?.'' *Plastic and reconstructive surgery. Global open* vol. 9,2 e3442. 18 Feb. 2021, doi:10.1097/GOX.0000000000003442 (The study estimates 4,297,850 nonemergency elective procedures (surgical and non-surgical) are performed each month. This value was multiplied by 12 months = 51,574,200. HHS adjusted by approximately one-third of one percent to account annual increase in volume since study publication resulting in 51,744,200). See also KFF Health Insurance Coverage of the Total Population.

[283] These estimates include the total number of health care facilities and health care providers from the preceding ICR Regarding Notice of Right to Good Faith Estimate.

[284] The burden is estimated as follows: 1,749,471 uninsured (or self-pay) individuals in need of good faith estimates without items and services × 0.50 hours = 874,736 hours. A labor rate of $101.32 is used for a business operations specialist. The labor rate is applied in the following calculation: 1,749,471 claims × 0.50 hours × $101.32 = $88,628,201.

self-pay) individuals require additional items and services, same number (1,749,471) of claims will be generated by co-providers or co-facilities. Therefore, the annual equivalent cost estimate for good faith estimates sent to convening providers by co-providers or co-facilities is $88,628,201.[285] HHS assumes that all communication between convening provider and convening facility, and co-provider or co-facility will be done electronically. Thus, the cost to generate a good faith estimate for both cases where additional items and services are needed and where no additional items and services are needed is $354,512,803.[286]

HHS estimates that it will take an average of 1 hour for a business operations specialist to determine a patient's insurance status, inform uninsured (or self-pay) individuals of their right to receive a good faith estimate of expected charges, and provide a good faith estimate, if additional items and services are needed. HHS assumes 1,749,471 (50 percent) of uninsured (or self-pay) individuals fall in this category. Therefore, the annual equivalent cost estimate is $177,256,402.[287] Thus, a total of $265,884,603 is estimated for business operations specialists, when adding the cost if no additional items and services are needed ($88,628,201) to the cost if additional items and services are needed ($177,256,402).

HHS estimates that approximately 90 percent of uninsured (or self-pay) individuals will receive a good faith estimate of expected charges through the mail that is 2 pages in length.[288] The remaining 10 percent of uninsured (or self-pay) individuals will receive the good faith estimate via electronic correspondence; costs are therefore accounted for in the 2 preceding paragraphs. HHS assumes that each convening provider or facility will incur a printing cost of $0.05 per page and materials for a total equivalent cost of $0.10 per good faith estimate. Therefore, the annual equivalent cost estimate for printing good faith estimates is $314,905 for all health care providers and health care facilities.[289]

HHS assumes that 5% of uninsured (or self-pay) individuals (*i.e.,* 157,452 uninsured (or self-pay) individuals) will request a mailed copy of their written good faith estimate of expected charges to a preferred location.[290] HHS assumes that it will take an average of 15 minutes for a medical secretary and administrative assistant to print and mail the good faith estimate to the uninsured (or self-pay) individual. HHS estimates a postage cost of $0.55 per mailing. Therefore, the annual equivalent cost estimate is $1,900,057 to mail the good faith estimate for all health care providers and health care facilities.[291]

TABLE 42—ESTIMATED ANNUAL COST AND HOUR BURDEN PER RESPONSE PER HEALTH CARE PROVIDER AND HEALTH CARE FACILITY TO ACCEPT AND FULFILL REQUESTS FOR MAILED GOOD FAITH ESTIMATES OF EXPECTED CHARGES

[Mailing costs only]

Occupation	Burden hours per response	Labor cost per hour	Total mailing cost per response
Medical Secretary and Administrative Assistant	0.25	$46.07	[292] $3.71
Total per Response	0.25		3.71

TABLE 43—ESTIMATED ANNUAL COST AND HOUR BURDEN FOR ALL HEALTH CARE PROVIDER AND HEALTH CARE FACILITY TO ACCEPT AND FULFILL REQUESTS FOR MAILED GOOD FAITH ESTIMATES OF EXPECTED CHARGES

Number of respondents	Number of responses	Burden hours per respondent	Total burden hours	Total labor costs of reporting	Mailing cost	Total annual cost
511,748	157,452	0.25	39,363	$1,813,458	$86,599	[293] $1,900,057

Summary

HHS estimates the annual cost to a convening provider or facility to provide a good faith estimate of expected charges to uninsured (or self-pay) individuals for scheduled items and services and upon requests between 2022–2024 to be $356,727,765 (inclusive of printing, materials, mailing costs) and total burden hours of 3,538,305, as shown in Table 44.

HHS estimates the annual cost for printing and materials to provide written good faith estimates to uninsured (or self-pay) individuals to be $314,905. The mailing costs of good faith estimates to uninsured (or self-pay)

[285] The burden is estimated as follows: 1,749,471 uninsured individuals in need of good faith estimates with additional items and services × 0.50 hours = 874,736 hours. A labor rate of $101.32 is used for a business operations specialist. The labor rate is applied in the following calculation: 1,749,471 claims × 0.50 hours × $101.32 = $88,628,201.

[286] The burden is estimated as follows: $88,628,201 + $177,256,402 + $88,628,201 = $354,512,803.

[287] The burden is estimated as follows: 1,749,471 claims × 1 hour = 1,749,471 hours. A labor rate of $101.32 is used for a business operations specialist. The labor rate is applied in the following calculation: 1,749,471 claims × 1 hour × $101.32 = $177,256,402.

[288] HHS assumes that the good faith estimate will be printed in 8.5'' x 11'' letter sized paper.

[289] The estimate is calculated as follows: $0.05 cost per page × 2 pages × 3,149,048 uninsured (or self-pay) individuals who receive a written good faith estimate = $314,905.

[290] An estimated 3,149,048 uninsured (or self-pay) individuals who receive a written good faith estimate × 5% = 157,452 uninsured (or self-pay) individuals who request a mailed good faith estimate of expected charges.

[291] The burden is estimated as follows: 157,452 good faith estimates × 0.25 hours = 39,363 hours. A labor rate of $46.07 is used for a medical secretary and administrative assistant. The labor rate is applied in the following calculation: 157,452 good faith estimates × 0.25 hours × $46.07 = $1,813,458. Therefore, 157,452 mailed good faith estimates × $0.55 postage cost = $86,599 in mailing costs + $1,813,458 in annual respondent time cost = $1,900,057.

[292] The cost per respondent is calculated as: $1,900,057 in medical secretary and administrative assistant annual respondent time cost to mail good faith estimate and mailing costs (printing costs are already accounted for in preceding section) divided by 511,748 health care providers and health care facilities = $3.71 cost per respondent.

[293] Therefore, 157,452 mailed good faith estimates × $0.55 postage cost = $86,599 in mailing costs + $1,813,458 in annual respondent time cost = $1,900,057.

individuals is $86,599 with an annual total burden hour estimate of 39,363 hours and a total annual respondent time cost of $1,813,458. This estimate is included in the total cost of $356,727,765. HHS invites comment on the assumptions and calculations made in this ICR.

TABLE 44—ANNUAL BURDEN AND TOTAL COST RELATED TO PROVISION OF GOOD FAITH ESTIMATES FOR UNINSURED (OR-SELF-PAY) INDIVIDUALS (LABOR, PRINTING, AND MAILING)

Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Total annual burden (hours)	Total annual respondent time cost	Printing and mailing costs (labor cost included) *	Total estimated cost
3,498,942	3,498,942	2.0	3,538,305	$354,512,803	$2,214,961	** $356,727,765

* This is calculated as following: $314,905 in printing costs + $86,599 in mailing costs + $1,813,458 in estimated annual respondent time cost to mail good faith estimate = $2,214,961. The Department assumes that it will take an average of fifteen minutes for a medical secretary and administrative assistant to print and mail the good faith estimate to the uninsured (or self-pay) individual. The annual burden hours associated with printing and mailing a good faith estimate of expected charges is 39,363 hours.

** The total estimated cost burden is the sum $88,628,201 (the GFE costs without co-providers or co-facilities) + $177,256,402 (the GFE costs with co-providers or co-facilities) + 88, 628, 201 (the GFE costs to convening providers) + $2,214,961 (printing and mailing costs, including labor).

8. ICRs Regarding Patient-Provider Dispute Resolution Process (45 CFR 149.620)

These interim final rules enable uninsured (or self-pay) individuals to initiate a patient-provider dispute resolution process if their final billed charges are in excess of the expected charges by at least $400 more than the amount listed in the good faith estimate supplied by the provider or facility. HHS does not have data on how many claims will be likely to result in patient-provider dispute resolution. For the estimates in this section, HHS relied on the experience of New York State. In 2015–2018 New York State had 1,486 disputes involving surprise bills submitted to IDR, 31% of these disputes (457 in all) were found ineligible for IDR for various reasons including 8% (approximately 36 cases) due to enrollment in self-insured plans.[294] For purposes of this analysis, HHS assumes that going forward, New York State will continue to see 40 IDR cases each year involving surprise bills for individuals enrolled with self-insured plans. Accordingly, the Departments estimate that there will be 26,659 claims that result in patient-provider dispute resolution each year.[295]

HHS estimates that it will take an average of 2 hours for an uninsured (or self-pay) individual or, if they use an authorized representative, 1 hour for their authorized representative to write, prepare, and send the notice to initiate the patient-provider dispute resolution to the Secretary of HHS. HHS assumes that uninsured (or self-pay) individuals will self-represent in 90% of the cases, while the remaining 10% will be represented by the uninsured (or self-pay) individual's authorized representative, as allowed by these interim final rules.

HHS assumes the authorized representative will be a lawyer. Additionally, HHS assumes that a small percentage of uninsured (or self-pay) individuals or their authorized representatives will be asked to resubmit or send additional materials to complete the initiation process. This results in an annual equivalent cost estimate of $3,789,694.[296] The patient-provider dispute resolution initiation notice must be submitted to the Secretary of HHS within 120 calendar days of receiving billed charges substantially in excess of the good faith estimate. HHS assumes for uninsured (or self-pay) individuals that 8,973 (34%) of initiation notices, including those that need to be resubmitted with additional materials, will be sent electronically and 17,419 (66%) of the initiation notices, including those that need to be resubmitted with additional materials will be mailed with an associated printing and materials and postage costs of $12,193.[297] [298] To facilitate communication between parties and compliance with this notice requirement, HHS is concurrently issuing a model notice that the parties may use to satisfy the patient-provider dispute resolution initiation notice requirement. HHS will consider timely use of the model notice in accordance with the accompanying instructions to satisfy the notice requirement.

These interim final rules require the SDR entity to attest to the Secretary of HHS whether a conflict of interest exists with the uninsured (or self-pay) individual, provider, or facility. HHS assumes that it will take an average of one hour for a general and operations manager and one hour for a lawyer to

[294] See *https://www.dfs.ny.gov/system/files/documents/2019/09/dfs_oon_idr.pdf.*

[295] The number is estimated as follows: 51,744,200 nonemergency elective procedures (surgical and non-surgical) performed annually × 9.2% uninsured rate = 4,760,466. HHS assumes that some uninsured (or self-pay) individuals will forego elective procedures because of costs. Therefore, a 30% decrease adjustment was included resulting in 3,332,326. HHS assumes that 10% of uninsured (or self-pay) individuals who undergo a nonemergency elective procedure will receive a billed charge that is $400 or greater more than the total expected charges listed in the good faith estimate, therefore 3,332,326 × 10% = 333,233. HHS assumes that 8% will engage the provider-patient dispute resolution process, therefore 333,233 × 8% = 26,659.

[296] The burden is estimated as follows: 26,659 × 90% = 23,993 uninsured (or self-pay) individuals will self-represent. 23,993 × 2 hours = 47,986 hours. A labor rate of $64.32 is used for uninsured (or self-pay) individuals (all occupations). The labor rate is applied in the following calculation: 23,993 claims × 2 hours × $64.32 = $3,086,427. HHS assumes that uninsured (or self-pay) individual will appoint an authorized representative in 10% of cases. .26,659 × 10% = 2,666 claims represented by an authorized representative. HHS assumes approximately 15% of uninsured (or self-pay) individuals will need to resubmit or submit additional materials to initiate IDR, either themselves or through their authorized representative. Therefore, the burden estimate is calculated as follows: 23,993 claims × 10% = 2,399 resubmitted claims by individual × 2 hours × $64.32 (labor rate) = $129,899. 2,666 claims × 5% = 133 resubmitted claims by authorized representative × 1 hour × $140.96 (labor rate) = $18,789. The total annual respondent time cost estimates are added as follows: $3,086,472 + $375,785 + $308,647 + $18,789 = $3,789,694. The total burden hours are 55,584.

[297] HHS assumes that the average initiation notice sent via mail by uninsured (or self-pay) individuals will be three pages in length and printed on 8.5'' x 11'' sized paper. HHS assumes a $0.05 cost in printing and materials cost per page and $0.55 in postage cost. Therefore, $0.05 cost per page × 3 pages × 17,419 mailed initiation notices (inclusive of notices that needed to be resubmitted) = $2,613 in printing and material costs. The postage costs are calculated as $0.55 cost per postage × 17,419 mailed initiation notices = $9,580 in postage cost. The total printing and materials and postage costs are therefore $2,613 + $9,580 = $12,193.

[298] According to data from the National Telecommunications and Information Agency, 34% of households in the United States accessed health records or health insurance online. *https://www.ntia.doc.gov/blog/2020/more-half-american-households-used-internet-health-related-activities-2019-ntia-data-show.*

determine whether a conflict of interest exists. HHS assumes all communication will be done electronically. This results in annual equivalent cost estimate of $7,024,811, as shown in Table 45.[299]

TABLE 45—ESTIMATED ANNUAL COST AND HOUR BURDEN RELATED TO ATTESTATION OF CONFLICT OF INTEREST WITH A PATIENT-PROVIDER DISPUTE RESOLUTION INITIATION NOTICE

Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Total annual burden (hours)	Total estimated cost
26,659	26,659	2	53,317	$7,024,811

These interim final rules also require the selected SDR entity to review eligibility and completeness of the initiation notice and notify uninsured (or self-pay) individuals, providers or facilities of the SDR entity's selection to conduct dispute resolution. Providers and facilities are thereafter required to furnish additional information to the SDR entity within 10 business days after receiving notification of SDR entity selection. This information must include: (1) A copy of the good faith estimate provided to the uninsured (or self-pay) individual for the items or services under dispute; (2) a copy of the bill provided to the uninsured (or self-pay) individual for items or services under dispute; and (3) documentation providing evidence to demonstrate the difference between the billed charge and the expected charges in the good faith estimate reflects a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided. HHS estimates that it will take an average of 1 hour for a general and operations manager to address these requirements and send to the SDR entity. This results in an annual equivalent cost estimate of $3,267,013.[300]

These interim final rules require the SDR entity to assess the information provided by the provider or facility according to the standards described in 45 CFR 149.620(f) and discussed in section VI.B.7 of the preamble. The SDR entity must respond within 30 days after receipt information from the provider or facility to make determinations on charges to the paid by the uninsured (or self-pay) individual. HHS estimates that it will take an average of 2 hours for a general and operations manager and 2 hours for a lawyer to assess the merits of the submitted information and determine a prevailing party. This results in an annual equivalent cost estimate of $14,049,622.[301]

TABLE 46—ESTIMATED ANNUAL BURDEN TO ASSESS THE SUBMITTED INFORMATION AND DETERMINE A PREVAILING PARTY

Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Total annual burden (hours)	Total estimated cost
26,659	26,659	4	106,634	$14,049,622

HHS estimates that it will take an average of 30 minutes for an SDR entity's general and operations manager to notify parties of the IDR determination. This results in an annual equivalent cost estimate of $1,633,506.[302]

The SDR entity must also submit the administrative fee to the Secretary of HHS on behalf of uninsured (or self-pay) individuals. This burden includes time to review instructions, search existing data resources, gather data needed, and complete and review information collection. HHS estimates that the time required to complete and submit this information collection is estimated to average a clerical worker 1.5 hours per month (or 18 hours annually), with a total annual cost of $2,982.42, as shown in Table 47.[303] HHS estimates the total annual ongoing costs associated with the implementation and administration of the patient-provider dispute resolution program, including system maintenance, and program support, is estimated to be 12.6 million this cost will be offset by the collection of the $25 administrative fee, resulting in a total anticipated collection of $655,475 and a total annual cost to the Federal Government of $12 million.

[299] The burden is estimated as follows: 26,659 claims × 1 hour = 26,659 hours. A labor rate of $122.55 is used for a general and operations manager. The labor rate is applied in the following calculation: 26,659 claims × 1 hour × $122.55 = $3,267,013. The burden for legal review is estimated as follows: 26,659 claims × 1 hour = 26,659 hours. A labor rate of $140.96 is used for a lawyer. The labor rates are applied in the following calculation: 26,659 claims × 1 hour × $140.96 = $3,757,798. The total annual response time cost estimates are added as follows: $3,267,013 + $3,757,798 = $7,024,811. The total burden hours are 53,317.

[300] The burden is estimated as follows: 26,659 claims × 1 hour = 26,659 hours. A labor rate of $101.32 is used for a general and operations manager. The labor rate is applied in the following calculation: 26,659 claims × 1 hour × $122.55 = $3,267,013. Total burden hours are 26,659 hours.

[301] The burden is estimated as follows: 26,659 claims × 2 hours = 53,317 hours. A labor rate of $122.55 is used for a general and operations manager. The labor rate is applied in the following calculation: 26,659 claims × 2 hours × $122.55 = $6,534,026. The burden for legal review is estimated as follows: 26,659 claims × 2 hours = 53,317 hours. A labor rate of $140.96 is used for a lawyer. The labor rates are applied in the following calculation: 53,317 × 2 hours × $140.96 = $7,515,596. The total annual respond time cost estimates are calculated as follows: $6,534,026 + $7,515,596 = $14,049,622. The total annual burden hours are 106,634 hours.

[302] The burden is estimated as follows: 26,659 claims × 0.50 hours = 13,329 hours. A labor rate of $122.55 is used for a general and operations manager. The labor rate is applied in the following calculation: 26,659 claims × 0.50 hours × $122.55 = $1,633,506.

[303] The burden is estimated as follows: A labor rate of $55.23 is used for a clerical worker. The labor rate is applied in the following calculation: 3 annual responses × 18 hours × $55.23 = $2,982.42.

TABLE 47—ESTIMATED ANNUAL BURDEN AND COST RELATED TO SDR SUBMISSION OF THE ADMINISTRATIVE FEE TO HHS

Estimated number of responses	Total annual burden (1.5 hours × 12 months)	Annual cost per IDR entity	Annual cost for all responses
3	18	994.14	$2,982.42

Summary

The total annual burden associated with the patient-provider dispute resolution process for uninsured (or self-pay) individuals and providers and facilities is 255,524 hours with an equivalent cost of $29,764,646, as shown in Table 48.[304] HHS invites comment on the assumptions and calculations made in this ICR.

TABLE 48—ANNUAL BURDEN AND COST RELATED TO PATIENT-PROVIDER DISPUTE RESOLUTION PROCESS FOR UNINSURED (SELF-PAY) INDIVIDUALS AND PROVIDERS AND FACILITIES

Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Total annual burden (hours)	Total estimated cost
26,659	26,659	13.50	255,524	$29,764,646

9. ICRs Regarding Patient-Provider Dispute Resolution Entity Certification (45 CR 149.620)

An SDR entity contracted by HHS must be certified under standards and procedures set forth in 45 CFR 149.620(d). HHS estimates that there will be between 1 and 3 entities that HHS contracts with to be an SDR entity.

To be an SDR entity, the entity will need to establish the processes and complete the corresponding paperwork. HHS estimates that on average it will take a general and operations manager 5 hours and medical secretary and administrative assistant 15 minutes to satisfy the requirement. As shown in Table 49, this result in an equivalent cost burden of $1,554 in the first year.[305]

TABLE 49—ESTIMATED FIRST YEAR ONE-TIME COST ANNUAL BURDEN AND COST RELATED TO PATIENT-PROVIDER SDR ENTITY CERTIFICATION PROCESS COST RELATED TO PATIENT-PROVIDER DISPUTE RESOLUTION PROCESS

Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Total annual burden (hours)	Total estimated cost
3	3	5.25	15.75	$1,873

HHS estimates that on average one-third of SDR entities (*i.e.,* one of the three contracted organizations) will need to be recertified or reapproved, through the contracting process, each year and that on average it will take a general and operations manager 2 hours and medical secretary and administrative assistant 15 minutes to satisfy the requirement. This results in an equivalent cost burden of $257.[306]

The total annual burden associated with the SDR entity certification is 16 hours with an equivalent cost of $1,873. In subsequent years, the total hour burden associated with the SDR entity certification or recertification is 2.25 hours with an equivalent cost of $257. HHS will assess whether the SDR entity's meets the certification standards as discussed in section VI.B.5. of this preamble as part of contracting per the contract period. HHS invites comment on the assumptions and calculations made in this ICR.

[304] The total estimated cost burden is the sum of $3,789,694 (the cost for uninsured or self-pay individuals and authorized representatives to write, prepare and send the initiation notice for the patient-provider dispute resolution to the Secretary of HHS, including resubmission costs) + $7,024,811 (the cost for SDR entities to attest whether a Conflict of Interest exists with the uninsured or self-pay individual, provider or facility) + $3,267,013 (the cost for uninsured or self-pay individuals and providers or facilities to furnish additional information to selected SDR entities) + $14,049,622 (the cost for the SDR entity to carry out the dispute outcome analysis for uninsured or self-pay individuals and providers and facilities) + 1,633,506 (the cost for the SDR entity to notify the parties of the SDR entity's determination) = $29,764,646. These costs represent 13.5 burden hours.

[305] The burden is estimated as follows: (3 SDR entities × 5 hours) + (3 SDR entities × 0.25 hours) = 15.75 hours. A labor rate of $101.32 is used for a general and operations manager and a labor rate of $46.07 is used for a medical secretary and administrative assistant. The labor rates are applied in the following calculation: (3 SDR entities × 5 hours × $101.32) + (3 SDR entities × 0.25 hours × $46.07) = $1,554.

[306] The burden is estimated as follows: (1 SDR entities × 2 hours) + (1 SDR entities × 0.25 hours) = 2.25 hours. A labor rate of $122.55 is used for a general and operations manager and a labor rate of $46.07 is used for medical secretary and administrative assistant. The labor rates are applied in the following calculation: (1 SDR entities × 2 hours × $122.55) + (1 SDR entities × 0.25 hours × $46.07) = $257.

TABLE 50—ANNUAL BURDEN AND COST RELATED TO SDR ENTITY RE-CERTIFICATION PROCESS

Year	Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Total annual burden (hours)	Total estimated cost
2023	1	1	2.25	2.25	$257

10. 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.

The total annual hour burden in the first six months associated with the Federal IDR process associated with HHS requirements is estimated to be 3,327,917 hours with an equivalent cost burden of $358,970,847. The total annual hour burden is 4,826,970 hours with an equivalent cost burden of $504,465,709.

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

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

The total annual hour burden in the first six months associated with the Federal IDR process for OPM is estimated to be 6,595 hours with an equivalent cost of $646,475. The total annual hour burden is estimated to be 13,190 hours with an equivalent cost burden of $1,292,950.

In terms of the cost burden, the total cost burden in the first six months associated with the Federal IDR process is $610,675. 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 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. As shown in Table 51, for HHS requirements, the total cost burden associated with the Federal IDR process in the first six months is $392,214. The total cost burden in the first year is estimated to be $784,429 and in subsequent years, the total cost burden associated with the Federal IDR process is estimated to be $735,318. Thus, the 3-year average cost burden associated with HHS requirements is $751,688.

As shown in Table 52, 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.

As shown in Table 52, for the Department of the Treasury 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 the Department of the Treasury requirements is $187,546.

As shown in Table 53, for OPM requirements, the total cost burden associated with the Federal IDR process in the first six months is $19,860. The total cost burden in the first year is estimated to $38,347 and in subsequent years, the total cost burden associated with the Federal IDR process is estimated to be $37,090. Thus, the 3-year average cost burden associated with OPM requirements is $37,509.

TABLE 51—HHS SUMMARY TABLE

Year	Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Total annual burden (hours)	Total estimated labor cost	Total estimated cost
2022	4,059,610	4,103,368	1.1763434	4,826,970	$504,465,709	$784,429
2023	4,059,610	4,103,368	1.1763434	4,826,970	504,465,709	735,318
2024	4,059,610	4,103,368	1.1763434	4,826,970	504,465,709	735,318
3 Year Average	4,059,610	4,103,368	1.1763434	4,826,970	504,465,709	751,688

TABLE 52—DOL'S AND DEPARTMENT OF THE TREASURY'S SUMMARY TABLE

Year	Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Total annual burden (hours)	Total estimated labor cost	Total estimated cost
2022	22,257	36,675	1.7981697	65,948	$6,464,751	$191,734

TABLE 52—DOL'S AND DEPARTMENT OF THE TREASURY'S SUMMARY TABLE—Continued

Year	Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Total annual burden (hours)	Total estimated labor cost	Total estimated cost
2023	22,257	36,675	1.7981697	65,948	6,464,751	185,452
2024	22,257	36,675	1.7981697	65,948	6,464,751	185,452
3 Year Average	22,257	36,675	1.7981697	65,948	6,464,751	187,546

TABLE 53—OPM'S SUMMARY TABLE

Year	Estimated number of respondents	Estimated number of responses	Burden per response (hours)	Total annual burden (hours)	Total estimated labor cost	Total estimated cost
2022	22,257	5,986	2.2034535	13,190	$1,292,950	$38,347
2023	22,257	5,986	2.2034535	13,190	1,292,950	37,090
2024	22,257	5,986	2.2034535	13,190	1,292,950	37,090
3 Year Average	22,257	5,986	2.2034535	13,190	1,292,950	37,509

These paperwork burden estimates are summarized as follows:

Agency: Centers for Medicare & Medicaid Services, Department of Health and Human Services.

Type of Review: New collection.

Title: Surprise Medical Billing: Independent Dispute Resolution.

OMB Control Number: 0938–NEW.

Affected Public: Businesses or other for-profits; not-for-profit institutions.

Estimated Number of Respondents: 4,059,610.

Estimated Number of Annual Responses: 4,103,368.

Frequency of Response: Occasionally.

Estimated Total Annual Burden Hours: 4,826,970 (3,327,917 during the first six months).

Estimated Total Annual Burden Cost: $751,688 ($392,214 during the first six months).

Agency: Employee Benefits Security Administration, Department of Labor.

Type of Review: New collection.

Title: Surprise Medical Billing: Independent Dispute Resolution.

OMB Control Number: 1210–New.

Affected Public: Businesses or other for-profits; not-for-profit institutions.

Estimated Number of Respondents: 22,257.

Estimated Number of Annual Responses: 36,675.

Frequency of Response: Occasionally.

Estimated Total Annual Burden Hours: 65,948 (32,974 during the first six months).

Estimated Total Annual Burden Cost: $187,546 ($99,300 during the first six months).

Agency: Internal Revenue Service, Department of the Treasury.

Type of Review: New collection.

Title: Surprise Medical Billing: Independent Dispute Resolution.

OMB Control Number: 1545–New.

Affected Public: Businesses or other for-profits; not-for-profit institutions.

Estimated Number of Respondents: 22,257

Estimated Number of Annual Responses: 36,675.

Frequency of Response: Occasionally.

Estimated Total Annual Burden Hours: 65,948 (32,974 during the first six months).

Estimated Total Annual Burden Cost: $187,546 ($99,300 during the first six months).

Agency: Office of Personnel Management.

Type of Review: New collection.

Title: Surprise Medical Billing: Independent Dispute Resolution.

OMB Control Number: NEW.

Affected Public: Businesses or other for-profits; not-for-profit institutions.

Estimated Number of Respondents: 22,257.

Estimated Number of Annual Responses: 5,986.

Frequency of Response: Occasionally.

Estimated Total Annual Burden Hours: 13,190 (6,595 during the first six months).

Estimated Total Annual Burden Cost: $37,509 ($19,860 during the first six months).

11. ICRs Regarding Internal Claims and Appeals and External Review Requirements for Non- Grandfathered Plans and Grandfathered Plans—Applicability (26 CFR 54.9815–2719, 29 CFR 2590.715–2719, and 45 CFR 147.136)

The No Surprises Act extends the protections related to external reviews to grandfathered plans. Grandfathered plans must comply either with a state external review process or a Federal review process. The disclosure requirements of the Federal external review process require: (1) A preliminary review by plans of requests for external review; (2) IROs to notify claimants of eligibility and acceptance for external review; (3) the plan or issuer to provide IROs with documentation and other information considered in making adverse benefit determination; (4) the IRO to forward to the plan or issuer any information submitted by the claimant; (5) plans to notify the claimant and IRO if it reverses its decision; (6) the IRO to provide notice of the final external review decision to the claimant and plan; and (7) the IRO to maintain records for six years.

The Departments already have an existing information collection on the claim, appeals, and external review requirements for non-grandfathered plans (1210–0144). Due to these interim final rules, the Departments have added the burden associated with the external review requirements for grandfathered plans and non-grandfathered plans in the information collection. The burden associated with the additional standards that non-grandfathered and grandfathered ERISA-covered plans must meet is shared equally between the Department of Labor and the Department of the Treasury. The burden associated with the additional standards that non-grandfathered and grandfathered non-Federal governmental plans and individual market policies must meet is assigned to the Department of Health and Human Services.

The Departments estimate that there are approximately 84.4 million participants in self-insured ERISA-covered plans. Prior to the interim final rules, the Departments estimate that there are approximately 8.1 million participants in ERISA-covered plans in

the states which have no external review laws or whose laws do not meet the Federal minimum requirements.[307] These estimates lead to a total of 92.5 million participants. Among the 92.5 million participants, 80.5 million participants in non-grandfathered plans and 12 million participants in grandfathered plans will be required to be covered by the external review requirement.

The Departments estimate that there are approximately 1.3 external reviews for every 10,000 participants [308] and that there will be approximately 12,275 external reviews annually. Experience from North Carolina indicates that about 75 percent of requests for external reviews are actually eligible to proceed to an external review,[309] therefore it is expected that there will be about 16,261 (12,275/0.7549) requests for external review. In addition, a 2 percent increase in the number of out-of-networks claims was incorporated in the estimate to capture the increase in burden on non-grandfathered plans resulting from the surprise billing and cost sharing protections of the external review.

As shown in Table 54, the hour burden related to the preliminary review by grandfathered and non-grandfathered plans subject to ERISA of the request for external review is estimated to be 4,0655 hours (16,261 * 0.25 hours) with an equivalent cost of $373,303 (4,065 hours * $91.83). The Departments assume that plans have a human resources specialist with a labor rate of $91.83. The human resource specialist will spend an average of 15 minutes for each of the requests, for a plan to make an eligibility determination. Plans will already have conducted internal reviews for eligible claimants; therefore, the required information for plans to make this determination should be readily available. Additionally, plans will incur material costs of $0.05 for paper and printing and $0.55 for postage for each request for external review, resulting in a cost of $9,756 (16,261 * $0.60).

TABLE 54—ANNUAL BURDEN AND COST FOR PLANS TO CONDUCT A PRELIMINARY REVIEW OF THE REQUEST FOR THE EXTERNAL REVIEW STARTING IN 2022

Year	Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
2022	16,261	4,065	$373,303	$9,756	$383,060

Once an eligibility determination is made, plans must provide the IRO with all documentation and other information considered in making an adverse benefit determination. The Departments assume that plans have clerical staff with a labor rate of $55.23. The clerical staff will spend an average of 5 minutes for each of the requests for a plan to send documentation to the IRO. As shown in Table 55, for the 12,275 verified requests for external review the hour burden for grandfathered and non-grandfathered plans is estimated as 1,023 hours (12,275 * 5 minutes), with an equivalent cost of $56,494 (1,023 * $55.23). Additionally, plans will incur material costs of $0.05 for each sheet of paper. The Departments assume that each set of documentation will be 20 pages. Plans will also incur a cost of $0.55 for postage for each set of documentation, resulting in a cost burden of $19,026 (12,275 × $0.05 × 20 + 12,275 * $0.55). The Departments estimate that this will cost, on average, $1.55 per claimant.

TABLE 55—ANNUAL BURDEN AND COST FOR PLANS TO PROVIDE THE IRO WITH DOCUMENTATION STARTING IN 2022

Year	Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
2022	12,275	1,023	$56,494	$19,026	$75,519

IROs must also send each eligible claimant a notice of eligibility and acceptance. The Departments assume that the IRO has clerical staff with a labor rate of $55.23 that will spend, on average 5 minutes per claimant preparing the notice, and that IROs incur an average cost of $0.60 to print and mail the notice. As shown in Table 56, for the 12,275 verified requests for external review, the cost burden for the clerical worker to send the notice of eligibility and acceptance is estimated to be $56,493 (12,275 × 5 minutes × $55.23). Additionally, IROs will incur material costs of $0.05 for each sheet of paper. The Departments assume that each notice of eligibility and acceptance will be 1 page. Plans will also incur a cost of $0.55 for postage for each set of documentation, resulting in a cost of $7,365 (12,275 × $0.05 + 12,275 * $0.55). Thus, the total cost burden relating to the notice of eligibility and acceptance is $63,858.

[307] These states are Alabama, Florida, Georgia, Pennsylvania, Texas, and Wisconsin. See Affordable Care Act: Working with States to Protect Consumers, available at *https://www.cms.gov/CCIIO/Resources/Files/external_appeals.html.*

[308] AHIP Center for Policy and Research, ''An Update on State External Review Programs, 2006,'' July 2008. *https://www.cms.gov/CCIIO/Resources/Files/external_appeals.html.*

[309] North Carolina Department of Insurance. ''Health Insurance Smart NC: Annual Report on External Review Activity 2013.'' *https://digital.ncdcr.gov/digital/collection/p249901coll22/id/730531.*

TABLE 56—ANNUAL BURDEN AND COST FOR IROS TO SEND NOTICES OF ELIGIBILITY AND ACCEPTANCE STARTING IN 2022

Year	Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
2022	12,275	0	$0	$63,858	$63,858

IROs are required to send to plans all documents that claimants submit. The Departments do not know what fraction of claimants will submit additional documentation, but for purposes of this burden analysis assume that half of claimants (6,137) do. The Departments assume that the IRO has clerical staff with a labor rate of $55.23 that will spend, on average 5 minutes per claimant preparing and forwarding the required documents, and that IROs incur an average cost of $1.05 to print and mail the documents. As shown in Table 57, for the 6,137 verified requests for external review, the cost burden for the clerical worker to send the claimants' documentation to the plans is estimated to be $28,247 (6,137 × 5 minutes × $55.23). Additionally, IROs will incur material costs of $0.05 for each sheet of paper. The Departments assume that such documentation will be 10 pages. Plans will also incur a cost of $0.55 for postage for each set of documentation, resulting in a cost of $6,444 (6,137 × $0.05 × 10 + 12,275 * $0.55). Thus, the total cost burden relating to preparing and forwarding the required documents is $34,691.

TABLE 57—ANNUAL BURDEN AND COST FOR IROS TO SEND PLANS ALL DOCUMENTS THAT CLAIMANTS SUBMIT STARTING IN 2022

Year	Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
2022	6,137	0	$0	$34,691	$34,691

IROs are required to provide the notice of the final external review decision to the claimant and plan. The Departments estimate that preparing and sending the notices for each of the 12,275 external reviews will take IRO clerical staff, with a labor rate of $55.23, on average 5 minutes per claimant, and that IROs will incur an average cost of $1.05 to mail the documents. As shown in Table 58, for the 12,275 verified requests for external review, the cost burden for the clerical worker to send the notice is estimated to be $56,494 (12,275 × 5 minutes × $55.23). Additionally, IROs will incur material costs of $0.05 for each sheet of paper. The Departments assume that such documentation will be 10 pages. Plans will also incur a cost of $0.55 for postage for each set of documentation, resulting in a cost of $12,888 (12,275 × $0.05 × 10 + 12,275 * $0.55). Thus, the total cost burden relating to notifying the claimant and plan of the final external review decision is $69,382.

TABLE 58—ANNUAL BURDEN AND COST FOR IROS TO NOTIFY THE CLAIMANT AND PLAN OF THE RESULT OF THE FINAL EXTERNAL REVIEW DECISION STARTING IN 2022

Year	Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
2022	12,275	0	$0	$69,382	$69,382

IROs also are required to maintain records of all claims and notices associated with the external review process for six years. The Departments are of the view that these documents would be retained as a customary part of business, but estimate that clerical staff will spend on average an additional 5 minutes per claimant ensuring all files are complete. As shown in Table 59, for the 12,275 verified requests for external review, the cost burden for the clerical worker to maintain records is estimated to be $56,494 (12,275 × 5 minutes × $55.23).

TABLE 59—ANNUAL BURDEN AND COST FOR IROS TO MAINTAIN RECORD OF ALL CLAIMS AND NOTICES STARTING IN 2022

Year	Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
2022	12,275	0	$0	$56,494	$56,494

The Departments estimate that the Federal external review process will result in an hour burden of 5,088 hours with an equivalent cost of $429,797 related to external reviews. The cost burden of approximately $253,207 annually. The cost burden results from the cost associated with preparing and

mailing required notices and documents.

The Departments are not able to estimate the number of reversals and the associated notices to claimants and IROs that plans would send due to reversing prior decisions, but the Departments are of the view that the number would be small.

The existing information collection had an estimated hour burden of 1,394 hours with an equivalent cost of $97,616 and an estimated cost burden by $3,002,150.

In summary, the total burden associated the information collection for DOL and the Department of the Treasury, including the existing collection, is approximately 6,482 hours at an equivalent cost of $527,413 annually. The cost burden is approximately $3,255,357 annually. Because the burden is shared equally between the DOL and the Department of the Treasury, the DOL's share is 3,241 hours at an equivalent cost of $263,706 annually. The DOL's share of the cost burden is $1,627,679 annually. The summary of burden for DOL and the Department of the Treasury's information collection has also been provided below.

TABLE 60—DOL AND DEPARTMENT OF THE TREASURY'S SUMMARY TABLE

Year	Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
2022	381,826	3,241	$263,706	$1,627,679	$1,891,385
2023	381,826	3,241	263,706	1,627,679	1,891,385
2024	381,826	3,241	263,706	1,627,679	1,891,385
3 Year Average	381,826	3,241	263,706	1,627,679	1,891,385

HHS estimates that there are approximately 13.5 million individual market enrollees and 19.3 million non-Federal governmental plans enrollees.[310] These estimates lead to a total of 32.8 million total enrollees in individual market and non-Federal Government plans. Among the 32.8 million participants, 2.6 million are in grandfathered plans and 30.1 million are in non-grandfathered plans. HHS also added a two percent increase in the number of out-of-networks claims to capture the increase in burden on non-grandfathered plans resulting from the surprise billing and cost sharing protections of the external review resulting in an adjusted total of 30.7 million for non-grandfathered plans and an adjusted total of 33.3 million for all individual market and non-Federal Government plans.

HHS also estimates there are an estimated 1.3 external reviews for every 10,000 participants and that there will be approximately 4,337 total external reviews annually for individual market and non-Federal Government plans. This amount includes 3,994 reviews for non-grandfathered plans and 343 for grandfathered plans. Experience from North Carolina indicates that about 75 percent of requests for external reviews are actually eligible to proceed to an external review, therefore it is expected that there will be about 5,783 requests for external review. This amount includes 5,326 requests for non-grandfathered plans and 457 requests for grandfathered plans.

HHS estimated the burden for the disclosure requirements of the Federal external review process to align with the methodologies used to calculate the amounts in Tables 54 through 59. As shown in Table 61, HHS estimates that the disclosure requirements will require 3,066 burden hours that result in $222,224 in estimated labor costs and $19,625 in other costs for printing and mailing. The total estimated updated burden for Federal external review to individual market and non-Federal Government plans is $241,850. This amount includes $222,729 in costs for non-grandfathered plans and $19,121 for grandfathered plans. The existing collection for HHS for Federal external review is $128,876.

TABLE 61—HHS' SUMMARY TABLE NEW COLLECTION BURDEN FOR FEDERAL EXTERNAL REVIEW

Year	Estimated number of responses	Total annual burden (hours)	Total estimated labor cost	Other costs	Total estimated cost
2022	5,783	3,066	$222,224	$19,625	$241,850
2023	5,783	3,066	222,224	19,625	241,850
2024	5,783	3,066	222,224	19,625	241,850
3 Year Average	5,783	3,066	222,224	19,625	241,850

Summary of Burden

Type of Review: Revised Collection.

Agency: DOL–EBSA.

Title: Affordable Care Act Internal Claims and Appeals and External Review Procedures for Plans.

OMB Numbers: 1210–0144.

Affected Public: Businesses or other for-profits, Not-for-profit institutions.

Estimated Number of Respondents: 2,524,241.

Estimated Number of Annual Responses: 381,826.

Frequency of Response: Occasionally.

Estimated Total Annual Burden Hours: 3,241.

Estimated Total Annual Burden Cost: $1,627,679.

Type of Review: Revised Collection.

Agency: Treasury—IRS.

Title: Affordable Care Act Internal Claims and Appeals and External Review Procedures for Plans.

OMB Numbers: 1545–2182.

Affected Public: Businesses or other for-profits, Not-for-profit institutions.

Estimated Number of Respondents: 2,524,241.

[310] Individual market data is based on data from MLR annual report for the 2019 MLR reporting year, available at *https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.* Non-federal government plans data from Agency for Healthcare Research and Quality, Center for Financing, Access and Cost Trends. 2019 Medical Expenditure Panel Survey-Insurance Component.

Estimated Number of Annual Responses: 381,826.

Frequency of Response: Occasionally.

Estimated Total Annual Burden Hours: 3,241.

Estimated Total Annual Burden Cost: $1,627,679.

Type of Review: Revised Collection.

Agency: Centers for Medicare & Medicaid Services, Department of Health and Human Services.

Title: Affordable Care Act Internal Claims and Appeals and External Review Procedures for Plans.

OMB Numbers: 0938–1099.

Affected Public: Businesses or other for-profits, Not-for-profit institutions.

Estimated Number of Respondents: 5,783.

Estimated Number of Annual Responses: 5,783.

Frequency of Response: Occasionally.

Estimated Total Annual Burden Hours: 3,066.

Estimated Total Annual Burden Cost: $241,850.

D. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) imposes certain requirements with respect to Federal rules that are (1) required to be published as a notice of proposed rulemaking subject to the notice and comment requirements of the Administrative Procedure Act (5 U.S.C. 553(b)) and (2) likely to have a significant economic impact on a substantial number of small entities. The RFA generally defines a ''small entity'' as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a not-for-profit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of ''small entity.'' The Departments use a change in revenues of more than 3 to 5 percent as its measure of significant economic impact on a substantial number of small entities.

These interim final rules are exempt from the RFA because the Departments were not required to publish a notice of proposed rulemaking. Therefore, the RFA does not apply and the Departments are not required to either certify that the interim final rules will not have a significant economic impact on a substantial number of small entities or conduct a regulatory flexibility analysis. Nevertheless, the Departments carefully considered the likely impact of the interim final rules on small entities in connection with its assessment of the interim final rules' cost and benefits under Executive Order 12866.

Table 58 summarizes the estimated costs on small issuers, physicians, and providers of air ambulance services. The original analysis was based on a cost per IDR payment determination basis. To break down the cost to a per-entity basis, the Departments assume that the distribution of per-entity costs is proportional to annual receipts. The affected entities are estimated based on the SBA's size standards. The size standards applied for issuers is North American Industry Classification System (NAICS) 524114, for which a business with less than $41.5 million in receipts is considered to be small. The size standard applied for physicians is NAICS 62111, for which a business with less than $12.0 million in receipts is considered to be small.[311]

TABLE 62—SUMMARY OF ESTIMATES COSTS ON SMALL ENTITIES

Affected entity	Affected small entities [312]	Aggregate annual cost for small entities [313]	Annual cost per entity [314]
Issuer	132	$714,065	$5,410
Physicians [315]	61,890	136,976,819	2,213

The Departments do not have the same level of data used in the table above the air ambulance sub-sector and are of the view that this sub-sector is likely to differ from the ambulance services industry as a whole. In 2020, the total revenue of providers of air ambulance services is estimated to be $4.2 billion with 1,073 businesses in the industry.[316] This results in an industry average of $3.9 million per business. Accordingly, the Departments are of the view that most providers of air ambulance services are likely to be small entities.

Additionally, this analysis also excludes certified IDR entities and their respective costs, as the Departments do not have information on how many certified IDR entities are likely to be small entities.

Consistent with the policy of the RFA, the Departments seek comment regarding the impact of these interim final rules on small entities.

E. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed agency rule, or a finalization of such a proposal, that may result in an expenditure of $100 million or more (adjusted annually

[311] U.S. Small Business Administration. ''Table of Size Standards.'' (August 2019). *https://www.sba.gov/document/support--table-size-standards.*

[312] For issuers, it is assumed that the size distribution across establishments is the same for issuers as their respective industry. For physicians, it is assumed that the size distribution across employment is the same for physicians as the respective industry. For more information, refer to the Affected Entities section in the Regulatory Impact Analysis.

[313] To estimate the proportion of the total costs that would fall onto small entities, the Departments assume that the proportion of costs is proportional to the industry receipts. The Departments are of the view that this assumption is reasonable, as the number of IDR payment determinations an entity is involved in is likely to be proportional to the amount of business in which the entity is involved. Applying data from the Census bureau of receipts by size for each industry, the Departments estimate that small issuers will incur 0.2 percent of the total costs incurred by all issuers, that physicians in small offices will incur 36.8 percent of total costs incurred by all physicians, and small providers of air ambulance services will incur 31.0 percent of total costs incurred by all providers of air ambulance services. (*See* Census Bureau. ''2017 SUSB Annual Data Tables by Establishment Industry, Data by Enterprise Receipt Size.'' (May 2021). *https://www.census.gov/data/tables/2017/econ/susb/2017-susb-annual.html.*)

[314] The Annual Cost per Entity is calculated by dividing the estimated Aggregate Annual Cost for Small Entities by the Estimated Affected Small Entities.

[315] The costs for physicians refers to the cost associated with each physician. The Departments estimate that 140,270 physicians, on average, bill on an out-of-network basis and will be affected by these interim final rules, but the Departments do not have data on how many of the affected physicians are employed in small offices. This analysis is based on the number physicians affected, not the number of physician offices.

[316] IBIS World. ''Air Ambulance Service Industry in the US—Market Research Report.'' (December 2020). *https://www.ibisworld.com/united-states/market-research-reports/air-ambulance-services-industry/.*

for inflation with the base year 1995) in any one year by state, local, and tribal governments, in the aggregate, or by the private sector.[317] However, Section 202 of UMRA does not apply to interim final rules or non-notice rules issued under the 'good cause' exemption in 5 U.S.C. 553(b)(B).[318] For purposes of the UMRA, this rule does not include any Federal mandate that the Departments expect to result in such expenditures by state, local, or tribal governments.

F. Federalism Statement

Executive Order 13132 outlines fundamental principles of Federalism and requires Federal agencies to adhere to specific criteria when formulating and implementing policies that have ''substantial direct effects'' on the states, the relationship between the national government and states, or on the distribution of power and responsibilities among the various levels of government. Federal agencies promulgating regulations that have Federalism implications must consult with state and local officials and describe the extent of their consultation and the nature of the concerns of state and local officials in the preamble to the final rule.

In the Departments' view, these interim final rules have Federalism implications because they have direct effects on the states, the relationship between the national government and the states, or the distribution of power and responsibilities among various levels of government. State and local government health plans may be subject to the Federal IDR process, where a specified state law does not apply. Additionally, the No Surprises Act authorizes states to enforce the new requirements, including those related to balance billing, with respect to issuers, providers, facilities, and providers of air ambulance services, with HHS enforcing only in cases where the state has notified HHS that the state does not have the authority to enforce or is otherwise not enforcing, or HHS has made a determination that a state has failed to substantially enforce the requirements. However, in the Departments' view, the Federalism implications of these interim final rules are substantially mitigated because the Departments expect that some states will have their own process for determining the total amount payable under such a plan or coverage for emergency services and to out-of-network providers at in-network facilities. Where a state has such a specified state law, the state law, rather than the Federal IDR process, will apply. The Departments anticipate that some states with their own IDR process may want to change their laws or adopt new laws in response to these interim final rules. The Departments anticipate that these states will incur a small incremental cost when making changes to their laws.

In general, ERISA section 514 supersedes state laws to the extent that they relate to any covered employee benefit plan, including covered group health plans, and preserves state laws that regulate insurance, banking, or securities. While ERISA prohibits states from regulating a plan as an insurance or investment company or bank, the preemption provisions of ERISA section 731 and PHS Act section 2724 (implemented in 29 CFR 2590.731(a) and 45 CFR 146.143(a)) apply so that requirements of Part 7 of ERISA and title XXVII of the PHS Act (including those of the Affordable Care Act) are not to be ''construed to supersede any provision of state law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with group health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement'' of a Federal standard. The conference report accompanying HIPAA indicates that this is intended to be the ''narrowest'' preemption of state laws.[319] Additionally, the No Surprises Act requires that when a state law determines the total amount payable under such a plan, coverage, or issuer for emergency services or to out-of-network providers at in-network facilities, such state law will apply, rather than the Federal IDR process specified in these regulations.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have Federalism implications or limit the policy making discretion of the states, the Departments have engaged in efforts to consult with and work cooperatively with affected states, including participating in conference calls with and attending conferences of the NAIC, and consulting with state insurance officials on a state-by-state basis. In addition, the Departments consulted with the NAIC, as required by the No Surprises Act, to establish the geographic regions to be used in the methodology for calculating the QPA as detailed in the July 2021 interim final rule.

While developing these interim final rules, the Departments and OPM attempted to balance the states' interests in regulating health insurance issuers, providers, and facilities with the need to ensure at least the minimum Federal consumer protections in every state. By doing so, the Departments and OPM complied with the requirements of Executive Order 13132. The Departments welcome input from affected states regarding this assessment.

G. Congressional Review Act

These interim final rules are determined to be major and are subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and will be transmitted to the Congress and to the Comptroller General for review in accordance with such provisions.

Laurie Bodenheimer,

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Douglas W. O'Donnell,

Deputy Commissioner for Services and Enforcement, Internal Revenue Service.

Lily L. Batchelder,

Assistant Secretary of the Treasury (Tax Policy).

Ali Khawar,

Acting Assistant Secretary, Employee Benefits Security Administration, U.S. Department of Labor.

Xavier Becerra,

Secretary, Department of Health and Human Services.

Office of Personnel Management

5 CFR Chapter I

For the reasons stated in the preamble, the Office of Personnel Management amends 5 CFR part 890 as follows:

PART 890—FEDERAL EMPLOYEES HEALTH BENEFITS PROGRAM

■ 1. The authority citation for part 890 continues to read as follows:

Authority: 5 U.S.C. 8913; Sec. 890.102 also issued under sections 11202(f), 11232(e), and 11246 (b) of Pub. L. 105–33, 111 Stat. 251; Sec. 890.111 also issued under section 1622(b) of Pub. L. 104–106, 110 Stat. 521 (36 U.S.C. 5522); Sec. 890.112 also issued under section 1 of Pub. L. 110–279, 122 Stat. 2604 (2 U.S.C. 2051); Sec. 890.113 also issued under section 1110 of Pub. L. 116–92, 133 Stat. 1198 (5 U.S.C. 8702 note); Sec. 890.301

[317] 2 U.S.C. 1501 *et seq.* (1995).

[318] See OMB, Memorandum for the Heads of Executive Departments and Agencies, M–95–09, ''Guidance for Implementing Title II of S.1,'' 1995, available at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/1995-1998/m95-09.pdf.*

[319] *See* House Conf. Rep. No. 104–736, at 205, reprinted in 1996 U.S. Code Cong. & Admin. News 2018.

also issued under section 311 of Pub. L. 111–3, 123 Stat. 64 (26 U.S.C. 9801); Sec. 890.302(b) also issued under section 1001 of Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111–152, 124 Stat. 1029 (42 U.S.C. 300gg-14); Sec. 890.803 also issued under 50 U.S.C. 3516 (formerly 50 U.S.C. 403p) and 22 U.S.C. 4069c and 4069c–1; subpart L also issued under section 599C of Pub. L. 101–513, 104 Stat. 2064 (5 U.S.C. 5561 note), as amended; and subpart M also issued under section 721 of Pub. L. 105–261 (10 U.S.C. 1108), 112 Stat. 2061.

Subpart A—Administration and General Provisions

■ 2. Amend § 890.114 by revising paragraph (a) and adding paragraph (d) to read as follows:

§ 890.114 Surprise billing.

(a) A carrier must comply with requirements described in 26 CFR 54.9816–3T through 54.9816–8T, 54.9817–1T, 54.9817–2T and 54.9822–1T; 29 CFR 2590.716–3 through 2590.716–8, 2590.717–1, 2590.717–2 and 2590.722; and 45 CFR 149.30, 149.110 through 149.140, 149.310, 149.510, and 149.520, in the same manner as such provisions apply to a group health plan or health insurance issuer offering group or individual health insurance coverage, subject to 5 U.S.C. 8902(m)(1), and the provisions of the carrier's contract. For purposes of application of such sections, all carriers are deemed to offer health benefits in the large group market.

* * * * *

(d)(1) In addition to notification to the Department per 26 CFR 54.9816–8T(b)(2)(iii), 29 CFR 2590.716–8(b)(2)(iii), and 45 CFR 149.510(b)(2)(iii), a carrier must notify the Director of its intent to initiate the Federal IDR process, or its receipt of written notice that a provider, facility, or provider of air ambulance services has initiated the Federal IDR process, upon sending or receiving such notice.

(2) The Director will coordinate with the Departments in resolving matters under 26 CFR 54.9816–8T(c)(4)(vi)(A)(*1*), 29 CFR 2590.716–8(c)(4)(vi)(A)(*1*), or 45 CFR 149.510(c)(4)(vi)(A)(*1*) where fraud or misrepresentation are presented, and matters involving 26 CFR 54.9816–8T(c)(4)(vii)(A)(*2*), 29 CFR 2590.716–8(c)(4)(vii)(A)(*2*), and 45 CFR 149.510(c)(4)(vii)(A)(*2*). The Director will coordinate with the Departments in oversight of reports submitted by certified IDR entities with respect to carriers pursuant to 26 CFR 54.9816–8T(f), 29 CFR 2590.716–8(f), or 45 CFR 149.510(f).

Department of the Treasury

Internal Revenue Service

26 CFR Chapter I

Accordingly, 26 CFR part 54 is amended as follows:

PART 54—PENSION EXCISE TAXES

■ 3. The authority citation for part 54 continues to read, in part, as follows:

Authority: 26 U.S.C. 7805, unless otherwise noted.

* * * * *

■ 4. Section 54.9815–2719T is added to read as follows:

§ 54.9815–2719T Internal claims and appeals and external review processes (temporary).

(a) *Scope and definitions*—(1) *Scope*—(i) *In general.* This section sets forth requirements with respect to internal claims and appeals and external review processes for group health plans and health insurance issuers. Paragraph (b) of this section provides requirements for internal claims and appeals processes. Paragraph (c) of this section sets forth rules governing the applicability of State external review processes. Paragraph (d) of this section sets forth a Federal external review process for plans and issuers not subject to an applicable State external review process. Paragraph (e) of this section prescribes requirements for ensuring that notices required to be provided under this section are provided in a culturally and linguistically appropriate manner. Paragraph (f) of this section describes the authority of the Secretary to deem certain external review processes in existence on March 23, 2010, as in compliance with paragraph (c) or (d) of this section.

(ii) *Application to grandfathered health plans and health insurance coverage.* The provisions of this section generally do not apply to coverage offered by health insurance issuers and group health plans that are grandfathered health plans, as defined under § 54.9815–1251. However, the external review process requirements under paragraphs (c) and (d) of this section, and related notice requirements under paragraph (e) of this section, apply to grandfathered health plans or coverage with respect to adverse benefit determinations involving items and services within the scope of the requirements for out-of-network emergency services, nonemergency services performed by nonparticipating providers at participating facilities, and air ambulance services furnished by nonparticipating providers of air ambulance services under sections 9816 and 9817 and §§ 54.9816–4T through 54.9816–5T and 54.9817–1T.

(2) *Definitions.* For purposes of this section, the following definitions apply—

(i) *Adverse benefit determination.* An *adverse benefit determination* means an adverse benefit determination as defined in 29 CFR 2560.503–1, as well as any rescission of coverage, as described in § 54.9815–2712(a)(2) (whether or not, in connection with the rescission, there is an adverse effect on any particular benefit at that time).

(ii) *Appeal (or internal appeal).* An *appeal* or *internal appeal* means review by a plan or issuer of an adverse benefit determination, as required in paragraph (b) of this section.

(iii) *Claimant. Claimant* means an individual who makes a claim under this section. For purposes of this section, references to claimant include a claimant's authorized representative.

(iv) *External review. External review* means a review of an adverse benefit determination (including a final internal adverse benefit determination) conducted pursuant to an applicable State external review process described in paragraph (c) of this section or the Federal external review process of paragraph (d) of this section.

(v) *Final internal adverse benefit determination.* A *final internal adverse benefit determination* means an adverse benefit determination that has been upheld by a plan or issuer at the completion of the internal appeals process applicable under paragraph (b) of this section (or an adverse benefit determination with respect to which the internal appeals process has been exhausted under the deemed exhaustion rules of paragraph (b)(2)(ii)(F) of this section).

(vi) *Final external review decision.* A *final external review decision* means a determination by an independent review organization at the conclusion of an external review.

(vii) *Independent review organization (or IRO).* An *independent review organization* (or *IRO*) means an entity that conducts independent external reviews of adverse benefit determinations and final internal adverse benefit determinations pursuant to paragraph (c) or (d) of this section.

(viii) *NAIC Uniform Model Act.* The *NAIC Uniform Model Act* means the Uniform Health Carrier External Review Model Act promulgated by the National Association of Insurance Commissioners in place on July 23, 2010.

(b) *Internal claims and appeals process*—(1) *In general.* A group health plan and a health insurance issuer offering group health insurance

coverage must implement an effective internal claims and appeals process, as described in this paragraph (b).

(2) *Requirements for group health plans and group health insurance issuers.* A group health plan and a health insurance issuer offering group health insurance coverage must comply with all the requirements of this paragraph (b)(2). In the case of health insurance coverage offered in connection with a group health plan, if either the plan or the issuer complies with the internal claims and appeals process of this paragraph (b)(2), then the obligation to comply with this paragraph (b)(2) is satisfied for both the plan and the issuer with respect to the health insurance coverage.

(i) *Minimum internal claims and appeals standards.* A group health plan and a health insurance issuer offering group health insurance coverage must comply with all the requirements applicable to group health plans under 29 CFR 2560.503–1, except to the extent those requirements are modified by paragraph (b)(2)(ii) of this section. Accordingly, under this paragraph (b), with respect to health insurance coverage offered in connection with a group health plan, the group health insurance issuer is subject to the requirements in 29 CFR 2560.503–1 to the same extent as the group health plan.

(ii) *Additional standards.* In addition to the requirements in paragraph (b)(2)(i) of this section, the internal claims and appeals processes of a group health plan and a health insurance issuer offering group health insurance coverage must meet the requirements of this paragraph (b)(2)(ii).

(A) *Clarification of meaning of adverse benefit determination.* For purposes of this paragraph (b)(2), an ''adverse benefit determination'' includes an adverse benefit determination as defined in paragraph (a)(2)(i) of this section. Accordingly, in complying with 29 CFR 2560.503–1, as well as the other provisions of this paragraph (b)(2), a plan or issuer must treat a rescission of coverage (whether or not the rescission has an adverse effect on any particular benefit at that time) as an adverse benefit determination. (Rescissions of coverage are subject to the requirements of § 54.9815–2712.)

(B) *Expedited notification of benefit determinations involving urgent care.* The requirements of 29 CFR 2560.503–1(f)(2)(i) (which generally provide, among other things, in the case of urgent care claims for notification of the plan's benefit determination (whether adverse or not) as soon as possible, taking into account the medical exigencies, but not later than 72 hours after the receipt of the claim) continue to apply to the plan and issuer. For purposes of this paragraph (b)(2)(ii)(B), a claim involving urgent care has the meaning given in 29 CFR 2560.503–1(m)(1), as determined by the attending provider, and the plan or issuer shall defer to such determination of the attending provider.

(C) *Full and fair review.* A plan and issuer must allow a claimant to review the claim file and to present evidence and testimony as part of the internal claims and appeals process. Specifically, in addition to complying with the requirements of 29 CFR 2560.503–1(h)(2)—

(*1*) The plan or issuer must provide the claimant, free of charge, with any new or additional evidence considered, relied upon, or generated by the plan or issuer (or at the direction of the plan or issuer) in connection with the claim; such evidence must be provided as soon as possible and sufficiently in advance of the date on which the notice of final internal adverse benefit determination is required to be provided under 29 CFR 2560.503–1(i) to give the claimant a reasonable opportunity to respond prior to that date; and

(*2*) Before the plan or issuer can issue a final internal adverse benefit determination based on a new or additional rationale, the claimant must be provided, free of charge, with the rationale; the rationale must be provided as soon as possible and sufficiently in advance of the date on which the notice of final internal adverse benefit determination is required to be provided under 29 CFR 2560.503–1(i) to give the claimant a reasonable opportunity to respond prior to that date. Notwithstanding the rules of 29 CFR 2560.503–1(i), if the new or additional evidence is received so late that it would be impossible to provide it to the claimant in time for the claimant to have a reasonable opportunity to respond, the period for providing a notice of final internal adverse benefit determination is tolled until such time as the claimant has a reasonable opportunity to respond. After the claimant responds, or has a reasonable opportunity to respond but fails to do so, the plan administrator shall notify the claimant of the plan's benefit determination as soon as a plan acting in a reasonable and prompt fashion can provide the notice, taking into account the medical exigencies.

(D) *Avoiding conflicts of interest.* In addition to the requirements of 29 CFR 2560.503–1(b) and (h) regarding full and fair review, the plan and issuer must ensure that all claims and appeals are adjudicated in a manner designed to ensure the independence and impartiality of the persons involved in making the decision. Accordingly, decisions regarding hiring, compensation, termination, promotion, or other similar matters with respect to any individual (such as a claims adjudicator or medical expert) must not be made based upon the likelihood that the individual will support the denial of benefits.

(E) *Notice.* A plan and issuer must provide notice to individuals, in a culturally and linguistically appropriate manner (as described in paragraph (e) of this section) that complies with the requirements of 29 CFR 2560.503–1(g) and (j). The plan and issuer must also comply with the additional requirements of this paragraph (b)(2)(ii)(E).

(*1*) The plan and issuer must ensure that any notice of adverse benefit determination or final internal adverse benefit determination includes information sufficient to identify the claim involved (including the date of service, the health care provider, the claim amount (if applicable), and a statement describing the availability, upon request, of the diagnosis code and its corresponding meaning, and the treatment code and its corresponding meaning).

(*2*) The plan and issuer must provide to participants and beneficiaries, as soon as practicable, upon request, the diagnosis code and its corresponding meaning, and the treatment code and its corresponding meaning, associated with any adverse benefit determination or final internal adverse benefit determination. The plan or issuer must not consider a request for such diagnosis and treatment information, in itself, to be a request for an internal appeal under this paragraph (b) or an external review under paragraphs (c) and (d) of this section.

(*3*) The plan and issuer must ensure that the reason or reasons for the adverse benefit determination or final internal adverse benefit determination includes the denial code and its corresponding meaning, as well as a description of the plan's or issuer's standard, if any, that was used in denying the claim. In the case of a notice of final internal adverse benefit determination, this description must include a discussion of the decision.

(*4*) The plan and issuer must provide a description of available internal appeals and external review processes, including information regarding how to initiate an appeal.

(*5*) The plan and issuer must disclose the availability of, and contact

information for, any applicable office of health insurance consumer assistance or ombudsman established under PHS Act section 2793 to assist individuals with the internal claims and appeals and external review processes.

(F) *Deemed exhaustion of internal claims and appeals processes.* (*1*) In the case of a plan or issuer that fails to strictly adhere to all the requirements of this paragraph (b)(2) with respect to a claim, the claimant is deemed to have exhausted the internal claims and appeals process of this paragraph (b), except as provided in paragraph (b)(2)(ii)(F)(*2*) of this section. Accordingly the claimant may initiate an external review under paragraph (c) or (d) of this section, as applicable. The claimant is also entitled to pursue any available remedies under section 502(a) of ERISA or under State law, as applicable, on the basis that the plan or issuer has failed to provide a reasonable internal claims and appeals process that would yield a decision on the merits of the claim. If a claimant chooses to pursue remedies under section 502(a) of ERISA under such circumstances, the claim or appeal is deemed denied on review without the exercise of discretion by an appropriate fiduciary.

(*2*) Notwithstanding paragraph (b)(2)(ii)(F)(*1*) of this section, the internal claims and appeals process of this paragraph (b) will not be deemed exhausted based on de minimis violations that do not cause, and are not likely to cause, prejudice or harm to the claimant so long as the plan or issuer demonstrates that the violation was for good cause or due to matters beyond the control of the plan or issuer and that the violation occurred in the context of an ongoing, good faith exchange of information between the plan and the claimant. This exception is not available if the violation is part of a pattern or practice of violations by the plan or issuer. The claimant may request a written explanation of the violation from the plan or issuer, and the plan or issuer must provide such explanation within 10 days, including a specific description of its bases, if any, for asserting that the violation should not cause the internal claims and appeals process of this paragraph (b) to be deemed exhausted. If an external reviewer or a court rejects the claimant's request for immediate review under paragraph (b)(2)(ii)(F)(*1*) of this section on the basis that the plan met the standards for the exception under this paragraph (b)(2)(ii)(F)(*2*), the claimant has the right to resubmit and pursue the internal appeal of the claim. In such a case, within a reasonable time after the external reviewer or court rejects the claim for immediate review (not to exceed 10 days), the plan shall provide the claimant with notice of the opportunity to resubmit and pursue the internal appeal of the claim. Time periods for re-filing the claim shall begin to run upon claimant's receipt of such notice.

(iii) *Requirement to provide continued coverage pending the outcome of an appeal.* A plan and issuer subject to the requirements of this paragraph (b)(2) are required to provide continued coverage pending the outcome of an appeal. For this purpose, the plan and issuer must comply with the requirements of 29 CFR 2560.503–1(f)(2)(ii), which generally provides that benefits for an ongoing course of treatment cannot be reduced or terminated without providing advance notice and an opportunity for advance review.

(c) *State standards for external review*—(1) *In general.* (i) If a State external review process that applies to and is binding on a health insurance issuer offering group health insurance coverage includes at a minimum the consumer protections in the NAIC Uniform Model Act, then the issuer must comply with the applicable State external review process and is not required to comply with the Federal external review process of paragraph (d) of this section. In such a case, to the extent that benefits under a group health plan are provided through health insurance coverage, the group health plan is not required to comply with either this paragraph (c) or the Federal external review process of paragraph (d) of this section.

(ii) To the extent that a group health plan provides benefits other than through health insurance coverage (that is, the plan is self-insured) and is subject to a State external review process that applies to and is binding on the plan (for example, is not preempted by ERISA) and the State external review process includes at a minimum the consumer protections in the NAIC Uniform Model Act, then the plan must comply with the applicable State external review process and is not required to comply with the Federal external review process of paragraph (d) of this section. Where a self-insured plan is not subject to an applicable State external review process, but the State has chosen to expand access to its process for plans that are not subject to the applicable State laws, the plan may choose to comply with either the applicable State external review process or the Federal external review process of paragraph (d) of this section.

(iii) If a plan or issuer is not required under paragraph (c)(1)(i) or (ii) of this section to comply with the requirements of this paragraph (c), then the plan or issuer must comply with the Federal external review process of paragraph (d) of this section, except to the extent, in the case of a plan, the plan is not required under paragraph (c)(1)(i) of this section to comply with paragraph (d) of this section.

(2) *Minimum standards for State external review processes.* An applicable State external review process must meet all the minimum consumer protections in this paragraph (c)(2). The Department of Health and Human Services will determine whether State external review processes meet these requirements.

(i) The State process must provide for the external review of adverse benefit determinations (including final internal adverse benefit determinations) by issuers (or, if applicable, plans) that are based on the issuer's (or plan's) requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit, as well as a consideration of whether a plan or issuer is complying with the surprise billing and cost-sharing protections under sections 9816 and 9817 and §§ 54.9816–1T through 54.9816–6T and 54.9817–1T.

(ii) The State process must require issuers (or, if applicable, plans) to provide effective written notice to claimants of their rights in connection with an external review for an adverse benefit determination.

(iii) To the extent the State process requires exhaustion of an internal claims and appeals process, exhaustion must be unnecessary where the issuer (or, if applicable, the plan) has waived the requirement; the issuer (or the plan) is considered to have exhausted the internal claims and appeals process under applicable law (including by failing to comply with any of the requirements for the internal appeal process, as outlined in paragraph (b)(2) of this section), or the claimant has applied for expedited external review at the same time as applying for an expedited internal appeal.

(iv) The State process provides that the issuer (or, if applicable, the plan) against which a request for external review is filed must pay the cost of the IRO for conducting the external review. Notwithstanding this requirement, a State external review process that expressly authorizes, as of November 18, 2015, a nominal filing fee may continue to permit such fees. For this purpose, to be considered nominal, a filing fee must not exceed $25; it must be refunded to the claimant if the adverse benefit determination (or final

internal adverse benefit determination) is reversed through external review; it must be waived if payment of the fee would impose an undue financial hardship; and the annual limit on filing fees for any claimant within a single plan year must not exceed $75.

(v) The State process may not impose a restriction on the minimum dollar amount of a claim for it to be eligible for external review. Thus, the process may not impose, for example, a $500 minimum claims threshold.

(vi) The State process must allow at least four months after the receipt of a notice of an adverse benefit determination or final internal adverse benefit determination for a request for an external review to be filed.

(vii) The State process must provide that IROs will be assigned on a random basis or another method of assignment that assures the independence and impartiality of the assignment process (such as rotational assignment) by a State or independent entity, and in no event selected by the issuer, plan, or the individual.

(viii) The State process must provide for maintenance of a list of approved IROs qualified to conduct the external review based on the nature of the health care service that is the subject of the review. The State process must provide for approval only of IROs that are accredited by a nationally recognized private accrediting organization.

(ix) The State process must provide that any approved IRO has no conflicts of interest that will influence its independence. Thus, the IRO may not own or control, or be owned or controlled by a health insurance issuer, a group health plan, the sponsor of a group health plan, a trade association of plans or issuers, or a trade association of health care providers. The State process must further provide that the IRO and the clinical reviewer assigned to conduct an external review may not have a material professional, familial, or financial conflict of interest with the issuer or plan that is the subject of the external review; the claimant (and any related parties to the claimant) whose treatment is the subject of the external review; any officer, director, or management employee of the issuer; the plan administrator, plan fiduciaries, or plan employees; the health care provider, the health care provider's group, or practice association recommending the treatment that is subject to the external review; the facility at which the recommended treatment would be provided; or the developer or manufacturer of the principal drug, device, procedure, or other therapy being recommended.

(x) The State process allows the claimant at least five business days to submit to the IRO in writing additional information that the IRO must consider when conducting the external review, and it requires that the claimant is notified of the right to do so. The process must also require that any additional information submitted by the claimant to the IRO must be forwarded to the issuer (or, if applicable, the plan) within one business day of receipt by the IRO.

(xi) The State process must provide that the decision is binding on the plan or issuer, as well as the claimant except to the extent the other remedies are available under State or Federal law, and except that the requirement that the decision be binding shall not preclude the plan or issuer from making payment on the claim or otherwise providing benefits at any time, including after a final external review decision that denies the claim or otherwise fails to require such payment or benefits. For this purpose, the plan or issuer must provide benefits (including by making payment on the claim) pursuant to the final external review decision without delay, regardless of whether the plan or issuer intends to seek judicial review of the external review decision and unless or until there is a judicial decision otherwise.

(xii) The State process must require, for standard external review, that the IRO provide written notice to the issuer (or, if applicable, the plan) and the claimant of its decision to uphold or reverse the adverse benefit determination (or final internal adverse benefit determination) within no more than 45 days after the receipt of the request for external review by the IRO.

(xiii) The State process must provide for an expedited external review if the adverse benefit determination (or final internal adverse benefit determination) concerns an admission, availability of care, continued stay, or health care service for which the claimant received emergency services, but has not been discharged from a facility; or involves a medical condition for which the standard external review time frame would seriously jeopardize the life or health of the claimant or jeopardize the claimant's ability to regain maximum function. As expeditiously as possible but within no more than 72 hours after the receipt of the request for expedited external review by the IRO, the IRO must make its decision to uphold or reverse the adverse benefit determination (or final internal adverse benefit determination) and notify the claimant and the issuer (or, if applicable, the plan) of the determination. If the notice is not in writing, the IRO must provide written confirmation of the decision within 48 hours after the date of the notice of the decision.

(xiv) The State process must require that issuers (or, if applicable, plans) include a description of the external review process in or attached to the summary plan description, policy, certificate, membership booklet, outline of coverage, or other evidence of coverage it provides to participants, beneficiaries, or enrollees, substantially similar to what is set forth in section 17 of the NAIC Uniform Model Act.

(xv) The State process must require that IROs maintain written records and make them available upon request to the State, substantially similar to what is set forth in section 15 of the NAIC Uniform Model Act.

(xvi) The State process follows procedures for external review of adverse benefit determinations (or final internal adverse benefit determinations) involving experimental or investigational treatment, substantially similar to what is set forth in section 10 of the NAIC Uniform Model Act.

(3) *Transition period for external review processes.* (i) Through December 31, 2017, an applicable State external review process applicable to a health insurance issuer or group health plan is considered to meet the requirements of PHS Act section 2719(b). Accordingly, through December 31, 2017, an applicable State external review process will be considered binding on the issuer or plan (in lieu of the requirements of the Federal external review process). If there is no applicable State external review process, the issuer or plan is required to comply with the requirements of the Federal external review process in paragraph (d) of this section.

(ii) An applicable State external review process must apply for final internal adverse benefit determinations (or, in the case of simultaneous internal appeal and external review, adverse benefit determinations) provided on or after January 1, 2018. The Federal external review process will apply to such internal adverse benefit determinations unless the Department of Health and Human Services determines that a State law meets all the minimum standards of paragraph (c)(2) of this section. Through December 31, 2017, a State external review process applicable to a health insurance issuer or group health plan may be considered to meet the minimum standards of paragraph (c)(2), if it meets the temporary standards established by the

Secretary in guidance for a process similar to the NAIC Uniform Model Act.

(d) *Federal external review process.* A plan or issuer not subject to an applicable State external review process under paragraph (c) of this section must provide an effective Federal external review process in accordance with this paragraph (d) (except to the extent, in the case of a plan, the plan is described in paragraph (c)(1)(i) of this section as not having to comply with this paragraph (d)). In the case of health insurance coverage offered in connection with a group health plan, if either the plan or the issuer complies with the Federal external review process of this paragraph (d), then the obligation to comply with this paragraph (d) is satisfied for both the plan and the issuer with respect to the health insurance coverage. A Multi State Plan or MSP, as defined by 45 CFR 800.20, must provide an effective Federal external review process in accordance with this paragraph (d). In such circumstances, the requirement to provide external review under this paragraph (d) is satisfied when a Multi State Plan or MSP complies with standards established by the Office of Personnel Management.

(1) *Scope.*—(i) *In general.* The Federal external review process established pursuant to this paragraph (d) applies to the following:

(A) An adverse benefit determination (including a final internal adverse benefit determination) by a plan or issuer that involves medical judgment (including, but not limited to, those based on the plan's or issuer's requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit; its determination that a treatment is experimental or investigational; its determination whether a participant or beneficiary is entitled to a reasonable alternative standard for a reward under a wellness program; its determination whether a plan or issuer is complying with the nonquantitative treatment limitation provisions of Code section 9812 and § 54.9812–1, which generally require, among other things, parity in the application of medical management techniques), as determined by the external reviewer. (A denial, reduction, termination, or a failure to provide payment for a benefit based on a determination that a participant or beneficiary fails to meet the requirements for eligibility under the terms of a group health plan or health insurance coverage is not eligible for the Federal external review process under this paragraph (d));

(B) An adverse benefit determination that involves consideration of whether a plan or issuer is complying with the surprise billing and cost-sharing protections set forth in sections 9816 and 9817 and §§ 54.9816–4T through 54.9816–5T and 54.9817–1T; and

(C) A rescission of coverage (whether or not the rescission has any effect on any particular benefit at that time).

(ii) *Examples.* The rules of paragraph (d)(1)(i) of this section are illustrated by the following examples:

(A) *Example 1*—(*1*) *Facts.* A group health plan provides coverage for 30 physical therapy visits generally. After the 30th visit, coverage is provided only if the service is preauthorized pursuant to an approved treatment plan that takes into account medical necessity using the plan's definition of the term. Individual *A* seeks coverage for a 31st physical therapy visit. *A's* health care provider submits a treatment plan for approval, but it is not approved by the plan, so coverage for the 31st visit is not preauthorized. With respect to the 31st visit, *A* receives a notice of final internal adverse benefit determination stating that the maximum visit limit is exceeded.

(*2*) *Conclusion.* In this Example 1, the plan's denial of benefits is based on medical necessity and involves medical judgment. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section. Moreover, the plan's notification of final internal adverse benefit determination is inadequate under paragraphs (b)(2)(i) and (b)(2)(ii)(E)(3) of this section because it fails to make clear that the plan will pay for more than 30 visits if the service is preauthorized pursuant to an approved treatment plan that takes into account medical necessity using the plan's definition of the term. Accordingly, the notice of final internal adverse benefit determination should refer to the plan provision governing the 31st visit and should describe the plan's standard for medical necessity, as well as how the treatment fails to meet the plan's standard.

(B) *Example 2*—(*1*) *Facts.* A group health plan does not provide coverage for services provided out of network, unless the service cannot effectively be provided in network. Individual *B* seeks coverage for a specialized medical procedure from an out-of-network provider because *B* believes that the procedure cannot be effectively provided in network. *B* receives a notice of final internal adverse benefit determination stating that the claim is denied because the provider is out-of-network.

(*2*) *Conclusion.* In this Example 2, the plan's denial of benefits is based on whether a service can effectively be provided in network and, therefore, involves medical judgment. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section. Moreover, the plan's notice of final internal adverse benefit determination is inadequate under paragraphs (b)(2)(i) and (b)(2)(ii)(E)(*3*) of this section because the plan does provide benefits for services on an out-of-network basis if the services cannot effectively be provided in network. Accordingly, the notice of final internal adverse benefit determination is required to refer to the exception to the out-of-network exclusion and should describe the plan's standards for determining effectiveness of services, as well as how services available to the claimant within the plan's network meet the plan's standard for effectiveness of services.

(C) *Example 3*—(*1*) *Facts.* A group health plan generally provides benefits for services in an emergency department of a hospital or independent freestanding emergency department. Individual *C* receives pre-stabilization emergency treatment in an out-of-network emergency department of a hospital. The group health plan determines that protections for emergency services under § 54.9816–4T do not apply because the treatment did not involve ''emergency services'' within the meaning of § 54.9816–4T(c)(2)(i). *C* receives an adverse benefit determination, and the plan imposes cost-sharing requirements that are greater than the requirements that would apply if the same services were provided in an in-network emergency department.

(*2*) *Conclusion.* In this *Example 3,* the plan's determination that treatment received by *C* did not include emergency services involves medical judgment and consideration of whether the plan complied with § 54.9816–4T. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section.

(D) *Example 4*—(*1*) *Facts.* A group health plan generally provides benefits for anesthesiology services. Individual *D* undergoes a surgery at an in-network health care facility and during the course of the surgery, receives anesthesiology services from an out-of-network provider. The plan decides the claim for these services without regard to the protections related to items and services furnished by out-of-network providers at in-network facilities under § 54.9816–5T. As a result, *D* receives an adverse benefit determination for the

services and is subject to cost-sharing liability that is greater than it would be if cost sharing had been calculated in a manner consistent with the requirements of § 54.9816–5T.

(*2*) *Conclusion.* In this *Example 4,* whether the plan was required to decide the claim in a manner consistent with the requirements of § 54.9816–5T involves considering whether the plan complied with § 54.9816–5T, as well as medical judgment, because it requires consideration of the health care setting and level of care. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section.

(E) *Example 5*—(*1*) *Facts.* A group health plan generally provides benefits for services in an emergency department of a hospital or independent freestanding emergency department. Individual *E* receives emergency services in an out-of-network emergency department of a hospital, including certain post-stabilization services. The plan processes the claim for the post-stabilization services as not being for emergency services under § 54.9816–4T(c)(2)(ii) based on representations made by the treating provider that *E* was in a condition to receive notice from the provider about cost-sharing and surprise billing protections for these services, and subsequently gave informed consent to waive those protections. *E* receives an adverse benefit determination and is subject to cost-sharing requirements that are greater than the cost-sharing requirements that would apply if the services were processed in a manner consistent with § 54.9816–4T.

(*2*) *Conclusion.* In this *Example 5,* whether *E* was in a condition to receive notice about the availability of cost-sharing and surprise billing protections and give informed consent to waive those protections involves medical judgment and consideration of whether the plan complied with the requirements under § 54.9816–4T(c)(2)(ii). Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section.

(F) *Example 6*—(*1*) *Facts.* Individual *F* gives birth to a baby at an in-network hospital. The baby is born prematurely and receives certain neonatology services from a nonparticipating provider during the same visit as the birth. *F* was given notice about cost-sharing and surprise billing protections for these services, and subsequently gave informed consent to waive those protections. The claim for the neonatology services is coded as a claim for routine post-natal services and the plan decides the claim without regard to the requirements under § 54.9816–5T(a) and the fact that those protections may not be waived for neonatology services under § 54.9816–5T(b).

(*2*) *Conclusion.* In this *Example 6,* medical judgment is necessary to determine whether the correct code was used and compliance with § 54.9816–5T(a) and (b) must also be considered. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section. The Departments also note that, to the extent the nonparticipating provider balance bills Individual *F* for the outstanding amounts not paid by the plan for the neonatology services, such provider would be in violation of PHS Act section 2799B–2 and its implementing regulations at 45 CFR 149.420(a).

(G) *Example 7*—(*1*) *Facts.* A group health plan generally provides benefits to cover knee replacement surgery. Individual *G* receives a knee replacement surgery at an in-network facility and, after receiving proper notice about the availability of cost-sharing and surprise billing protections, provides informed consent to waive those protections. However, during the surgery, certain anesthesiology services are provided by an out-of-network nurse anesthetist. The claim for these anesthesiology services is decided by the plan without regard to the requirements under § 54.9816–5T(a) or to the fact that those protections may not be waived for ancillary services such as anesthesiology services provided by an out-of-network provider at an in-network facility under § 54.9816–5T(b). *G* receives an adverse benefit determination and is subject to cost-sharing requirements that are greater than the cost-sharing requirements that would apply if the services were provided in a manner consistent with § 54.9816–5T(a) and (b).

(*2*) *Conclusion.* In this *Example 7,* consideration of whether the plan complied with the requirements in § 54.9816–5T(a) and (b) is necessary to determine whether cost-sharing requirements were applied appropriately. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section.

(2) *External review process standards.* The Federal external review process established pursuant to this paragraph (d) is considered similar to the process set forth in the NAIC Uniform Model Act and, therefore satisfies the requirements of paragraph (d)(2) if such process provides the following.

(i) *Request for external review.* A group health plan or health insurance issuer must allow a claimant to file a request for an external review with the plan or issuer if the request is filed within four months after the date of receipt of a notice of an adverse benefit determination or final internal adverse benefit determination. If there is no corresponding date four months after the date of receipt of such a notice, then the request must be filed by the first day of the fifth month following the receipt of the notice. For example, if the date of receipt of the notice is October 30, because there is no February 30, the request must be filed by March 1. If the last filing date would fall on a Saturday, Sunday, or Federal holiday, the last filing date is extended to the next day that is not a Saturday, Sunday, or Federal holiday.

(ii) *Preliminary review*—(A) *In general.* Within five business days following the date of receipt of the external review request, the group health plan or health insurance issuer must complete a preliminary review of the request to determine whether:

(*1*) The claimant is or was covered under the plan or coverage at the time the health care item or service was requested or, in the case of a retrospective review, was covered under the plan or coverage at the time the health care item or service was provided;

(*2*) The adverse benefit determination or the final adverse benefit determination does not relate to the claimant's failure to meet the requirements for eligibility under the terms of the group health plan or health insurance coverage (*e.g.,* worker classification or similar determination);

(*3*) The claimant has exhausted the plan's or issuer's internal appeal process unless the claimant is not required to exhaust the internal appeals process under paragraph (b)(1) of this section; and

(*4*) The claimant has provided all the information and forms required to process an external review.

(B) Within one business day after completion of the preliminary review, the plan or issuer must issue a notification in writing to the claimant. If the request is complete but not eligible for external review, such notification must include the reasons for its ineligibility and current contact information, including the phone number, for the Employee Benefits Security Administration. If the request is not complete, such notification must describe the information or materials needed to make the request complete, and the plan or issuer must allow a claimant to perfect the request for external review within the four-month filing period or within the 48 hour period following the receipt of the notification, whichever is later.

(iii) *Referral to Independent Review Organization*—(A) *In general.* The group health plan or health insurance issuer must assign an IRO that is accredited by URAC or by similar nationally-recognized accrediting organization to conduct the external review. The IRO referral process must provide for the following:

(*1*) The plan or issuer must ensure that the IRO process is not biased and ensures independence;

(*2*) The plan or issuer must contract with at least three (3) IROs for assignments under the plan or coverage and rotate claims assignments among them (or incorporate other independent, unbiased methods for selection of IROs, such as random selection); and

(*3*) The IRO may not be eligible for any financial incentives based on the likelihood that the IRO will support the denial of benefits.

(*4*) The IRO process may not impose any costs, including filing fees, on the claimant requesting the external review.

(B) *IRO contracts.* A group health plan or health insurance issuer must include the following standards in the contract between the plan or issuer and the IRO:

(*1*) The assigned IRO will utilize legal experts where appropriate to make coverage determinations under the plan or coverage.

(*2*) The assigned IRO will timely notify a claimant in writing whether the request is eligible for external review. This notice will include a statement that the claimant may submit in writing to the assigned IRO, within ten business days following the date of receipt of the notice, additional information. This additional information must be considered by the IRO when conducting the external review. The IRO is not required to, but may, accept and consider additional information submitted after ten business days.

(*3*) Within five business days after the date of assignment of the IRO, the plan or issuer must provide to the assigned IRO the documents and any information considered in making the adverse benefit determination or final internal adverse benefit determination. Failure by the plan or issuer to timely provide the documents and information must not delay the conduct of the external review. If the plan or issuer fails to timely provide the documents and information, the assigned IRO may terminate the external review and make a decision to reverse the adverse benefit determination or final internal adverse benefit determination. Within one business day after making the decision, the IRO must notify the claimant and the plan.

(*4*) Upon receipt of any information submitted by the claimant, the assigned IRO must within one business day forward the information to the plan or issuer. Upon receipt of any such information, the plan or issuer may reconsider its adverse benefit determination or final internal adverse benefit determination that is the subject of the external review. Reconsideration by the plan or issuer must not delay the external review. The external review may be terminated as a result of the reconsideration only if the plan decides, upon completion of its reconsideration, to reverse its adverse benefit determination or final internal adverse benefit determination and provide coverage or payment. Within one business day after making such a decision, the plan must provide written notice of its decision to the claimant and the assigned IRO. The assigned IRO must terminate the external review upon receipt of the notice from the plan or issuer.

(*5*) The IRO will review all of the information and documents timely received. In reaching a decision, the assigned IRO will review the claim de novo and not be bound by any decisions or conclusions reached during the plan's or issuer's internal claims and appeals process applicable under paragraph (b) of this section. In addition to the documents and information provided, the assigned IRO, to the extent the information or documents are available and the IRO considers them appropriate, will consider the following in reaching a decision:

(*i*) The claimant's medical records;

(*ii*) The attending health care professional's recommendation;

(*iii*) Reports from appropriate health care professionals and other documents submitted by the plan or issuer, claimant, or the claimant's treating provider;

(*iv*) The terms of the claimant's plan or coverage to ensure that the IRO's decision is not contrary to the terms of the plan or coverage, unless the terms are inconsistent with applicable law;

(*v*) Appropriate practice guidelines, which must include applicable evidence-based standards and may include any other practice guidelines developed by the Federal Government, national or professional medical societies, boards, and associations;

(*vi*) Any applicable clinical review criteria developed and used by the plan or issuer, unless the criteria are inconsistent with the terms of the plan or coverage or with applicable law; and

(*vii*) To the extent the final IRO decision maker is different from the IRO's clinical reviewer, the opinion of such clinical reviewer, after considering information described in this notice, to the extent the information or documents are available and the clinical reviewer or reviewers consider such information or documents appropriate.

(*6*) The assigned IRO must provide written notice of the final external review decision within 45 days after the IRO receives the request for the external review. The IRO must deliver the notice of the final external review decision to the claimant and the plan or issuer.

(*7*) The assigned IRO's written notice of the final external review decision must contain the following:

(*i*) A general description of the reason for the request for external review, including information sufficient to identify the claim (including the date or dates of service, the health care provider, the claim amount (if applicable), and a statement describing the availability, upon request, of the diagnosis code and its corresponding meaning, the treatment code and its corresponding meaning, and the reason for the plan's or issuer's denial);

(*ii*) The date the IRO received the assignment to conduct the external review and the date of the IRO decision;

(*iii*) References to the evidence or documentation, including the specific coverage provisions and evidence-based standards, considered in reaching its decision;

(*iv*) A discussion of the principal reason or reasons for its decision, including the rationale for its decision and any evidence-based standards that were relied on in making its decision;

(*v*) A statement that the IRO's determination is binding except to the extent that other remedies may be available under State or Federal law to either the group health plan or health insurance issuer or to the claimant, or to the extent the health plan or health insurance issuer voluntarily makes payment on the claim or otherwise provides benefits at any time, including after a final external review decision that denies the claim or otherwise fails to require such payment or benefits;

(*vi*) A statement that judicial review may be available to the claimant; and

(*vii*) Current contact information, including phone number, for any applicable office of health insurance consumer assistance or ombudsman established under PHS Act section 2793.

(*viii*) After a final external review decision, the IRO must maintain records of all claims and notices associated with the external review process for six years. An IRO must make such records available for examination by the claimant, plan, issuer, or State or Federal oversight agency upon request,

except where such disclosure would violate State or Federal privacy laws.

(*iv*) *Reversal of plan's or issuer's decision.* Upon receipt of a notice of a final external review decision reversing the adverse benefit determination or final adverse benefit determination, the plan or issuer immediately must provide coverage or payment (including immediately authorizing care or immediately paying benefits) for the claim.

(3) *Expedited external review.* A group health plan or health insurance issuer must comply with the following standards with respect to an expedited external review:

(i) *Request for external review.* A group health plan or health insurance issuer must allow a claimant to make a request for an expedited external review with the plan or issuer at the time the claimant receives:

(A) An adverse benefit determination if the adverse benefit determination involves a medical condition of the claimant for which the timeframe for completion of an expedited internal appeal under paragraph (b) of this section would seriously jeopardize the life or health of the claimant or would jeopardize the claimant's ability to regain maximum function and the claimant has filed a request for an expedited internal appeal; or

(B) A final internal adverse benefit determination, if the claimant has a medical condition where the timeframe for completion of a standard external review would seriously jeopardize the life or health of the claimant or would jeopardize the claimant's ability to regain maximum function, or if the final internal adverse benefit determination concerns an admission, availability of care, continued stay, or health care item or service for which the claimant received emergency services, but has not been discharged from the facility.

(ii) *Preliminary review.* Immediately upon receipt of the request for expedited external review, the plan or issuer must determine whether the request meets the reviewability requirements set forth in paragraph (d)(2)(ii) of this section for standard external review. The plan or issuer must immediately send a notice that meets the requirements set forth in paragraph (d)(2)(ii)(B) for standard review to the claimant of its eligibility determination.

(iii) *Referral to independent review organization.* (A) Upon a determination that a request is eligible for expedited external review following the preliminary review, the plan or issuer will assign an IRO pursuant to the requirements set forth in paragraph (d)(2)(iii) of this section for standard review. The plan or issuer must provide or transmit all necessary documents and information considered in making the adverse benefit determination or final internal adverse benefit determination to the assigned IRO electronically or by telephone or facsimile or any other available expeditious method.

(B) The assigned IRO, to the extent the information or documents are available and the IRO considers them appropriate, must consider the information or documents described above under the procedures for standard review. In reaching a decision, the assigned IRO must review the claim de novo and is not bound by any decisions or conclusions reached during the plan's or issuer's internal claims and appeals process.

(iv) *Notice of final external review decision.* The plan's or issuer's contract with the assigned IRO must require the IRO to provide notice of the final external review decision, in accordance with the requirements set forth in paragraph (d)(2)(iii)(B) of this section, as expeditiously as the claimant's medical condition or circumstances require, but in no event more than 72 hours after the IRO receives the request for an expedited external review. If the notice is not in writing, within 48 hours after the date of providing that notice, the assigned IRO must provide written confirmation of the decision to the claimant and the plan or issuer.

(4) *Alternative, federally-administered external review process.* Insured coverage not subject to an applicable State external review process under paragraph (c) of this section may elect to use either the Federal external review process, as set forth under paragraph (d) of this section or the federally-administered external review process, as set forth by HHS in guidance. In such circumstances, the requirement to provide external review under this paragraph (d) is satisfied.

(e) *Form and manner of notice*—(1) *In general.* For purposes of this section, a group health plan and a health insurance issuer offering group health insurance coverage are considered to provide relevant notices in a culturally and linguistically appropriate manner if the plan or issuer meets all the requirements of paragraph (e)(2) of this section with respect to the applicable non-English languages described in paragraph (e)(3) of this section.

(2) *Requirements.* (i) The plan or issuer must provide oral language services (such as a telephone customer assistance hotline) that includes answering questions in any applicable non-English language and providing assistance with filing claims and appeals (including external review) in any applicable non-English language;

(ii) The plan or issuer must provide, upon request, a notice in any applicable non-English language; and

(iii) The plan or issuer must include in the English versions of all notices, a statement prominently displayed in any applicable non-English language clearly indicating how to access the language services provided by the plan or issuer.

(3) *Applicable non-English language.* With respect to an address in any United States county to which a notice is sent, a non-English language is an applicable non-English language if ten percent or more of the population residing in the county is literate only in the same non-English language, as determined in guidance published by the Secretary.

(f) *Secretarial authority.* The Secretary may determine that the external review process of a group health plan or health insurance issuer, in operation as of March 23, 2010, is considered in compliance with the applicable process established under paragraph (c) or (d) of this section if it substantially meets the requirements of paragraph (c) or (d) of this section, as applicable.

(g) *Applicability date.* The provisions of this section generally are applicable to group health plans and health insurance issuers for plan years beginning on or after January 1, 2017. The external review scope provision at paragraph (d)(1)(i)(B) of this section is applicable for plan years beginning on or after January 1, 2022. The external review provisions described in paragraphs (c) and (d) of this section are applicable to grandfathered health plans, with respect to the types of claims specified under paragraph (a)(1)(ii) of this section, for plan years beginning on or after January 1, 2022.

■ 5. Section 54.9816–1T is revised to read as follows:

§ 54.9816–1T Basis and scope (temporary).

(a) *Basis.* This section and §§ 54.9816–2T through 54.9816–8T, 54.9817–1T, 54.9817–2T, and 54.9822–1T implement subchapter B of chapter 100 of the Internal Revenue Code of 1986.

(b) *Scope.* This part establishes standards for group health plans with respect to surprise medical bills, transparency in health care coverage, and additional patient protections. This part also establishes an independent dispute resolution process and standards for certifying independent dispute resolution entities.

■ 6. Section 54.9816–2T is amended by revising paragraph (a) and paragraph (b) introductory text to read as follows:

§ 54.9816–2T Applicability (temporary).

(a) *In general.* (1) The requirements in §§ 54.9816–4T through 54.9816–7T, 54.9817–1T, and 54.9822–1T apply to group health plans (including grandfathered health plans as defined in § 54.9815–1251), except as specified in paragraph (b) of this section.

(2) The requirements in §§ 54.9816–8T and 54.9817–2T apply to certified IDR entities and group health plans (including grandfathered health plans as defined in § 54.9815–1251) except as specified in paragraph (b) of this section.

(b) *Exceptions.* The requirements in §§ 54.9816–4T through 54.9816–8T, 54.9817–1T, 54.9817–2T, and 54.9822–1T do not apply to the following:

* * * * *

■ 7. Section 54.9816–8T is added to read as follows:

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

(a) *Scope and definitions*—(1) *Scope.* This section sets forth requirements with respect to the independent dispute resolution (IDR) process (referred to in this section as the Federal IDR process) under which a nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services (as applicable); and a group health plan complete a requisite open negotiation period, and at least one party submits a notification under paragraph (b) of this section to initiate the Federal IDR process under paragraph (c) of this section, and under which an IDR entity (as certified under paragraph (e) of this section) determines the amount of payment under the plan for an item or service furnished by the provider or facility.

(2) *Definitions.* Unless otherwise stated, the definitions in § 54.9816–3T apply to this section. Additionally, for purposes of this section, the following definitions apply:

(i) *Batched items and services* means multiple qualified IDR items or services that are considered jointly as part of one payment determination by a certified IDR entity for purposes of the Federal IDR process. In order for a qualified IDR item or service to be included in a batched item or service, the qualified IDR item or service must meet the criteria set forth in paragraph (c)(3) of this section.

(ii) *Breach* means the acquisition, access, use, or disclosure of individually identifiable health information (IIHI) in a manner not permitted under paragraph (e)(2)(v) of this section that compromises the security or privacy of the IIHI.

(A) Breach excludes:

(*1*) Any unintentional acquisition, access, or use of IIHI by personnel, a contractor, or a subcontractor of a certified IDR entity that is acting under the authority of that certified IDR entity, if the acquisition, access, or use was made in good faith and within the scope of that authority and that does not result in further use or disclosure in a manner not permitted under paragraph (e)(2)(v) of this section.

(*2*) Any inadvertent disclosure by a person who is authorized to access IIHI at a certified IDR entity to another person authorized to access IIHI at the same certified IDR entity, and the information received as a result of the disclosure is not further used or disclosed in a manner not permitted under paragraph (e)(2)(v) of this section.

(*3*) A disclosure of IIHI in which a certified IDR entity has a good faith belief that an unauthorized person to whom the disclosure was made would not reasonably have been able to retain such information.

(B) Except as provided in paragraph (a)(2)(ii)(A) of this section, access, use, or disclosure of IIHI in a manner not permitted under paragraph (e)(2)(v) of this section is presumed to be a breach unless the certified IDR entity demonstrates that there is a low probability that the security or privacy of the IIHI has been compromised based on a risk assessment encompassing at least the following factors:

(*1*) The nature and extent of the IIHI involved, including the types of identifiers and the likelihood of re-identification;

(*2*) The unauthorized person who used the IIHI or to whom the disclosure was made;

(*3*) Whether the IIHI was actually acquired or viewed; and

(*4*) The extent to which the risk to the IIHI has been mitigated.

(iii) *Certified IDR entity* means an entity responsible for conducting determinations under paragraph (c) of this section that meets the certification criteria specified in paragraph (e) of this section and that has been certified by the Secretary, jointly with the Secretaries of Health and Human Services and Labor.

(iv) *Conflict of interest* means, with respect to a party to a payment determination or certified IDR entity, a material relationship, status, or condition of the party or certified IDR entity that impacts the ability of the certified IDR entity to make an unbiased and impartial payment determination. For purposes of this section, a conflict of interest exists when a certified IDR entity is:

(A) A group health plan; a health insurance issuer offering group health insurance coverage, individual health insurance coverage, or short-term, limited-duration insurance; a carrier offering a health benefits plan under 5 U.S.C. 8902; or a provider, a facility or a provider of air ambulance services;

(B) An affiliate or a subsidiary of a group health plan; a health insurance issuer offering group health insurance coverage, individual health insurance coverage, or short-term, limited-duration insurance; a carrier offering a health benefits plan under 5 U.S.C. 8902; or a provider, a facility, or a provider of air ambulance services;

(C) An affiliate or subsidiary of a professional or trade association representing group health plans; health insurance issuers offering group health insurance coverage, individual health insurance coverage, or short-term, limited-duration insurance; carriers offering a health benefits plan under 5 U.S.C. 8902; or providers, facilities, or providers of air ambulance services.

(D) A certified IDR entity that has, or that has any personnel, contractors, or subcontractors assigned to a determination who have, a material familial, financial, or professional relationship with a party to the payment determination being disputed, or with any officer, director, or management employee of the plan, issuer, or carrier offering a health benefits plan under 5 U.S.C. 8902; the plan administrator, plan fiduciaries, or plan, issuer, or carrier employees; the health care provider, the health care provider's group or practice association; the provider of air ambulance services, the provider of air ambulance services' group or practice association, or the facility that is a party to the dispute.

(v) *Credible information* means information that upon critical analysis is worthy of belief and is trustworthy.

(vi) *IDR entity* means an entity that may apply or has applied for certification to conduct determinations under paragraph (c) of this section, and that currently is not certified by the Secretary, jointly with the Secretaries of Health and Human Services and Labor, pursuant to paragraph (e) of this section.

(vii) *Individually identifiable health information (IIHI)* means any information, including demographic data, that relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or

future payment for the provision of health care to an individual; and

(A) That identifies the individual; or

(B) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

(viii) *Material difference* means a substantial likelihood that a reasonable person with the training and qualifications of a certified IDR entity making a payment determination would consider the submitted information significant in determining the out of network rate and would view the information as showing that the qualifying payment amount is not the appropriate out-of-network rate.

(ix) *Material familial relationship* means any relationship as a spouse, domestic partner, child, parent, sibling, spouse's or domestic partner's parent, spouse's or domestic partner's sibling, spouse's or domestic partner's child, child's parent, child's spouse or domestic partner, or sibling's spouse or domestic partner.

(x) *Material financial relationship* means any financial interest of more than five percent of total annual revenue or total annual income of a certified IDR entity, or an officer, director, or manager thereof, or of a reviewer or reviewing physician employed or engaged by a certified IDR entity to conduct or participate in any review in the Federal IDR process. The terms annual revenue and annual income do not include mediation fees received by mediators who are also arbitrators, provided that the mediator acts in the capacity of a mediator and does not represent a party in the mediation.

(xi) *Material professional relationship* means any physician-patient relationship, any partnership or employment relationship, any shareholder or similar ownership interest in a professional corporation, partnership, or other similar entity; or any independent contractor arrangement that constitutes a material financial relationship with any expert used by the certified IDR entity or any officer or director of the certified IDR entity.

(xii) *Qualified IDR item or service* means an item or service:

(A) That is an emergency service furnished by a nonparticipating provider or nonparticipating facility subject to the protections of § 54.9816–4T, 29 CFR 2590.716–4, or 45 CFR 149.110, as applicable, for which the conditions of 45 CFR 149.410(b) are not met, or an item or service furnished by a nonparticipating provider at a participating health care facility, subject to the requirements of § 54.9816–5T, 29 CFR 2590.716–5, or 45 CFR 149.120, as applicable, for which the conditions of 45 CFR 149.420(c) through (i) are not met, or air ambulance services furnished by a nonparticipating provider of air ambulance services subject to the protections of § 54.9817–1T, 29 CFR 2590.717–1, or 45 CFR 149.130, as applicable, and for which the out-of-network rate is not determined by reference to an All-Payer Model Agreement under section 1115A of the Social Security Act or a specified State law as defined in § 54.9816–3T;

(B) With respect to which a provider or facility (as applicable) or group health plan submits a notification under paragraph (b)(2) of this section;

(C) That is not an item or service that is the subject of an open negotiation under paragraph (b)(1) of this section; and

(D) That is not an item or service for which a notification under paragraph (b)(2) of this section is submitted during the 90-calendar-day period under paragraph (c)(4)(vi)(B) of this section, but that may include such an item or service if the notification is submitted during the subsequent 30-business-day period under paragraph (c)(4)(vi)(C) of this section.

(xiii) *Unsecured IIHI* means IIHI that is not rendered unusable, unreadable, or indecipherable to unauthorized persons through the use of a technology or methodology specified by the Secretary, jointly with the Secretary of Health and Human Services and the Secretary of Labor.

(b) *Determination of payment amount through open negotiation and initiation of the Federal IDR process*—(1) *Determination of payment amount through open negotiation*—(i) *In general.* With respect to an item or service that meets the requirements of paragraph (a)(2)(xii)(A) of this section, the provider, facility, or provider of air ambulance services or the group health plan may, during the 30-business-day period beginning on the day the provider, facility, or provider of air ambulance services receives an initial payment or notice of denial of payment regarding the item or service, initiate an open negotiation period for purposes of determining the out-of-network rate for such item or service. To initiate the open negotiation period, a party must send a notice to the other party (open negotiation notice) in accordance with paragraph (b)(1)(ii) of this section.

(ii) *Open negotiation notice*—(A) *Content.* The open negotiation notice must include information sufficient to identify the item(s) and service(s) (including the date(s) the item(s) or service(s) were furnished, the service code, and initial payment amount, if applicable), an offer of an out-of-network rate, and contact information for the party sending the open negotiation notice.

(B) *Manner.* The open negotiation notice must be provided, using the standard form developed by the Secretary, in writing within 30 business days beginning on the day the provider, facility, or provider of air ambulance services receives an initial payment or a notice of denial of payment from the plan regarding the item or service. The day on which the open negotiation notice is first sent by a party is the date the 30-business-day open negotiation period begins. This notice may be provided to the other party electronically (such as by email) if the following two conditions are satisfied:

(*1*) The party sending the open negotiation notice has a good faith belief that the electronic method is readily accessible by the other party; and

(*2*) The notice is provided in paper form free of charge upon request.

(2) *Initiating the Federal IDR process*—(i) *In general.* With respect to an item or service for which the parties do not agree upon an out-of-network rate by the last day of the open negotiation period under paragraph (b)(1) of this section, either party may initiate the Federal IDR process. To initiate the Federal IDR process, a party must submit a written notice of IDR initiation to the other party and to the Secretary, using the standard form developed by the Secretary, during the 4-business-day period beginning on the 31st business day after the start of the open negotiation period.

(ii) *Exception for items and services provided by certain nonparticipating providers and facilities.* A party may not initiate the Federal IDR process with respect to an item or service if, with respect to that item or service, the party knows (or reasonably should have known) that the provider or facility provided notice and received consent under 45 CFR 149.410(b) or 149.420(c) through (i).

(iii) *Notice of IDR initiation*—(A) *Content.* The notice of IDR initiation must include:

(*1*) Information sufficient to identify the qualified IDR items or services under dispute (and whether the qualified IDR items or services are designated as batched items and services as described in paragraph (c)(3) of this section), including the date(s) and location the item or service was furnished, the type of item or service (such as whether the qualified IDR item or service is an emergency service as defined in § 54.9816–4T(c)(2)(i), 29 CFR

2590.716–4(c)(2)(i), or 45 CFR 149.110(c)(2)(i), as applicable, an emergency service as defined in § 54.9816–4T(c)(2)(ii), 29 CFR 2590.716–4(c)(2)(ii), or 45 CFR 149.110(c)(2)(ii), as applicable, or a nonemergency service; and whether any service is a professional service or facility-based service), corresponding service codes, place of service code, the amount of cost sharing allowed, and the amount of the initial payment made for the qualified IDR item or service, if applicable;

(*2*) Names of the parties involved and contact information, including name, email address, phone number, and mailing address;

(*3*) State where the qualified IDR item or service was furnished;

(*4*) Commencement date of the open negotiation period under paragraph (b)(1) of this section;

(*5*) Preferred certified IDR entity;

(*6*) An attestation that the items and services under dispute are qualified IDR items or services;

(*7*) Qualifying payment amount;

(*8*) Information about the qualifying payment amount as described in § 54.9816–6T(d); and

(*9*) General information describing the Federal IDR process as specified by the Secretary.

(B) *Manner.* The initiating party must provide written notice of IDR initiation to the other party. The initiating party may satisfy this requirement by furnishing the notice of IDR initiation to the other party electronically (such as by email) if the following two conditions are satisfied—

(*1*) The initiating party has a good faith belief that the electronic method is readily accessible by the other party; and

(*2*) The notice is provided in paper form free of charge upon request.

(C) *Notice to the Secretary.* The initiating party must also furnish the notice of IDR initiation to the Secretary by submitting the notice through the Federal IDR portal. The initiation date of the Federal IDR process will be the date of receipt by the Secretary.

(c) *Federal IDR process following initiation*—(1) *Selection of certified IDR entity*—(i) *In general.* The plan or the provider, facility, or provider of air ambulance services receiving the notice of IDR initiation under paragraph (b)(2) of this section may agree or object to the preferred certified IDR entity identified in the notice of IDR initiation. If the party in receipt of the notice of IDR initiation fails to object within 3 business days, the preferred certified IDR entity identified in the notice of IDR initiation will be selected and will be treated as jointly agreed to by the parties, provided that the certified IDR entity does not have a conflict of interest. If the party in receipt of the notice of IDR initiation objects, that party must notify the initiating party of the objection and propose an alternative certified IDR entity. The initiating party must then agree or object to the alternative certified IDR entity; if the initiating party fails to agree or object to the alternative certified IDR entity, the alternative certified IDR entity will be selected and will be treated as jointly agreed to by the parties. In order to select a preferred certified IDR entity, the plan and the provider, facility, or provider of air ambulance services, must jointly agree on a certified IDR entity not later than 3 business days after the initiation date of the Federal IDR process. If the plan and the provider, facility, or provider of air ambulance services fail to agree upon a certified IDR entity within that time, the Secretary shall select a certified IDR entity in accordance with paragraph (c)(1)(iv) of this section.

(ii) *Requirements for selected certified IDR entity.* The certified IDR entity selected must be an IDR entity certified under paragraph (e) of this section, that:

(A) Does not have a conflict of interest as defined in paragraph (a)(2) of this section;

(B) Ensures that assignment of personnel to a payment determination and decisions regarding hiring, compensation, termination, promotion, or other similar matters related to personnel assigned to the dispute are not made based upon the likelihood that the assigned personnel will support a particular party to the determination being disputed other than as outlined under paragraph (c)(4)(iii) of this section; and

(C) Ensures that any personnel assigned to a payment determination do not have any conflicts of interests as defined in paragraph (a)(2) of this section regarding any party to the dispute within the 1 year immediately preceding an assignment of dispute determination, similar to the requirements laid out in 18 U.S.C. 207(b).

(iii) *Notice of certified IDR entity selection.* Upon the selection of a certified IDR entity, in accordance with paragraph (c)(1)(i) of this section, the plan or the provider or emergency facility that submitted the notice of IDR initiation under paragraph (b)(2) of this section must notify the Secretary of the selection as soon as reasonably practicable, but no later than 1 business day after such selection, through the Federal IDR portal. In addition, if the non-initiating party believes that the Federal IDR process is not applicable, the non-initiating party must also provide information regarding the Federal IDR process's inapplicability through the Federal IDR portal by the same date that the notice of certified IDR entity selection must be submitted.

(A) *Content.* If the parties have agreed on the selection of a certified IDR entity or the party in receipt of the notice of IDR initiation has not objected to the other party's selection, the notice of the certified IDR entity selection must include the following information:

(*1*) Name of the certified IDR entity;

(*2*) The certified IDR entity number; and

(*3*) Attestation by both parties, or by the initiating party if the non-initiating party fails to object to the selection of the certified IDR entity, that the selected certified IDR entity meets the requirements of paragraph (c)(1)(ii) of this section.

(B) [Reserved]

(iv) *Failure to select a certified IDR entity.* If the plan and the provider, facility, or provider of air ambulance services fail to select a certified IDR entity in accordance with paragraph (c)(1)(i) of this section, the initiating party must notify the Secretary of the failure no later than 1 business day after the date of such failure (or in other words, 4 business days after initiation of the Federal IDR process) by electronically submitting the notice as described in paragraph (c)(1)(iii) of this section but indicating that the parties have failed to select a certified IDR entity. In addition, if the non-initiating party believes that the Federal IDR process is not applicable, the non-initiating party must also provide information regarding the Federal IDR process's inapplicability through the Federal IDR portal by the same date that the notice of failure to select must be submitted. Upon notification of the failure of the parties to select a certified IDR entity, the Secretary will select a certified IDR entity that charges a fee within the allowed range of certified IDR entity fees through a random selection method not later than 6 business days after the date of initiation of the Federal IDR process and will notify the plan and the provider or facility of the selection. If there are insufficient certified IDR entities that charge a fee within the allowed range of certified IDR entity fees available to arbitrate the dispute, the Secretary, jointly with the Secretary of Health and Human Services and Secretary of Labor, will select a certified IDR entity that has received approval, as described in paragraph (e)(2)(vi)(B) of this section, to

charge a fee outside of the allowed range of certified IDR entity fees.

(v) *Review by certified IDR entity.* After selection by the parties (including when the initiating party selects a certified IDR entity and the other party does not object), or by the Secretary under paragraph (c)(1)(iv) of this section, the certified IDR entity must review the selection and attest that it meets the requirements of paragraph (c)(1)(ii) of this section. If the certified IDR entity is unable to attest that it meets the requirements of paragraph (c)(1)(ii) within 3 business days of selection, the parties, upon notification, must select another certified IDR entity under paragraph (c)(1) of this section, treating the date of notification of the failure to attest to the requirements of (c)(1)(ii) of this section as the date of initiation of the Federal IDR process for purposes of the time periods in paragraphs (c)(1)(i) and (iv) of this section. Additionally, the certified IDR entity selected must review the information submitted in the notice of IDR initiation to determine whether the Federal IDR process applies. If the Federal IDR process does not apply, the certified IDR entity must notify the Secretary and the parties within 3 business days of making that determination.

(2) *Authority to continue negotiations*—(i) *In general.* If the parties to the Federal IDR process agree on an out-of-network rate for a qualified IDR item or service after providing the notice of IDR initiation to the Secretary consistent with paragraph (b)(2) of this section, but before the certified IDR entity has made its payment determination, the amount agreed to by the parties for the qualified IDR item or service will be treated as the out-of-network rate for the qualified IDR item or service. To the extent the amount exceeds the initial payment amount (or initial denial of payment) and any cost sharing paid or required to be paid by the participant or beneficiary, payment must be made directly by the plan to the nonparticipating provider, facility, or nonparticipating provider of air ambulance services not later than 30 business days after the agreement is reached. In no instance may either party seek additional payment from the participant or beneficiary, including in instances in which the out-of-network rate exceeds the qualifying payment amount. The initiating party must send a notification to the Secretary and to the certified IDR entity (if selected) electronically through the Federal IDR portal, as soon as possible, but no later than 3 business days after the date of the agreement. The notification must include the out-of-network rate for the qualified IDR item or service and signatures from authorized signatories for both parties.

(ii) *Method of allocation of the certified IDR entity fee.* In the case of an agreement described in paragraph (c)(2)(i) of this section, the certified IDR entity is required to return half of each parties' certified IDR entity fee, unless directed otherwise by both parties. The administrative fee under paragraph (d)(2) of this section will not be returned to the parties.

(3) *Treatment of batched items and services*—(i) *In general.* Batched items and services may be submitted and considered jointly as part of one payment determination by a certified IDR entity only if the batched items and services meet the requirements of this paragraph (c)(3). Batched items and services submitted and considered jointly as part of one payment determination under this paragraph (c)(3)(i) are treated as a batched determination and subject to the fee for batched determinations under this section.

(A) The qualified IDR items and services are billed by the same provider or group of providers, the same facility, or the same provider of air ambulance services. Items and services are billed by the same provider or group of providers, the same facility, or the same provider of air ambulance services if the items or services are billed with the same National Provider Identifier or Tax Identification Number;

(B) Payment for the qualified IDR items and services would be made by the same plan;

(C) The qualified IDR items and services are the same or similar items and services. The qualified IDR items and services are considered to be the same or similar items or services if each is billed under the same service code, or a comparable code under a different procedural code system, such as Current Procedural Terminology (CPT) codes with modifiers, if applicable, Healthcare Common Procedure Coding System (HCPCS) with modifiers, if applicable, or Diagnosis-Related Group (DRG) codes with modifiers, if applicable; and

(D) All the qualified IDR items and services were furnished within the same 30-business-day period, or the same 90-calendar-day period under paragraph (c)(4)(vi)(B) of this section, as applicable.

(ii) *Treatment of bundled payment arrangements.* In the case of qualified IDR items and services billed by a provider, facility, or provider of air ambulance services as part of a bundled payment arrangement, or where a plan makes or denies an initial payment as a bundled payment, the qualified IDR items and services may be submitted as part of one payment determination. Bundled payment arrangements submitted under this paragraph (c)(3)(ii) are subject to the rules for batched determinations set forth in paragraph (c)(3)(i) of this section and the certified IDR entity fee for single determinations as set forth in paragraph (e)(2)(vii) of this section.

(4) *Payment determination for a qualified IDR item or service*—(i) *Submission of offers.* Not later than 10 business days after the selection of the certified IDR entity, the plan and the provider, facility, or provider of air ambulance services:

(A) Must each submit to the certified IDR entity:

(*1*) An offer of an out-of-network rate expressed as both a dollar amount and the corresponding percentage of the qualifying payment amount represented by that dollar amount;

(*2*) Information requested by the certified IDR entity relating to the offer.

(*3*) The following additional information, as applicable—

(*i*) For providers and facilities, information on the size of the provider's practice or of the facility (if applicable). Specifically, a group of providers must specify whether the providers' practice 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;

(*ii*) For providers and facilities, information on the practice specialty or type, respectively (if applicable);

(*iii*) For plans, information on the coverage area of the plan, the relevant geographic region for purposes of the qualifying payment amount, whether the coverage is fully-insured or partially or fully self-insured; and

(*iv*) The qualifying payment amount for the applicable year for the same or similar item or service as the qualified IDR item or service.

(B) May each submit to the certified IDR entity any information relating to the offer that was submitted by either party, except that the information may not include information on factors described in paragraph (c)(4)(v) of this section.

(ii) *Payment determination and notification.* Not later than 30 business days after the selection of the certified IDR entity, the certified IDR entity must:

(A) Select as the out-of-network rate for the qualified IDR item or service one

of the offers submitted under paragraph (c)(4)(i) of this section, taking into account the considerations specified in paragraph (c)(4)(iii) of this section (as applied to the information provided by the parties pursuant to paragraph (c)(4)(i) of this section). The certified IDR entity must select the offer closest to the qualifying payment amount unless the certified IDR entity determines that credible information submitted by either party under paragraph (c)(4)(i) clearly demonstrates that the qualifying payment amount is materially different from the appropriate out-of-network rate, or if the offers are equally distant from the qualifying payment amount but in opposing directions. In these cases, the certified IDR entity must select the offer as the out-of-network rate that the certified IDR entity determines best represents the value of the qualified IDR item or services, which could be either offer.

(B) Notify the plan and the provider or facility, as applicable, of the selection of the offer under paragraph (c)(4)(ii)(A) of this section, and provide the written decision required under (c)(4)(vi) of this section.

(iii) *Considerations in determination.* In determining which offer to select, the certified IDR entity must consider:

(A) The qualifying payment amount(s) for the applicable year for the same or similar item or service.

(B) Information requested by the certified IDR entity under paragraph (c)(4)(i)(A)(*2*) of this section relating to the offer, to the extent a party provides credible information.

(C) Additional information submitted by a party, provided the information is credible and relates to the circumstances described in paragraphs (c)(4)(iii)(C)(*1*) through (*5*) of this section, with respect to a qualified IDR item or service of a nonparticipating provider, facility, or group health plan that is the subject of a payment determination. This information must also clearly demonstrate that the qualifying payment amount is materially different from the appropriate out-of-network rate.

(*1*) The level of training, experience, and quality and outcomes measurements of the provider or facility that furnished the qualified IDR item or service (such as those endorsed by the consensus-based entity authorized in section 1890 of the Social Security Act).

(*2*) The market share held by the provider or facility or that of the plan in the geographic region in which the qualified IDR item or service was provided.

(*3*) The acuity of the participant, or beneficiary, receiving the qualified IDR item or service, or the complexity of furnishing the qualified IDR item or service to the participant or beneficiary.

(*4*) The teaching status, case mix, and scope of services of the facility that furnished the qualified IDR item or service, if applicable.

(*5*) Demonstration of good faith efforts (or lack thereof) made by the provider or facility or the plan to enter into network agreements with each other, and, if applicable, contracted rates between the provider or facility, as applicable, and the plan during the previous 4 plan years.

(D) Additional information submitted by a party, provided the information is credible and relates to the offer submitted by either party and does not include information on factors described in paragraph (c)(4)(v) of this section.

(iv) *Examples.* The rules of paragraph (c)(4)(iii) of this section are illustrated by the following examples:

(A) *Example 1*—(*1*) *Facts.* A nonparticipating provider and a group health plan are parties to a payment determination in the Federal IDR process. The nonparticipating provider submits an offer and additional written information asserting that the provider has made good faith efforts to enter into network agreements with the plan. The nonparticipating provider fails to provide any documentation of these efforts, such as correspondence or records of conversations with representatives of the plan.

(*2*) *Conclusion.* In this *Example 1,* the nonparticipating provider has submitted additional information. However, this information is not credible, as the nonparticipating provider has failed to provide any documentation in support of the provider's assertions of good faith efforts to enter into network agreements with the plan. Therefore, the certified IDR entity cannot consider the information.

(B) *Example 2*—(*1*) *Facts.* A nonparticipating provider and a group health plan are parties to a payment determination in the Federal IDR process. The nonparticipating provider submits credible information relating to the provider's level of training, experience, and quality and outcome measurements from 2019. The provider also submits credible information that clearly demonstrates that the provider's level of training and expertise was necessary for providing the service that is the subject of the payment determination to the particular patient. Further, the provider submits credible information that clearly demonstrates that the qualifying payment amount generally presumes the service would be delivered by a provider with a lower level of training, experience, and quality and outcome measurements. This information, taken together, demonstrates that the qualifying payment amount is not an appropriate payment amount, and the provider submits an offer that is higher than the qualifying payment amount and commensurate with the provider's level of training, experience, and quality and outcome measurements with respect to the service provided. The plan submits the qualifying payment amount as its offer with no additional information.

(*2*) *Conclusion.* In this *Example 2,* the nonparticipating provider has submitted information that is credible. Moreover, the credible information clearly demonstrates that the qualifying payment amount does not adequately take into account the provider's level of training, experience, and quality and outcome measurements with respect to the service provided, and that the appropriate out-of-network rate should therefore be higher than the qualifying payment amount. Accordingly, the certified IDR entity must select the provider's offer, as that offer best represents the value of the service that is the subject of the payment determination.

(C) *Example 3*—(*1*) *Facts.* A nonparticipating provider and a group health plan are parties to a payment determination in the Federal IDR process. The nonparticipating provider submits credible information to the certified IDR entity relating to the acuity of the patient that received the service, and the complexity of furnishing the service to the patient, by providing details of the service at issue and the training required to furnish the complex service. The provider contends that this information demonstrates that the qualifying payment amount is not an appropriate payment amount, and the provider submits an offer that is higher than the qualifying payment amount and equal to what the provider believes is commensurate with the acuity of the patient and the complexity of the service that is the subject of the payment determination. However, the evidence submitted by the provider does not clearly demonstrate that the qualifying payment amount fails to encompass the acuity and complexity of the service. The plan submits the qualifying payment amount as its offer, along with credible information that demonstrates how the qualifying payment amount was calculated for this particular service, taking into consideration the acuity of the patient and the complexity of the service.

(*2*) *Conclusion.* The information submitted by the provider to the certified IDR entity is credible with respect to the acuity of the patient and complexity of the service. However, in this example, the provider has not clearly demonstrated that the qualifying payment amount is materially different from the appropriate out-of-network rate, based on the acuity of the patient and the complexity of the service that is the subject of the payment determination. Accordingly, the certified IDR entity must select the offer closest to the qualifying payment amount, which is the plan's offer.

(D) *Example 4*—(*1*) *Facts.* A nonparticipating provider and a group health plan are parties to a payment determination in the Federal IDR process. The plan submits credible information demonstrating that the patent for the item that is the subject of the payment determination has expired, including written documentation that demonstrates how much the cost of the item was at the time the provider rendered service and how the qualifying payment amount exceeds that cost. The plan submits an offer that is lower than the qualifying payment amount and commensurate with the cost of the item at the time service was rendered. The nonparticipating provider submits the qualifying payment amount as its offer and also submits credible information demonstrating the provider's level of training, experience, and quality and outcome measurements from 2019, but the provider does not explain how this additional information is relevant to the cost of the item.

(*2*) *Conclusion.* In this *Example 4,* both the nonparticipating provider and plan submitted information that is credible and that may be considered by the certified IDR entity. However, only the plan provided credible information that was relevant to the service that is the subject of the payment determination. Moreover, the plan has clearly demonstrated that the qualifying payment amount does not adequately take into account the complexity of the item furnished—in this case that the item is no longer patent protected. While the provider submitted credible information, the provider failed to show how the information was relevant to the item that is the subject of the payment determination. Accordingly, the certified IDR entity must select the offer that best represents the value of the item, which is the plan's offer in this example.

(v) *Prohibition on consideration of certain factors.* In determining which offer to select, the certified IDR entity must not consider:

(A) Usual and customary charges (including payment or reimbursement rates expressed as a proportion of usual and customary charges);

(B) The amount that would have been billed by the provider or facility with respect to the qualified IDR item or service had the provisions of 45 CFR 149.410 and 149.420 (as applicable) not applied; or

(C) The payment or reimbursement rate for items and services furnished by the provider or facility payable by a public payor, including under the Medicare program under title XVIII of the Social Security Act; the Medicaid program under title XIX of the Social Security Act; the Children's Health Insurance Program under title XXI of the Social Security Act; the TRICARE program under chapter 55 of title 10, United States Code; chapter 17 of title 38, United States Code; or demonstration projects under section 1115 of the Social Security Act.

(vi) *Written decision.* (A) The certified IDR entity must explain its determination in a written decision submitted to the parties and the Secretary, in a form and manner specified by the Secretary;

(B) 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 qualifying payment amount was materially different from the appropriate out-of-network rate, based on the considerations allowed under paragraphs (c)(4)(iii)(B) through (D) of this section, with respect to the qualified IDR item or service.

(vii) *Effects of determination*—(A) *Binding.* A determination made by a certified IDR entity under paragraph (c)(4)(ii) of this section:

(*1*) Is binding upon the parties, in the absence of fraud or evidence of intentional misrepresentation of material facts presented to the certified IDR entity regarding the claim; and

(*2*) Is not subject to judicial review, except in a case described in any of paragraphs (1) through (4) of section 10(a) of title 9, United States Code.

(B) *Suspension of certain subsequent IDR requests.* In the case of a determination made by a certified IDR entity under paragraph (c)(4)(ii) of this section, the party that submitted the initial notification under paragraph (b)(2) of this section may not submit a subsequent notification involving the same other party with respect to a claim for the same or similar item or service that was the subject of the initial notification during the 90-calendar-day period following the determination.

(C) *Subsequent submission of requests permitted.* If the end of the open negotiation period specified in paragraph (b)(1) of this section occurs during the 90-calendar-day suspension period regarding claims for the same or similar item or service that were the subject of the initial notice of IDR determination as described in paragraph (c)(4)(vi) of this section, either party may initiate the Federal IDR process for those claims by submitting a notification as specified in paragraph (b)(2) of this section during the 30-business-day period beginning on the day after the last day of the 90-calendar-day suspension period.

(viii) *Recordkeeping requirements.* The certified IDR entity must maintain records of all claims and notices associated with the Federal IDR process with respect to any determination for 6 years. The certified IDR entity must make these records available for examination by the plan, provider, facility, provider of air ambulance services, or a State or Federal oversight agency upon request, except to the extent the disclosure would violate either State or Federal privacy law.

(ix) *Payment.* If applicable, the amount of the offer selected by the certified IDR entity (less the sum of the initial payment and any cost sharing paid or owed by the participant or beneficiary) must be paid directly to the provider, facility, or provider of air ambulance services not later than 30 calendar days after the determination by the certified IDR entity. If the offer selected by the certified IDR entity is less than the sum of the initial payment and any cost sharing paid by the participant or beneficiary, the provider, facility, or provider of air ambulance services will be liable to the plan for the difference. The provider, facility, or provider of air ambulance services must pay the difference directly to the plan not later than 30 calendar days after the determination by the certified IDR entity.

(d) *Costs of IDR process*—(1) *Certified IDR entity fee.* (i) With respect to the Federal IDR process described in paragraph (c) of this section, the party whose offer submitted to the certified IDR entity under paragraph (c)(4)(ii)(A) of this section is not selected is responsible for the payment to the certified IDR entity of the predetermined fee charged by the certified IDR entity.

(ii) Each party to a determination for which a certified IDR entity is selected under paragraph (c)(1) of this section must pay the predetermined certified

IDR entity fee charged by the certified IDR entity to the certified IDR entity at the time the parties submit their offers under (c)(4)(i) of this section. The certified IDR entity fee paid by the prevailing party whose offer is selected by the certified IDR entity will be returned to that party within 30 business days following the date of the certified IDR entity's determination.

(2) *Administrative fee.* (i) Each party to a determination for which a certified IDR entity is selected under paragraph (c)(1) of this section must, at the time the certified IDR entity is selected under paragraph (c)(1), pay to the certified IDR entity a non-refundable administrative fee due to the Secretary for participating in the Federal IDR process described in this section.

(ii) The administrative fee amount will be established in guidance published annually by the Secretary in a manner such that the total fees paid for a year are estimated to be equal to the projected amount of expenditures by the Departments of the Treasury, Labor, and Health and Human Services for the year in carrying out the Federal IDR process.

(e) *Certification of IDR entity*—(1) *In general.* In order to be selected under paragraph (c)(1) of this section—

(i) An IDR entity must meet the standards described in this paragraph (e) and be certified by the Secretary, jointly with the Secretaries of Health and Human Services and Labor, as set forth in this paragraph (e) and guidance promulgated by the Secretary. Once certified, the IDR entity will be provided with a certified IDR entity number.

(ii) An IDR entity must provide written documentation to the Secretary regarding general company information (such as contact information, Taxpayer Identification Number, and website), as well as the applicable service area in which the IDR entity intends to conduct payment determinations under the Federal IDR process. IDR entities may choose to submit their application for all States or self-limit to a particular subset of States.

(iii) An IDR entity that the Secretary, jointly with the Secretary of Labor and the Secretary of Health and Human Services, certifies must enter into an agreement as a condition of certification. The agreement shall include specified provisions encompassed by this section, including, but not limited to, the requirements applicable to certified IDR entities when making payment determinations, as well as the requirements regarding certification and revocation (such as specifications for wind-down activities and reallocation of certified IDR entity fees, where warranted).

(2) *Requirements.* An IDR entity must provide written documentation to the Secretary through the Federal IDR portal that demonstrates that the IDR entity satisfies the following standards to be a certified IDR entity under this paragraph (e):

(i) Possess (directly or through contracts or other arrangements) sufficient arbitration and claims administration of health care services, managed care, billing and coding, medical and legal expertise to make the payment determinations described in paragraph (c) of this section within the time prescribed in paragraph (c)(4)(ii) of this section.

(ii) Employ (directly or through contracts or other arrangements) a sufficient number of personnel to make the determinations described in paragraph (c) of this section within the time prescribed by (c)(4)(ii) of this section. To satisfy this standard, the written documentation must include a description of the IDR entity's organizational structure and capabilities, including an organizational chart and the credentials, responsibilities, and number of personnel employed to make determinations described in paragraph (c) of this section.

(iii) Maintain a current accreditation from a nationally recognized and relevant accrediting organization, such as URAC, or ensure that it otherwise possesses the requisite training to conduct payment determinations (for example, providing documentation that personnel employed by the IDR entity have completed arbitration training by the American Arbitration Association, the American Health Law Association, or a similar organization);

(iv) Have a process to ensure that no conflict of interest, as defined in paragraph (a)(2) of this section, exists between the parties and the personnel the certified IDR entity assigns to a payment determination to avoid violating paragraph (c)(1)(ii) of this section, including policies and procedures for conducting ongoing audits for conflicts of interest, to ensure that should any conflicts of interest arise, the certified IDR entity has procedures in place to inform the Secretary, jointly with the Secretary of Health and Human Services and the Secretary of Labor, of the conflict of interest and to mitigate the risk by reassigning the dispute to other personnel in the event that any personnel previously assigned have a conflict of interest.

(v) Have a process to maintain the confidentiality of IIHI obtained in the course of conducting determinations. A certified IDR entity's responsibility to comply with these confidentiality requirements shall survive revocation of the IDR entity's certification for any reason, and IDR entities must comply with the record retention and disposal requirements described in this section. Under this process, once certified, the certified IDR entity must comply with the following requirements:

(A) *Privacy.* The certified IDR entity may create, collect, handle, disclose, transmit, access, maintain, store, and/or use IIHI, only to perform:

(*1*) The certified IDR entity's required duties described in this section; and

(*2*) Functions related to carrying out additional obligations as may be required under applicable Federal or State laws or regulations.

(B) *Security.* (*1*) The certified IDR entity must ensure the confidentiality of all IIHI it creates, obtains, maintains, stores, and transmits;

(*2*) The certified IDR entity must protect against any reasonably anticipated threats or hazards to the security of this information;

(*3*) The certified IDR entity must ensure that IIHI is securely destroyed or disposed of in an appropriate and reasonable manner 6 years from either the date of its creation or the first date on which the certified IDR entity had access to it, whichever is earlier;

(*4*) The certified IDR entity must implement policies and procedures to prevent, detect, contain, and correct security violations in the event of a breach of IIHI;

(C) *Breach notification.* The certified IDR entity must, following the discovery of a breach of unsecured IIHI, notify of the breach the provider, facility, or provider of air ambulance services; the plan; the Secretary, jointly with the Secretary of Health and Human Services and the Secretary of Labor; and each individual whose unsecured IIHI has been, or is reasonably believed to have been, subject to the breach, to the extent possible.

(*1*) *Breaches treated as discovered.* For purposes of this paragraph (e)(2)(v)(C), a breach shall be treated as discovered by a certified IDR entity as of the first day on which the breach is known to the certified IDR entity or, by exercising reasonable diligence, would have been known to the certified IDR entity. A certified IDR entity shall be deemed to have knowledge of a breach if the breach is known, or by exercising reasonable diligence would have been known, to any person, other than the person committing the breach, who is

an employee, officer, or other agent of the certified IDR entity;

(*2*) *Timing of notification.* A certified IDR entity must provide the notification required by this paragraph (e)(2)(v)(C) without unreasonable delay and in no case later than 60 calendar days after discovery of a breach.

(*3*) *Content of notification.* The notification required by this paragraph (e)(2)(v)(C) must include, to the extent possible:

(*i*) 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;

(*ii*) 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;

(*iii*) 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);

(*iv*) 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

(*v*) 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.

(*4*) *Method for providing notification.* A certified IDR entity must submit the notification required by this paragraph (e)(2)(v)(C) in written form (in clear and understandable language) either on paper or electronically through the Federal IDR portal or electronic mail.

(D) *Application to contractor and subcontractors.* The certified IDR entity must ensure compliance with this paragraph (e)(2)(v) of this section by any contractor or subcontractor with access to IIHI performing any duties related to the Federal IDR process.

(vi) Meet appropriate indicators of fiscal integrity and stability by demonstrating that the certified IDR entity has a system of safeguards and controls in place to prevent and detect improper financial activities by its employees and agents to assure fiscal integrity and accountability for all certified IDR entity fees and administrative fees received, held, and disbursed and by submitting 3 years of financial statements or, if not available, other information to demonstrate fiscal stability of the IDR entity;

(vii) Provide a fixed fee for single determinations and a separate fixed fee for batched determinations within the upper and lower limits for each, as set forth in guidance issued by the Secretary. The certified IDR entity may not charge a fee that is not within the approved limits as set forth in guidance unless the certified IDR entity or IDR entity seeking certification receives written approval from the Secretary to charge a flat rate beyond the upper or lower limits approved by the Secretary for fees. The certified IDR entity or IDR entity seeking certification may update its fees and seek approval from the Secretary to charge a flat fee beyond the upper or lower limits for fees annually as provided in guidance. In order for the certified IDR entity to receive the Secretary's written approval to charge a flat fee beyond the upper or lower limits for fees as set forth in guidance, it must satisfy both conditions in paragraphs (e)(2)(vii)(A) and (B) of this section as follows:

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

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

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

(*3*) A description of how the alternative flat rate will be used to mitigate the effects of these circumstances; and

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

(viii) Have a procedure in place to retain the certified IDR entity fees described in paragraph (d)(1) of this section paid by both parties in a trust or escrow account and to return the certified IDR entity fee paid by the prevailing party of an IDR payment determination, or half of each party's certified IDR entity fee in the case of an agreement described in paragraph (c)(2)(i) of this section, within 30 business days following the date of the determination;

(ix) Have a procedure in place to retain the administrative fees described in paragraph (d)(2) of this section and to remit the administrative fees to the Secretary in accordance with the timeframe and procedures set forth in guidance published by the Secretary;

(x) Discharge its responsibilities in accordance with paragraph (c) of this section, including not making any determination with respect to which the certified IDR entity would not be eligible for selection pursuant to paragraph (c)(1) of this section; and

(xi) Collect the information required to be reported to the Secretary under paragraph (f) of this section and report the information on a timely basis in the form and manner provided in guidance published by the Secretary.

(3) *Conflict-of-interest standards.* In addition to the general standards set forth in paragraph (e)(2)(iv) of this section, an IDR entity must provide written documentation that the IDR entity satisfies the standards to be a certified IDR entity under this paragraph (e)(3).

(i) The IDR entity must provide an attestation indicating that it does not have a conflict of interest as defined in paragraph (a)(2) of this section;

(ii) The IDR entity must have procedures in place to ensure that personnel assigned to a determination do not have any conflicts of interest regarding any party to the dispute within the 1 year immediately preceding an assignment of dispute determination, similar to the requirements laid out in 18 U.S.C. 207(b). In order to satisfy this requirement, if certified, the IDR entity must ensure that any personnel assigned to a determination do not have any conflicts of interest as defined in paragraph (a)(2) of this section.

(iii) Following certification under this paragraph (e), if a certified IDR entity acquires control of, becomes controlled by, or comes under common control with any entity described in paragraph (e)(3)(i) of this section, the certified IDR entity must notify the Secretary in writing no later than 3 business days after the acquisition or exercise of control and shall be subject to revocation of certification under paragraph (e)(6)(ii) of this section.

(4) *Period of certification.* Subject to paragraphs (e)(5) and (6) of this section, each certification (including a recertification) of a certified IDR entity under the process described in paragraph (e)(1) of this section will be effective for a 5-year period.

(5) *Petition for denial or revocation*—(i) *In general.* An individual, provider, facility, provider of air ambulance services, plan, or issuer may petition for a denial of a certification for an IDR entity or a revocation of a certification for a certified IDR entity for failure to meet a requirement of this section using the standard form and manner set forth in guidance issued by the Secretary. The petition for denial of a certification must be submitted within the timeframe set forth in guidance issued by the Secretary.

(ii) *Content of petition.* The individual, provider, facility, provider of air ambulance services, plan, or issuer seeking denial or revocation of certification must submit a written petition using the standard form issued by the Secretary including the following information:

(A) The identity of the IDR entity seeking certification or certified IDR entity that is the subject of the petition;

(B) The reason(s) for the petition;

(C) Whether the petition seeks denial or revocation of a certification;

(D) Documentation to support the reasons outlined in the petition; and

(E) Other information as may be required by the Secretary.

(iii) *Process.* (A) The Secretary, jointly with the Secretary of Health and Human Services and the Secretary of Labor, will acknowledge receipt of the petition within 10 business days of receipt of the petition.

(B) If the Secretary finds that the petition adequately shows a failure of the IDR entity seeking certification or the certified IDR entity to follow the requirements of this paragraph (e), the Secretary, jointly with the Secretary of Health and Human Services and the Secretary of Labor, will notify the IDR entity seeking certification or the certified IDR entity by providing a de-identified copy of the petition. Following the notification, the IDR entity seeking certification or certified IDR entity will have 10 business days to provide a response. After the time period for providing the response has passed, the Secretary, jointly with the Secretary of Health and Human Services and the Secretary of Labor, will review the response (if any), determine whether a denial or revocation of a certification is warranted, and issue a notice of the decision to the IDR entity or certified IDR entity and to the petitioner. This decision will be subject to the appeal requirements of paragraph (e)(6)(v) of this section.

(C) Effect on certification under petition. Regarding a petition for revocation of a certified IDR entity's certification, if the Secretary, jointly with the Secretary of Health and Human Services and the Secretary of Labor, finds that the petition adequately shows a failure to comply with the requirements of this paragraph (e), following the Secretary's notification of the failure to the certified IDR entity under paragraph (e)(5)(iii)(B) of this section, the certified IDR entity may continue to work on previously assigned determinations but may not accept new determinations until the Secretary issues a notice of the decision to the certified IDR entity finding that a revocation of certification is not warranted.

(6) *Denial of IDR entity certification or revocation of certified IDR entity certification*—(i) *Denial of IDR entity certification.* The Secretary, jointly with the Secretary of Health and Human Services and the Secretary of Labor, may deny the certification of an IDR entity under paragraph (e)(1) of this section if, during the process of certification, including as a result of a petition described in paragraph (e)(5) of this section, the Secretary determines the following:

(A) The IDR entity fails to meet the applicable standards set forth under this paragraph (e);

(B) The IDR entity has committed or participated in fraudulent or abusive activities, including, during the certification process, submitting fraudulent data, or submitting information or data the IDR entity knows to be false to the Secretary, the Secretary of Health and Human Services, or the Secretary of Labor;

(C) The IDR entity has failed to comply with requests for information from the Secretary, the Secretary of Health and Human Services, or the Secretary of Labor as part of the certification process;

(D) In conducting payment determinations, including those outside the Federal IDR process, the IDR entity has failed to meet the standards that applied to those determinations or reviews, including standards of independence and impartiality; or

(E) The IDR entity is otherwise not fit or qualified to make determinations under the Federal IDR process.

(ii) *Revocation of certification of a certified IDR entity.* The Secretary, jointly with the Secretary of Health and Human Services and the Secretary of Labor, may revoke the certification of a certified IDR entity under paragraph (e)(1) of this section if, as a result of an audit, a petition described in paragraph (e)(5) of this section, or otherwise, the Secretary determines the following:

(A) The certified IDR entity has a pattern or practice of noncompliance with any requirements of this paragraph (e);

(B) The certified IDR entity is operating in a manner that hinders the efficient and effective administration of the Federal IDR process;

(C) The certified IDR entity no longer meets the applicable standards for certification set forth under this paragraph (e);

(D) The certified IDR entity has committed or participated in fraudulent or abusive activities, including submission of false or fraudulent data to the Secretary, the Secretary of Health and Human Services, or the Secretary of Labor;

(E) The certified IDR entity lacks the financial viability to provide arbitration under the Federal IDR process;

(F) The certified IDR entity has failed to comply with requests from the Secretary, the Secretary of Health and Human Services, or the Secretary of Labor made as part of an audit, including failing to submit all records of the certified IDR entity that pertain to its activities within the Federal IDR process; or

(G) The certified IDR entity is otherwise no longer fit or qualified to make determinations.

(iii) *Notice of denial or revocation.* The Secretary, jointly with the Secretary of Health and Human Services and the Secretary of Labor, will issue a written notice of denial to the IDR entity or revocation to the certified IDR entity within 10 business days of the Secretary's decision, including the effective date of denial or revocation, the reason(s) for denial or revocation, and the opportunity to request appeal of the denial or revocation.

(iv) *Request for appeal of denial or revocation.* To request an appeal, the IDR entity or certified IDR entity must submit a request for appeal to the Secretary within 30 business days of the date of the notice under paragraph (e)(6)(iii) of this section of denial or revocation and in the manner prescribed by the instructions to the notice. During this time period, the Secretary, jointly with the Secretary of Health and Human Services and the Secretary of Labor, will not issue a notice of final denial or revocation and a certified IDR entity may continue to work on previously assigned determinations but may not accept new determinations. If the IDR entity or certified IDR entity does not timely submit a request for appeal of the denial or revocation, the Secretary, jointly with the Secretary of Health and Human Services and the Secretary of Labor, will issue a notice of final denial or revocation to the IDR entity or certified IDR entity (if applicable) and the petitioner.

(v) *Denial or final revocation.* Upon notice of denial or final revocation, the IDR entity shall not be considered a certified IDR entity and therefore shall not be eligible to accept payment determinations under the Federal IDR process. Moreover, after a notice of final revocation, the IDR entity may not re-apply to be a certified IDR entity until on or after the 181st day after the date of the notice of denial or final revocation.

(f) *Reporting of information relating to the Federal IDR process*—(1) *Reporting of information.* Within 30 business days of the close of each month, for qualified IDR items and services furnished on or after January 1, 2022, each certified IDR entity must, in a form and manner specified by the Secretary, report:

(i) The number of notices of IDR initiation submitted under paragraph (b)(2) of this section to the certified IDR entity during the immediately preceding month;

(ii) The size of the provider practices and the size of the facilities submitting notices of IDR initiation under paragraph (b)(2) of this section during the immediately preceding month, as required to be provided to the certified IDR entity under paragraph (c)(4)(i)(A)(*2*) of this section;

(iii) The number of such notices of IDR initiation with respect to which a determination was made under paragraph (c)(4)(ii) of this section;

(iv) The number of times during the month that the out-of-network rate determined (or agreed to) under this section has exceeded the qualifying payment amount, specified by qualified IDR items and services;

(v) With respect to each notice of IDR initiation under paragraph (b)(2) of this section for which such a determination was made, the following information:

(A) A description of the qualified IDR items and services included with respect to the notification, including the relevant billing and service codes;

(B) The relevant geographic region for purposes of the qualifying payment amount for the qualified IDR items and services with respect to which the notification was provided;

(C) The amount of the offer submitted under paragraph (c)(4)(i) of this section by the plan and by the provider or facility (as applicable) expressed as a dollar amount and as a percentage of the qualifying payment amount;

(D) Whether the offer selected by the certified IDR entity under paragraph (c)(4) of this section was the offer submitted by the plan or by the provider or facility (as applicable);

(E) The amount of the selected offer expressed as a dollar amount and as a percentage of the qualifying payment amount;

(F) The rationale for the certified IDR entity's decision, including the extent to which the decision relied on the criteria in paragraph (c)(4)(iv) of this section;

(G) The practice specialty or type of each provider or facility, respectively, involved in furnishing each qualified IDR item or service;

(H) The identity for each plan, and provider or facility, with respect to the notification. Specifically, each certified IDR entity must provide each party's name and address, as applicable; and

(I) 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.

(vi) The total amount of certified IDR entity fees paid to the certified IDR entity under paragraph (d)(1) of this section during the month.

(g) *Extension of time periods for extenuating circumstances*—(1) *General.* The time periods specified in this section (other than the time for payment, if applicable, under paragraph (c)(4)(ix) of this section) may be extended in extenuating circumstances at the Secretary's discretion if:

(i) An extension is necessary to address delays due to matters beyond the control of the parties or for good cause; and

(ii) The parties attest that prompt action will be taken to ensure that the determination under this section is made as soon as administratively practicable under the circumstances.

(2) *Process to request an extension.* The parties may request an extension by submitting a request for extension due to extenuating circumstances through the Federal IDR portal if the extension is necessary to address delays due to matters beyond the control of the parties or for good cause.

(h) *Applicability date.* The provisions of this section are applicable with respect to plan years beginning on or after January 1, 2022, except that the provisions regarding IDR entity certification at paragraphs (a) and (e) of this section are applicable beginning on October 7, 2021.

■ 8. Section 54.9817–2T is added to read as follows:

§ 54.9817–2T Independent dispute resolution process for air ambulance services (temporary).

(a) *Definitions.* Unless otherwise stated, the definitions in § 54.9816–3T apply.

(b) *Determination of out-of-network rates to be paid by group health plans; independent dispute resolution process*—(1) *In general.* Except as provided in paragraphs (b)(2) and (3) of this section, in determining the out-of-network rate to be paid by group health plans for out-of-network air ambulance services, plans must comply with the requirements of § 54.9816–8T, except that references in § 54.9816–8T to the additional circumstances in § 54.9816–8T(c)(4)(iii)(C) shall be understood to refer to § 54.9817–2T(b)(2).

(2) *Additional information.* Additional information submitted by a party, provided the information is credible, relates to the circumstances described in paragraphs (b)(2)(i) through (vi) of this section, with respect to a qualified IDR service of a nonparticipating provider of air ambulance services or group health plan that is the subject of a payment determination. This information must also clearly demonstrate that the qualifying payment amount is materially different from the appropriate out-of-network rate.

(i) The quality and outcomes measurements of the provider that furnished the services.

(ii) The acuity of the condition of the participant or beneficiary receiving the service, or the complexity of furnishing the service to the participant or beneficiary.

(iii) The training, experience, and quality of the medical personnel that furnished the air ambulance services.

(iv) Ambulance vehicle type, including the clinical capability level of the vehicle.

(v) Population density of the point of pick-up (as defined in 42 CFR 414.605) for the air ambulance (such as urban, suburban, rural, or frontier).

(vi) Demonstrations of good faith efforts (or lack thereof) made by the nonparticipating provider of air ambulance services or the plan to enter into network agreements with each other and, if applicable, contracted rates between the provider of air ambulance services and the plan during the previous 4 plan years.

(3) *Reporting of information relating to the IDR process.* In applying the requirements of § 54.9816–8T(f), within 30 business days of the close of each month, for services furnished on or after January 1, 2022, the information the certified IDR entity must report, in a form and manner specified by the Secretary, with respect to the Federal IDR process involving air ambulance services is:

(i) The number of notices of IDR initiation submitted under the Federal IDR process to the certified IDR entity that pertain to air ambulance services during the immediately preceding month;

(ii) The number of such notices of IDR initiation with respect to which a final determination was made under § 54.9816–8T(c)(4)(ii) (as applied by paragraph (b)(1) of this section);

(iii) The number of times the payment amount determined (or agreed to) under this subsection has exceeded the qualifying payment amount, specified by services;

(iv) With respect to each notice of IDR initiation under § 54.9816–8T(b)(2) (as applied by paragraph (b)(1) of this section) for which a determination was made, the following information:

(A) A description of each air ambulance service included in such notification, including the relevant billing and service codes;

(B) The point of pick-up (as defined in 42 CFR 414.605) for the services included in such notification;

(C) The amount of the offers submitted under § 54.9816–8T(c)(4)(i) (as applied by paragraph (b)(1) of this section) by the group health plan and by the nonparticipating provider of air ambulance services, expressed as a dollar amount and as a percentage of the qualifying payment amount;

(D) Whether the offer selected by the certified IDR entity under § 54.9816–8T(c)(4)(ii) (as applied by paragraph (b)(1) of this section) to be the payment amount applied was the offer submitted by the plan or by the provider of air ambulance services;

(E) The amount of the selected offer expressed as a dollar amount and as a percentage of the qualifying payment amount;

(F) The rationale for the certified IDR entity's decision, including the extent to which the decision relied on the criteria in paragraph (b)(2) of this section;

(G) Air ambulance vehicle type, including the clinical capability level of such vehicle (to the extent this information has been provided to the certified IDR entity);

(H) The identity for each plan and provider of air ambulance services, with respect to the notification. Specifically, each certified IDR entity must provide each party's name and address, as applicable; and

(I) For each determination, 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.

(v) The total amount of certified IDR entity fees paid to the certified IDR entity under paragraph § 54.9816–8T(d)(1) (as applied by paragraph (b)(1) of this section) during the month for determinations involving air ambulance services.

(c) *Applicability date.* The provisions of this section are applicable with respect to plan years beginning on or after January 1, 2022.

Employee Benefits Security Administration

29 CFR Chapter XXV

For the reasons set forth in the preamble, the Department of Labor amends 29 CFR part 2590 as set forth below:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ 9. The authority citation for part 2590 continues to read as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a–n, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104–191, 110 Stat. 1936; sec. 401(b), Pub. L. 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111–152, 124 Stat. 1029; Division M, Pub. L. 113–235, 128 Stat. 2130; Secretary of Labor's Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

Subpart C—Other Requirements

■ 10. Section 2590.715–2719 is amended by:

■ a. Revising paragraphs (a)(1), (c)(2)(i), and (d)(1)(i)(A) and (B);

■ b. Adding paragraph (d)(1)(i)(C);

■ c. Adding Examples 3 through 7 to paragraph (d)(1)(ii); and

■ d. Revising paragraph (g).

The revisions and additions read as follows:

§ 2590.715–2719 Internal claims and appeals and external review processes.

(a) *Scope and definitions*—(1) *Scope*—(i) *In general.* This section sets forth requirements with respect to internal claims and appeals and external review processes for group health plans and health insurance issuers. Paragraph (b) of this section provides requirements for internal claims and appeals processes. Paragraph (c) of this section sets forth rules governing the applicability of State external review processes. Paragraph (d) of this section sets forth a Federal external review process for plans and issuers not subject to an applicable State external review process. Paragraph (e) of this section prescribes requirements for ensuring that notices required to be provided under this section are provided in a culturally and linguistically appropriate manner. Paragraph (f) of this section describes the authority of the Secretary to deem certain external review processes in existence on March 23, 2010 as in compliance with paragraph (c) or (d) of this section.

(ii) *Application to grandfathered health plans and health insurance coverage.* The provisions of this section generally do not apply to coverage offered by health insurance issuers and group health plans that are grandfathered health plans, as defined under § 2590.715–1251. However, the external review process requirements under paragraphs (c) and (d) of this section, and related notice requirements under paragraph (e) of this section, apply to grandfathered health plans or coverage with respect to adverse benefit determinations involving items and services within the scope of the requirements for out-of-network emergency services, nonemergency services performed by nonparticipating providers at participating facilities, and air ambulance services furnished by nonparticipating providers of air ambulance services under ERISA sections 716 and 717 and §§ 2590.716–4 through 2590.716–5 and 2590.717–1.

* * * * *

(c) * * *

(2) * * *

(i) The State process must provide for the external review of adverse benefit determinations (including final internal adverse benefit determinations) by issuers (or, if applicable, plans) that are based on the issuer's (or plan's) requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit, as well as a consideration of whether a plan or issuer is complying with the surprise billing and cost-sharing protections under ERISA sections 716 and 717 and §§ 2590.716–4 through 2590.716–5 and 2590.717–1.

* * * * *

(d) * * *

(1) * * *

(i) * * *

(A) An adverse benefit determination (including a final internal adverse benefit determination) by a plan or issuer that involves medical judgment (including, but not limited to, those based on the plan's or issuer's requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit; its determination that a treatment is experimental or investigational; its determination whether a participant or beneficiary is entitled to a reasonable alternative standard for a reward under a wellness program; its determination whether a plan or issuer is complying with the nonquantitative treatment limitation provisions of ERISA section 712 and § 2590.712, which generally require, among other things, parity in the application of medical management techniques), as determined by the external reviewer. (A denial, reduction, termination, or a failure to provide payment for a benefit based on a determination that a participant or beneficiary fails to meet the

requirements for eligibility under the terms of a group health plan or health insurance coverage is not eligible for the Federal external review process under this paragraph (d));

(B) An adverse benefit determination that involves consideration of whether a plan or issuer is complying with the surprise billing and cost-sharing protections set forth in ERISA sections 716 and 717 and §§ 2590.716–4 through 2590.716–5 and 2590.717–1; and

(C) A rescission of coverage (whether or not the rescission has any effect on any particular benefit at that time).

(ii) * * *

Example 3. (i) *Facts.* A group health plan generally provides benefits for services in an emergency department of a hospital or independent freestanding emergency department. Individual *C* receives pre-stabilization emergency treatment in an out-of-network emergency department of a hospital. The group health plan determines that protections for emergency services under § 2590.716–4 do not apply because the treatment did not involve ''emergency services'' within the meaning of § 2590.716–4(c)(2)(i). *C* receives an adverse benefit determination and the plan imposes cost-sharing requirements that are greater than the requirements that would apply if the same services were provided in an in-network emergency department.

(ii) *Conclusion.* In this *Example 3,* the plan's determination that treatment received by *C* did not include emergency services involves medical judgment and consideration of whether the plan complied with § 2590.716–4. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section.

* * * * *

Example 4. (i) *Facts.* A group health plan generally provides benefits for anesthesiology services. Individual *D* undergoes a surgery at an in-network health care facility and during the course of the surgery, receives anesthesiology services from an out-of-network provider. The plan decides the claim for these services without regard to the protections related to items and services furnished by out-of-network providers at in-network facilities under § 2590.716–5. As a result, *D* receives an adverse benefit determination for the services and is subject to cost-sharing liability that is greater than it would be if cost sharing had been calculated in a manner consistent with the requirements of § 2590.716–5.

(ii) *Conclusion.* In this *Example 4,* whether the plan was required to decide the claim in a manner consistent with the requirements of § 2590.716–5 involves considering whether the plan complied with § 2590.716–5, as well as medical judgment, because it requires consideration of the health care setting and level of care. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section.

Example 5. (i) *Facts.* A group health plan generally provides benefits for services in an emergency department of a hospital or independent freestanding emergency department. Individual *E* receives emergency services in an out-of-network emergency department of a hospital, including certain post-stabilization services. The plan processes the claim for the post-stabilization services as not being for emergency services under § 2590.716–4(c)(2)(ii) based on representations made by the treating provider that *E* was in a condition to receive notice from the provider about cost-sharing and surprise billing protections for these services and subsequently gave informed consent to waive those protections. *E* receives an adverse benefit determination and is subject to cost-sharing requirements that are greater than the cost-sharing requirements that would apply if the services were processed in a manner consistent with § 2590.716–4.

(ii) *Conclusion.* In this *Example 5,* whether *E* was in a condition to receive notice about the availability of cost-sharing and surprise billing protections and give informed consent to waive those protections involves medical judgment and consideration of whether the plan complied with the requirements under § 2590.716–4(c)(2)(ii). Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section.

Example 6. (i) *Facts.* Individual *F* gives birth to a baby at an in-network hospital. The baby is born prematurely and receives certain neonatology services from a nonparticipating provider during the same visit as the birth. *F* was given notice about cost-sharing and surprise billing protections for these services, and subsequently gave informed consent to waive those protections. The claim for the neonatology services is coded as a claim for routine post-natal services and the plan decides the claim without regard to the requirements under § 2590.716–5(a) and the fact that those protections may not be waived for neonatology services under § 2590.716–5(b).

(ii) *Conclusion.* In this *Example 6,* medical judgment is necessary to determine whether the correct code was used and compliance with § 2590.716–5(a) and (b) must also be considered. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section. The Departments also note that, to the extent the nonparticipating provider balance bills Individual *F* for the outstanding amounts not paid by the plan for the neonatology services, such provider would be in violation of PHS Act section 2799B–2 and its implementing regulations at 45 CFR 149.420(a).

Example 7. (i) *Facts.* A group health plan generally provides benefits to cover knee replacement surgery. Individual *G* receives a knee replacement surgery at an in-network facility and, after receiving proper notice about the availability of cost-sharing and surprise billing protections, provides informed consent to waive those protections. However, during the surgery, certain anesthesiology services are provided by an out-of-network nurse anesthetist. The claim for these anesthesiology services is decided by the plan without regard to the requirements under § 2590.716–5(a) or to the fact that those protections may not be waived for ancillary services such as anesthesiology services provided by an out-of-network provider at an in-network facility under § 2590.716–5(b). *G* receives an adverse benefit determination and is subject to cost-sharing requirements that are greater than the cost-sharing requirements that would apply if the services were provided in a manner consistent with § 2590.716–5(a) and (b).

(ii) *Conclusion.* In this *Example 7,* consideration of whether the plan complied with the requirements in § 2590.716–5(a) and (b) is necessary to determine whether cost-sharing requirements were applied appropriately. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section.

* * * * *

(g) *Applicability date.* The provisions of this section generally are applicable to group health plans and health insurance issuers for plan years beginning on or after January 1, 2017. The external review scope provision at paragraph (d)(1)(i)(B) of this section is applicable for plan years beginning on or after January 1, 2022. The external review provisions described in paragraphs (c) and (d) of this section are applicable to grandfathered health plans, with respect to the types of claims specified under paragraph (a)(1)(ii) of this section, for plan years beginning on or after January 1, 2022.

■ 11. Section 2590.716–1 is amended by revising paragraph (b) to read as follows:

§ 716–1 Basis and scope.

* * * * *

(b) *Scope.* This part establishes standards for group health plans, and health insurance issuers offering group or individual health insurance coverage with respect to surprise medical bills, transparency in health care coverage, and additional patient protections. This part also establishes an independent dispute resolution process, and standards for certifying independent dispute resolution entities.

■ 12. Section 2590.716–2 is amended by revising paragraph (a) and paragraph (b) introductory text to read as follows:

§ 2590.716–2 Applicability.

(a) *In general.* (1) The requirements in §§ 2590.716–4 through 2590.716–7, 2590.717–1, and 2590.722 apply to group health plans and health insurance issuers offering group health insurance coverage (including grandfathered health plans as defined in § 2590.715–1251), except as specified in paragraph (b) of this section.

(2) The requirements in §§ 54.9816–8T and 54.9817–2T apply to certified IDR entities and group health plans and health insurance issuers offering group health insurance coverage (including grandfathered health plans as defined in § 2590.715–1251) except as specified in paragraph (b) of this section.

(b) *Exceptions.* The requirements in §§ 2590.716–4 through 2590.716–8, 2590.717–1, 2590.717–2 and 2590.722 do not apply to the following:

* * * * *

■ 13. Section 2590.716–8 is added to read as follows:

§ 2590.716—8 Independent dispute resolution process.

(a) *Scope and definitions*–(1) *Scope.* This section sets forth requirements with respect to the independent dispute resolution (IDR) process (referred to in this section as the Federal IDR process) under which a nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services (as applicable), and a group health plan or health insurance issuer offering group health insurance coverage completes a requisite open negotiation period and at least one party submits a notification under paragraph (b) of this section to initiate the Federal IDR process under paragraph (c) of this section, and under which an IDR entity (as certified under paragraph (e) of this section) determines the amount of payment under the plan or coverage for an item or service furnished by the provider or facility.

(2) *Definitions.* Unless otherwise stated, the definitions in § 2590.716–3 of this part apply to this section. Additionally, for purposes of this section, the following definitions apply:

(i) *Batched items and services* means multiple qualified IDR items or services that are considered jointly as part of one payment determination by a certified IDR entity for purposes of the Federal IDR process. In order for a qualified IDR item or service to be included in a batched item or service, the qualified IDR item or service must meet the criteria set forth in paragraph (c)(3) of this section.

(ii) *Breach* means the acquisition, access, use, or disclosure of individually identifiable health information (IIHI) in a manner not permitted under paragraph (e)(2)(v) of this section that compromises the security or privacy of the IIHI.

(A) Breach excludes:

(*1*) Any unintentional acquisition, access, or use of IIHI by personnel, a contractor, or a subcontractor of a certified IDR entity that is acting under the authority of that certified IDR entity, if the acquisition, access, or use was made in good faith and within the scope of that authority and that does not result in further use or disclosure in a manner not permitted under paragraph (e)(2)(v) of this section.

(*2*) Any inadvertent disclosure by a person who is authorized to access IIHI at a certified IDR entity to another person authorized to access IIHI at the same certified IDR entity, and the information received as a result of the disclosure is not further used or disclosed in a manner not permitted under paragraph (e)(2)(v) of this section.

(*3*) A disclosure of IIHI in which a certified IDR entity has a good faith belief that an unauthorized person to whom the disclosure was made would not reasonably have been able to retain such information.

(B) Except as provided in paragraph (a)(2)(ii)(A) of this section, access, use, or disclosure of IIHI in a manner not permitted under paragraph (e)(2)(v) of this section is presumed to be a breach unless the certified IDR entity demonstrates that there is a low probability that the security or privacy of the IIHI has been compromised based on a risk assessment encompassing at least the following factors:

(*1*) The nature and extent of the IIHI involved, including the types of identifiers and the likelihood of re-identification;

(*2*) The unauthorized person who used the IIHI or to whom the disclosure was made;

(*3*) Whether the IIHI was actually acquired or viewed; and

(*4*) The extent to which the risk to the IIHI has been mitigated.

(iii) *Certified IDR entity* means an entity responsible for conducting determinations under paragraph (c) of this section that meets the certification criteria specified in paragraph (e) of this section and that has been certified by the Secretary, jointly with the Secretaries of Health and Human Services and the Treasury.

(iv) *Conflict of interest* means, with respect to a party to a payment determination, or certified IDR entity, a material relationship, status, or condition of the party, or certified IDR entity that impacts the ability of the certified IDR entity to make an unbiased and impartial payment determination. For purposes of this section, a conflict of interest exists when a certified IDR entity is:

(A) A group health plan; a health insurance issuer offering group health insurance coverage, individual health insurance coverage, or short-term, limited-duration insurance; a carrier offering a health benefits plan under 5 U.S.C. 8902; or a provider, a facility, or a provider of air ambulance services;

(B) An affiliate or a subsidiary of a group health plan; a health insurance issuer offering group health insurance coverage, individual health insurance coverage, or short-term limited-duration insurance; a carrier offering a health benefits plan under 5 U.S.C. 8902; or a provider, a facility, or a provider of air ambulance services;

(C) An affiliate or subsidiary of a professional or trade association representing group health plans; health insurance issuers offering group health insurance coverage, individual health insurance coverage, or short-term limited duration insurance; carriers offering a health benefits plan under 5 U.S.C. 8902; or providers, facilities, or providers of air ambulance services.

(D) A certified IDR entity, that has, or that has any personnel, contractors, or subcontractors assigned to a determination who have, a material familial, financial, or professional relationship with a party to the payment determination being disputed, or with any officer, director, or management employee of the plan, issuer, or carrier offering a health benefits plan under 5 U.S.C. 8902; the plan administrator, plan fiduciaries, or plan, issuer, or carrier employees; the health care provider, the health care provider's group or practice association; the provider of air ambulance services, the provider of air ambulance services' group or practice association, or the facility that is a party to the dispute.

(v) *Credible information* means information that upon critical analysis is worthy of belief and is trustworthy.

(vi) *IDR entity* means an entity that may apply or has applied for certification to conduct determinations under paragraph (c) of this section, and that currently is not certified by the Secretary, jointly with the Secretaries of Health and Human Services and the Treasury, pursuant to paragraph (e) of this section.

(vii) *Individually identifiable health information (IIHI)* means any information, including demographic data, that relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and

(A) That identifies the individual; or

(B) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

(viii) *Material difference* means a substantial likelihood that a reasonable person with the training and qualifications of a certified IDR entity making a payment determination would consider the submitted information significant in determining the out of network rate and would view the information as showing that the qualifying payment amount is not the appropriate out-of-network rate.

(ix) *Material familial relationship* means any relationship as a spouse, domestic partner, child, parent, sibling, spouse's or domestic partner's parent, spouse's or domestic partner's sibling, spouse's or domestic partner's child, child's parent, child's spouse or domestic partner, or sibling's spouse or domestic partner.

(x) *Material financial relationship* means any financial interest of more than five percent of total annual revenue or total annual income of a certified IDR entity, or an officer, director, or manager thereof, or of a reviewer or reviewing physician employed or engaged by a certified IDR entity to conduct or participate in any review in the Federal IDR process. The terms annual revenue and annual income do not include mediation fees received by mediators who are also arbitrators, provided that the mediator acts in the capacity of a mediator and does not represent a party in the mediation.

(xi) *Material professional relationship* means any physician-patient relationship, any partnership or employment relationship, any shareholder or similar ownership interest in a professional corporation, partnership, or other similar entity; or any independent contractor arrangement that constitutes a material financial relationship with any expert used by the certified IDR entity or any officer or director of the certified IDR entity.

(xii) *Qualified IDR item or service* means an item or service:

(A) That is an emergency service furnished by a nonparticipating provider or nonparticipating facility subject to the protections of 26 CFR 54.9816–4T, § 2590.716–4, or 45 CFR 149.110, as applicable, for which the conditions of 45 CFR 149.410(b) are not met, or an item or service furnished by a nonparticipating provider at a participating health care facility, subject to the requirements of 26 CFR 54.9816–T, § 2590.716–5, or 45 CFR 149.120, as applicable, for which the conditions of 45 CFR 149.420(c) through (i) are not met, or air ambulance services furnished by a nonparticipating provider of air ambulance services subject to the protections of 26 CFR 54.9817–1T, § 2590.717–1, or 45 CFR 149.130, as applicable, and for which the out-of-network rate is not determined by reference to an All-Payer Model Agreement under section 1115A of the Social Security Act or a specified State law as defined in § 2590.716–3;

(B) With respect to which a provider or facility (as applicable) or group health plan or health insurance issuer offering group health insurance coverage submits a notification under paragraph (b)(2) of this section;

(C) That is not an item or service that is the subject of an open negotiation under paragraph (b)(1) of this section; and

(D) That is not an item or service for which a notification under paragraph (b)(2) of this section is submitted during the 90-calendar-day period under paragraph (c)(4)(vi)(B) of this section, but that may include such an item or service if the notification is submitted during the subsequent 30-business-day period under paragraph (c)(4)(vi)(C) of this section.

(xiii) *Unsecured IIHI* means IIHI that is not rendered unusable, unreadable, or indecipherable to unauthorized persons through the use of a technology or methodology specified by the Secretary, jointly with the Secretary of the Treasury and the Secretary of Health and Human Services.

(b) *Determination of payment amount through open negotiation and initiation of the Federal IDR process*—(1) *Determination of payment amount through open negotiation*—(i) *In general.* With respect to an item or service that meets the requirements of paragraph (a)(2)(xii)(A) of this section, the provider, facility, or provider of air ambulance services or the group health plan or health insurance issuer offering group or individual health insurance coverage may, during the 30-business-day period beginning on the day the provider, facility, or provider of air ambulance services receives an initial payment or notice of denial of payment regarding the item or service, initiate an open negotiation period for purposes of determining the out-of-network rate for such item or service. To initiate the open negotiation period, a party must send a notice to the other party (open negotiation notice) in accordance with paragraph (b)(1)(ii) of this section.

(ii) *Open negotiation notice*—(A) *Content.* The open negotiation notice must include information sufficient to identify the item(s) and service(s) (including the date(s) the item(s) or service(s) were furnished, the service code, and initial payment amount, if applicable), an offer of an out-of-network rate, and contact information for the party sending the open negotiation notice.

(B) *Manner.* The open negotiation notice must be provided, using the standard form developed by the Secretary, in writing within 30 business days beginning on the day the provider, facility, or provider of air ambulance services receives an initial payment or a notice of denial of payment from the plan or issuer regarding the item or service. The day on which the open negotiation notice is first sent by a party is the date the 30-business-day open negotiation period begins. This notice may be provided to the other party electronically (such as by email) if the following two conditions are satisfied—

(*1*) The party sending the open negotiation notice has a good faith belief that the electronic method is readily accessible by the other party; and

(*2*) The notice is provided in paper form free of charge upon request.

(2) *Initiating the Federal IDR process*—(i) *In general.* With respect to an item or service for which the parties do not agree upon an out-of-network rate by the last day of the open negotiation period under paragraph (b)(1) of this section, either party may initiate the Federal IDR process. To initiate the Federal IDR process, a party must submit a written notice of IDR initiation to the other party and to the Secretary, using the standard form developed by the Secretary, during the 4-business-day period beginning on the 31st business day after the start of the open negotiation period.

(ii) *Exception for items and services provided by certain nonparticipating*

providers and facilities. A party may not initiate the Federal IDR process with respect to an item or service if, with respect to that item or service, the party knows (or reasonably should have known) that the provider or facility provided notice and received consent under 45 CFR 149.410(b) or 149.420(c) through (i).

(iii) *Notice of IDR initiation*—(A) *Content.* The notice of IDR initiation must include:

(*1*) Information sufficient to identify the qualified IDR items or services under dispute (and whether the qualified IDR items or services are designated as batched items and services as described in paragraph (c)(3) of this section), including the date(s) and location the item or service was furnished, the type of item or service (such as whether the qualified IDR item or service is an emergency service as defined in 26 CFR 54.9816–4T(c)(2)(i), § 2590.716–4(c)(2)(i), or 45 CFR 149.110(c)(2)(i), as applicable, an emergency service as defined in 26 CFR 54.9816–4T(c)(2)(ii), § 2590.716–4(c)(2)(ii), or 45 CFR 149.110(c)(2)(ii), as applicable, or a nonemergency service; and whether any service is a professional service or facility-based service), corresponding service codes, place of service code, the amount of cost sharing allowed, and the amount of the initial payment made for the qualified IDR item or service, if applicable;

(*2*) Names of the parties involved and contact information, including name, email address, phone number, and mailing address;

(*3*) State where the qualified IDR item or service was furnished;

(*4*) Commencement date of the open negotiation period under paragraph (b)(1) of this section;

(*5*) Preferred certified IDR entity;

(*6*) An attestation that the items and services under dispute are qualified IDR items or services;

(*7*) Qualifying payment amount;

(*8*) Information about the qualifying payment amount as described in § 2590.716–6(d); and

(*9*) General information describing the Federal IDR process as specified by the Secretary.

(B) *Manner.* The initiating party must provide written notice of IDR initiation to the other party. The initiating party may satisfy this requirement by furnishing the notice of IDR initiation to the other party electronically (such as by email) if the following two conditions are satisfied –

(*1*) The initiating party has a good faith belief that the electronic method is readily accessible by the other party; and

(*2*) The notice is provided in paper form free of charge upon request.

(C) *Notice to the Secretary.* The initiating party must also furnish the notice of IDR initiation to the Secretary by submitting the notice through the Federal IDR portal. The initiation date of the Federal IDR process will be the date of receipt by the Secretary.

(c) *Federal IDR process following initiation*—(1) *Selection of certified IDR entity*—(i) *In general.* The plan or issuer or the provider, facility, or provider of air ambulance services receiving the notice of IDR initiation under paragraph (b)(2) of this section may agree or object to the preferred certified IDR entity identified in the notice of IDR initiation. If the party in receipt of the notice of IDR initiation fails to object within 3 business days, the preferred certified IDR entity identified in the notice of IDR initiation will be selected and will be treated as jointly agreed to by the parties, provided that the certified IDR entity does not have a conflict of interest. If the party in receipt of the notice of IDR initiation objects, that party must notify the initiating party of the objection and propose an alternative certified IDR entity. The initiating party must then agree or object to the alternative certified IDR entity; if the initiating party fails to agree or object to the alternative certified IDR entity, the alternative certified IDR entity will be selected and will be treated as jointly agreed to by the parties. In order to select a preferred certified IDR entity, the plan or issuer and the provider, facility, or provider of air ambulance services must jointly agree on a certified IDR entity not later than 3 business days after the initiation date of the Federal IDR process. If the plan or issuer and the provider, facility, or provider of air ambulance services fail to agree upon a certified IDR entity within that time, the Secretary shall select a certified IDR entity in accordance with paragraph (c)(1)(iv) of this section.

(ii) *Requirements for selected certified IDR entity.* The certified IDR entity selected must be an IDR entity certified under paragraph (e) of this section, that:

(A) Does not have a conflict of interest as defined in paragraph (a)(2) of this section;

(B) Ensures that assignment of personnel to a payment determination and decisions regarding hiring, compensation, termination, promotion, or other similar matters related to personnel assigned to the dispute are not made based upon the likelihood that the assigned personnel will support a particular party to the determination being disputed other than as outlined under paragraph (c)(4)(iii) of this section; and

(C) Ensures that any personnel assigned to a payment determination do not have any conflicts of interests as defined in paragraph (a)(2) of this section regarding any party to the dispute within the 1 year immediately preceding an assignment of dispute determination, similar to the requirements laid out in 18 U.S.C. 207(b).

(iii) *Notice of certified IDR entity selection.* Upon the selection of a certified IDR entity, in accordance with paragraph (c)(1)(i) of this section, the plan or issuer or the provider or emergency facility that submitted the notice of IDR initiation under paragraph (b)(2) of this section must notify the Secretary of the selection as soon as reasonably practicable, but no later than 1 business day after such selection, through the Federal IDR portal. In addition, if the non-initiating party believes that the Federal IDR process is not applicable, the non-initiating party must also provide information regarding the Federal IDR process's inapplicability through the Federal IDR portal by the same date that the notice of certified IDR entity selection must be submitted.

(A) *Content.* If the parties have agreed on the selection of a certified IDR entity or the party in receipt of the notice of IDR initiation has not objected to the other party's selection, the notice of the certified IDR entity selection must include the following information:

(*1*) Name of the certified IDR entity;

(*2*) The certified IDR entity number; and

(*3*) Attestation by both parties, or by the initiating party if the non-initiating party fails to object to the selection of the certified IDR entity, that the selected certified IDR entity meets the requirements of paragraph (c)(1)(ii) of this section.

(B) [Reserved]

(iv) *Failure to select a certified IDR entity.* If the plan or issuer and the provider, facility, or provider of air ambulance services fail to select a certified IDR entity in accordance with paragraph (c)(1)(i) of this section, the initiating party must notify the Secretary of the failure no later than 1 business day after the date of such failure (or in other words, 4 business days after initiation of the Federal IDR process) by electronically submitting the notice as described in paragraph (c)(1)(iii) of this section but indicating that the parties have failed to select a certified IDR entity. In addition, if the non-initiating party believes that the Federal IDR process is not applicable, the non-initiating party must also

provide information regarding the Federal IDR process's inapplicability through the Federal IDR portal by the same date that the notice of failure to select must be submitted. Upon notification of the failure of the parties to select a certified IDR entity, the Secretary will select a certified IDR entity that charges a fee within the allowed range of certified IDR entity fees through a random selection method not later than 6 business days after the date of initiation of the Federal IDR process and will notify the plan or issuer and the provider or facility of the selection. If there are insufficient certified IDR entities that charge a fee within the allowed range of certified IDR entity fees available to arbitrate the dispute, the Secretary, jointly with the Secretary of Health and Human Services and Secretary of the Treasury, will select a certified IDR entity that has received approval, as described in paragraph (e)(2)(vi)(B) of this section, to charge a fee outside of the allowed range of certified IDR entity fees.

(v) *Review by certified IDR entity.* After selection by the parties (including when the initiating party selects a certified IDR entity and the other party does not object), or by the Secretary under paragraph (c)(1)(iv) of this section, the certified IDR entity must review the selection and attest that it meets the requirements of paragraph (c)(1)(ii) of this section. If the certified IDR entity is unable to attest that it meets the requirements of paragraph (c)(1)(ii) within 3 business days of selection, the parties, upon notification, must select another certified IDR entity under paragraph (c)(1) of this section, treating the date of notification of the failure to attest to the requirements of (c)(1)(ii) as the date of initiation of the Federal IDR process for purposes of the time periods in paragraphs (c)(1)(i) and (iv) of this section. Additionally, the certified IDR entity selected must review the information submitted in the notice of IDR initiation to determine whether the Federal IDR process applies. If the Federal IDR process does not apply, the certified IDR entity must notify the Secretary and the parties within 3 business days of making that determination.

(2) *Authority to continue negotiations*—(i) *In general.* If the parties to the Federal IDR process agree on an out-of-network rate for a qualified IDR item or service after providing the notice of IDR initiation to the Secretary consistent with paragraph (b)(2) of this section, but before the certified IDR entity has made its payment determination, the amount agreed to by the parties for the qualified IDR item or service will be treated as the out-of-network rate for the qualified IDR item or service. To the extent the amount exceeds the initial payment amount (or initial denial of payment) and any cost sharing paid or required to be paid by the participant or beneficiary, payment must be made directly by the plan or issuer to the nonparticipating provider, facility, or nonparticipating provider of air ambulance services, not later than 30 business days after the agreement is reached. In no instance may either party seek additional payment from the participant or beneficiary, including in instances in which the out-of-network rate exceeds the qualifying payment amount. The initiating party must send a notification to the Secretary and to the certified IDR entity (if selected) electronically, through the Federal IDR portal, as soon as possible, but no later than 3 business days after the date of the agreement. The notification must include the out-of-network rate for the qualified IDR item or service and signatures from authorized signatories for both parties.

(ii) *Method of allocation of the certified IDR entity fee.* In the case of an agreement described in paragraph (c)(2)(i) of this section, the certified IDR entity is required to return half of each parties' certified IDR entity fee, unless directed otherwise by both parties. The administrative fee under paragraph (d)(2) of this section will not be returned to the parties.

(3) *Treatment of batched items and services*—(i) *In general.* Batched items and services may be submitted and considered jointly as part of one payment determination by a certified IDR entity only if the batched items and services meet the requirements of this paragraph (c)(3)(i). Batched items and services submitted and considered jointly as part of one payment determination under this paragraph (c)(3)(i) are treated as a batched determination and subject to the fee for batched determinations under this section.

(A) The qualified IDR items and services are billed by the same provider or group of providers, the same facility, or the same provider of air ambulance services. Items and services are billed by the same provider or group of providers, the same facility, or the same provider of air ambulance services if the items or services are billed with the same National Provider Identifier or Tax Identification Number;

(B) Payment for the qualified IDR items and services would be made by the same plan or issuer;

(C) The qualified IDR items and services are the same or similar items and services. The qualified IDR items and services are considered to be the same or similar items or services if each is billed under the same service code, or a comparable code under a different procedural code system, such as Current Procedural Terminology (CPT) codes with modifiers, if applicable, Healthcare Common Procedure Coding System (HCPCS) with modifiers, if applicable, or Diagnosis-Related Group (DRG) codes with modifiers, if applicable; and

(D) All the qualified IDR items and services were furnished within the same 30-business-day period, or the same 90-calendar-day period under paragraph (c)(4)(vi)(B) of this section, as applicable.

(ii) *Treatment of bundled payment arrangements.* In the case of qualified IDR items and services billed by a provider, facility, or provider of air ambulance services as part of a bundled payment arrangement, or where a plan or issuer makes or denies an initial payment as a bundled payment, the qualified IDR items and services may be submitted as part of one payment determination. Bundled payment arrangements submitted under this paragraph (c)(3)(ii) are subject to the rules for batched determinations and the certified IDR entity fee for single determinations.

(4) *Payment determination for a qualified IDR item or service*—(i) *Submission of offers.* Not later than 10 business days after the selection of the certified IDR entity, the plan or issuer and the provider, facility, or provider of air ambulance services:

(A) Must each submit to the certified IDR entity:

(*1*) An offer of an out-of-network rate expressed as both a dollar amount and the corresponding percentage of the qualifying payment amount represented by that dollar amount;

(*2*) Information requested by the certified IDR entity relating to the offer.

(*3*) The following additional information, as applicable—

(*i*) For providers and facilities, information on the size of the provider's practice or of the facility (if applicable). Specifically, a group of providers must specify whether the providers' practice 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;

(*ii*) For providers and facilities, information on the practice specialty or type, respectively (if applicable);

(*iii*) For plans and issuers, information on the coverage area of the plan or issuer, the relevant geographic region for purposes of the qualifying payment amount, whether the coverage is fully-insured or partially or fully self-insured; and

(*iv*) The qualifying payment amount for the applicable year for the same or similar item or service as the qualified IDR item or service.

(B) May each submit to the certified IDR entity any information relating to the offer that was submitted by either party, except that the information may not include information on factors described in paragraph (c)(4)(v) of this section.

(ii) *Payment determination and notification.* Not later than 30 business days after the selection of the certified IDR entity, the certified IDR entity must:

(A) Select as the out-of-network rate for the qualified IDR item or service one of the offers submitted under paragraph (c)(4)(i) of this section, taking into account the considerations specified in paragraph (c)(4)(iii) of this section (as applied to the information provided by the parties pursuant to paragraph (c)(4)(i) of this section). The certified IDR entity must select the offer closest to the qualifying payment amount unless the certified IDR entity determines that credible information submitted by either party under paragraph (c)(4)(i) clearly demonstrates that the qualifying payment amount is materially different from the appropriate out-of-network rate, or if the offers are equally distant from the qualifying payment amount but in opposing directions. In these cases, the certified IDR entity must select the offer as the out-of-network rate that the certified IDR entity determines best represents the value of the qualified IDR item or services, which could be either offer.

(B) Notify the plan or issuer and the provider or facility, as applicable, of the selection of the offer under paragraph (c)(4)(ii)(A) of this section, and provide the written decision required under (c)(4)(vi) of this section.

(iii) *Considerations in determination.* In determining which offer to select, the certified IDR entity must consider:

(A) The qualifying payment amount(s) for the applicable year for the same or similar item or service.

(B) Information requested by the certified IDR entity under paragraph (c)(4)(i)(A)(*2*) of this section relating to the offer, to the extent a party provides credible information.

(C) Additional information submitted by a party, provided the information is credible and relates to the circumstances described in paragraphs (c)(4)(iii)(C)(*1*) through (*5*) of this section, with respect to a qualified IDR item or service of a nonparticipating provider, facility, group health plan, or health insurance issuer of group or individual health insurance coverage that is the subject of a payment determination. This information must also clearly demonstrate that the qualifying payment amount is materially different from the appropriate out-of-network rate.

(*1*) The level of training, experience, and quality and outcomes measurements of the provider or facility that furnished the qualified IDR item or service (such as those endorsed by the consensus-based entity authorized in section 1890 of the Social Security Act).

(*2*) The market share held by the provider or facility or that of the plan or issuer in the geographic region in which the qualified IDR item or service was provided.

(*3*) The acuity of the participant, or beneficiary, receiving the qualified IDR item or service, or the complexity of furnishing the qualified IDR item or service to the participant or beneficiary.

(*4*) The teaching status, case mix, and scope of services of the facility that furnished the qualified IDR item or service, if applicable.

(*5*) Demonstration of good faith efforts (or lack thereof) made by the provider or facility or the plan or issuer to enter into network agreements with each other, and, if applicable, contracted rates between the provider or facility, as applicable, and the plan or issuer, as applicable, during the previous 4 plan years.

(D) Additional information submitted by a party, provided the information is credible and relates to the offer submitted by either party and does not include information on factors described in paragraph (c)(4)(v) of this section.

(iv) *Examples.* The rules of paragraph (c)(4)(iii) of this section are illustrated by the following examples:

(A) *Example 1*—(*1*) *Facts.* A nonparticipating provider and an issuer are parties to a payment determination in the Federal IDR process. The nonparticipating provider submits an offer and additional written information asserting that the provider has made good faith efforts to enter into network agreements with the issuer. The nonparticipating provider fails to provide any documentation of these efforts, such as correspondence or records of conversations with representatives of the issuer.

(*2*) *Conclusion.* In this *Example 1,* the nonparticipating provider has submitted additional information. However, this information is not credible, as the nonparticipating provider has failed to provide any documentation in support of the provider's assertions of good faith efforts to enter into network agreements with the issuer. Therefore, the certified IDR entity cannot consider the information.

(B) *Example 2*—(*1*) *Facts.* A nonparticipating provider and an issuer are parties to a payment determination in the Federal IDR process. The nonparticipating provider submits credible information relating to the provider's level of training, experience, and quality and outcome measurements from 2019. The provider also submits credible information that clearly demonstrates that the provider's level of training and expertise was necessary for providing the service that is the subject of the payment determination to the particular patient. Further, the provider submits credible information that clearly demonstrates that the qualifying payment amount generally presumes the service would be delivered by a provider with a lower level of training, experience, and quality and outcome measurements. This information, taken together, demonstrates that the qualifying payment amount is not an appropriate payment amount and the provider submits an offer that is higher than the qualifying payment amount and commensurate with the provider's level of training, experience, and quality and outcome measurements with respect to the service provided. The issuer submits the qualifying payment amount as its offer with no additional information.

(*2*) *Conclusion.* In this *Example 2,* the nonparticipating provider has submitted information that is credible. Moreover, the credible information clearly demonstrates that the qualifying payment amount does not adequately take into account the provider's level of training, experience, and quality and outcome measurements with respect to the service provided, and that the appropriate out-of-network rate should therefore be higher than the qualifying payment amount. Accordingly, the certified IDR entity must select the provider's offer, as that offer best represents the value of the service that is the subject of the payment determination.

(C) *Example 3*—(*1*) *Facts.* A nonparticipating provider and an issuer are parties to a payment determination in the Federal IDR process. The nonparticipating provider submits credible information to the certified IDR entity relating to the acuity of the patient that received the service, and the complexity of furnishing the service to

the patient, by providing details of the service at issue and the training required to furnish the complex service. The provider contends that this information demonstrates that the qualifying payment amount is not an appropriate payment amount, and the provider submits an offer that is higher than the qualifying payment amount and equal to what the provider believes is commensurate with the acuity of the patient and the complexity of the service that is the subject of the payment determination. However, the evidence submitted by the provider does not clearly demonstrate that the qualifying payment amount fails to encompass the acuity and complexity of the service. The issuer submits the qualifying payment amount as its offer, along with credible information that demonstrates how the qualifying payment amount was calculated for this particular service, taking into consideration the acuity of the patient and the complexity of the service.

(*2*) *Conclusion.* The information submitted by the provider to the certified IDR entity is credible with respect to the acuity of the patient and complexity of the service. However, in this example, the provider has not clearly demonstrated that the qualifying payment amount is materially different from the appropriate out-of-network rate, based on the acuity of the patient and the complexity of the service that is the subject of the payment determination. Accordingly, the certified IDR entity must select the offer closest to the qualifying payment amount, which is the issuer's offer.

(D) *Example 4*—(*1*) *Facts.* A nonparticipating provider and an issuer are parties to a payment determination in the Federal IDR process. The issuer submits credible information demonstrating that the patent for the item that is the subject of the payment determination has expired, including written documentation that demonstrates how much the cost of the item was at the time the provider rendered service and how the qualifying payment amount exceeds that cost. The issuer submits an offer that is lower than the qualifying payment amount and commensurate with the cost of the item at the time service was rendered. The nonparticipating provider submits the qualifying payment amount as its offer and also submits credible information demonstrating the provider's level of training, experience, and quality and outcome measurements from 2019, but the provider does not explain how this additional information is relevant to the cost of the item.

(*2*) *Conclusion.* In this *Example 4,* both the nonparticipating provider and issuer submitted information that is credible and that may be considered by the certified IDR entity. However, only the issuer provided credible information that was relevant to the service that is the subject of the payment determination. Moreover, the issuer has clearly demonstrated that the qualifying payment amount does not adequately take into account the complexity of the item furnished—in this case that the item is no longer patent protected. While the provider submitted credible information, the provider failed to show how the information was relevant to the item that is the subject of the payment determination. Accordingly, the certified IDR entity must select the offer that best represents the value of the item, which is the issuer's offer in this example.

(v) *Prohibition on consideration of certain factors.* In determining which offer to select, the certified IDR entity must not consider:

(A) Usual and customary charges (including payment or reimbursement rates expressed as a proportion of usual and customary charges);

(B) The amount that would have been billed by the provider or facility with respect to the qualified IDR item or service had the provisions of 45 CFR 149.410 and 149.420 (as applicable) not applied; or

(C) The payment or reimbursement rate for items and services furnished by the provider or facility payable by a public payor, including under the Medicare program under title XVIII of the Social Security Act; the Medicaid program under title XIX of the Social Security Act; the Children's Health Insurance Program under title XXI of the Social Security Act; the TRICARE program under chapter 55 of title 10, United States Code; chapter 17 of title 38, United States Code; or demonstration projects under section 1115 of the Social Security Act.

(vi) *Written decision.* (A) The certified IDR entity must explain its determination in a written decision submitted to the parties and the Secretary, in a form and manner specified by the Secretary;

(B) 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 qualifying payment amount was materially different from the appropriate out-of-network rate, based on the considerations allowed under paragraphs (c)(4)(iii)(B) through (D) of this section, with respect to the qualified IDR item or service.

(vii) *Effects of determination*—(A) *Binding.* A determination made by a certified IDR entity under paragraph (c)(4)(ii) of this section:

(*1*) Is binding upon the parties, in the absence of fraud or evidence of intentional misrepresentation of material facts presented to the certified IDR entity regarding the claim; and

(*2*) Is not subject to judicial review, except in a case described in any of paragraphs (1) through (4) of section 10(a) of title 9, United States Code.

(B) *Suspension of certain subsequent IDR requests.* In the case of a determination made by a certified IDR entity under paragraph (c)(4)(ii) of this section, the party that submitted the initial notification under paragraph (b)(2) of this section may not submit a subsequent notification involving the same other party with respect to a claim for the same or similar item or service that was the subject of the initial notification during the 90-calendar-day period following the determination.

(C) *Subsequent submission of requests permitted.* If the end of the open negotiation period specified in paragraph (b)(1) of this section occurs during the 90-calendar-day suspension period regarding claims for the same or similar item or service that were the subject of the initial notice of IDR determination as described in paragraph (c)(4)(vi) of this section, either party may initiate the Federal IDR process for those claims by submitting a notification as specified in paragraph (b)(2) of this section during the 30-business-day period beginning on the day after the last day of the 90-calendar-day suspension period.

(viii) *Recordkeeping requirements.* The certified IDR entity must maintain records of all claims and notices associated with the Federal IDR process with respect to any determination for 6 years. The certified IDR entity must make these records available for examination by the plan, issuer, provider, facility, or provider of air ambulance services, or a State or Federal oversight agency upon request, except to the extent the disclosure would violate either State or Federal privacy law.

(ix) *Payment.* If applicable, the amount of the offer selected by the certified IDR entity (less the sum of the initial payment and any cost sharing paid or owed by the participant or beneficiary) must be paid directly to the provider, facility, or provider of air ambulance services not later than 30 calendar days after the determination by

the certified IDR entity. If the offer selected by the certified IDR entity is less than the sum of the initial payment and any cost sharing paid by the participant or beneficiary, the provider, facility, or provider of air ambulance services will be liable to the plan or issuer for the difference. The provider, facility, or provider of air ambulance services must pay the difference directly to the plan or issuer not later than 30 calendar days after the determination by the certified IDR entity.

(d) *Costs of IDR process*—(1) *Certified IDR entity fee.* (i) With respect to the Federal IDR process described in paragraph (c) of this section, the party whose offer submitted to the certified IDR entity under paragraph (c)(4)(ii)(A) of this section is not selected is responsible for the payment to the certified IDR entity of the predetermined fee charged by the certified IDR entity.

(ii) Each party to a determination for which a certified IDR entity is selected under paragraph (c)(1) of this section must pay the predetermined certified IDR entity fee charged by the certified IDR entity to the certified IDR entity at the time the parties submit their offers under (c)(4)(i) of this section. The certified IDR entity fee paid by the prevailing party whose offer is selected by the certified IDR entity will be returned to that party within 30 business days following the date of the certified IDR entity's determination.

(2) *Administrative fee.* (i) Each party to a determination for which a certified IDR entity is selected under paragraph (c)(1) of this section must, at the time the certified IDR entity is selected under paragraph (c)(1), pay to the certified IDR entity a non-refundable administrative fee due to the Secretary for participating in the Federal IDR process described in this section.

(ii) The administrative fee amount will be established in guidance published annually by the Secretary in a manner such that the total fees paid for a year are estimated to be equal to the projected amount of expenditures by the Departments of the Treasury, Labor, and Health and Human Services for the year in carrying out the Federal IDR process.

(e) *Certification of IDR entity*—(1) *In general.* In order to be selected under paragraph (c)(1) of this section—

(i) An IDR entity must meet the standards described in this paragraph (e) and be certified by the Secretary, jointly with the Secretaries of Health and Human Services and the Treasury, as set forth in this paragraph (e) of this section and guidance promulgated by the Secretary. Once certified, the IDR entity will be provided with a certified IDR entity number.

(ii) An IDR entity must provide written documentation to the Secretary regarding general company information (such as contact information, Taxpayer Identification Number, and website), as well as the applicable service area in which the IDR entity intends to conduct payment determinations under the Federal IDR process. IDR entities may choose to submit their application for all States, or self-limit to a particular subset of States.

(iii) An IDR entity that the Secretary, jointly with the Secretary of the Treasury and the Secretary of Health and Human Services, certifies must enter into an agreement as a condition of certification. The agreement shall include specified provisions encompassed by this section, including, but not limited to, the requirements applicable to certified IDR entities when making payment determinations as well as the requirements regarding certification and revocation (such as specifications for wind down activities and reallocation of certified IDR entity fees, where warranted).

(2) *Requirements.* An IDR entity must provide written documentation to the Secretary through the Federal IDR portal that demonstrates that the IDR entity satisfies the following standards to be a certified IDR entity under this paragraph (e):

(i) Possess (directly or through contracts or other arrangements) sufficient arbitration and claims administration of health care services, managed care, billing and coding, medical and legal expertise to make the payment determinations described in paragraph (c) of this section within the time prescribed in paragraph (c)(4)(ii) of this section.

(ii) Employ (directly or through contracts or other arrangements) a sufficient number of personnel to make the determinations described in paragraph (c) of this section within the time prescribed by (c)(4)(ii) of this section. To satisfy this standard, the written documentation must include a description of the IDR entity's organizational structure and capabilities, including an organizational chart and the credentials, responsibilities, and number of personnel employed to make determinations described in paragraph (c) of this section.

(iii) Maintain a current accreditation from a nationally recognized and relevant accrediting organization, such as URAC, or ensure that it otherwise possesses the requisite training to conduct payment determinations (for example, providing documentation that personnel employed by the IDR entity have completed arbitration training by the American Arbitration Association, the American Health Law Association, or a similar organization);

(iv) Have a process to ensure that no conflict of interest, as defined in paragraph (a)(2) of this section, exists between the parties and the personnel the certified IDR entity assigns to a payment determination to avoid violating paragraph (c)(1)(ii) of this section, including policies and procedures for conducting ongoing audits for conflicts of interest, to ensure that should any arise, the certified IDR entity has procedures in place to inform the Secretary, jointly with the Secretary of the Treasury and the Secretary of Health and Human Services of the conflict of interest and to mitigate the risk by reassigning the dispute to other personnel in the event that any personnel previously assigned have a conflict of interest.

(v) Have a process to maintain the confidentiality of IIHI obtained in the course of conducting determinations. A certified IDR entity's responsibility to comply with these confidentiality requirements shall survive revocation of the IDR entity's certification for any reason, and IDR entities must comply with the record retention and disposal requirements described in this section. Under this process, once certified, the certified IDR entity must comply with the following requirements:

(A) *Privacy.* The certified IDR entity may create, collect, handle, disclose, transmit, access, maintain, store, and/or use IIHI, only to perform:

(*1*) The certified IDR entity's required duties described in this section; and

(*2*) Functions related to carrying out additional obligations as may be required under applicable Federal or State laws or regulations.

(B) *Security.* (*1*) The certified IDR entity must ensure the confidentiality of all IIHI it creates, obtains, maintains, stores, and transmits;

(*2*) The certified IDR entity must protect against any reasonably anticipated threats or hazards to the security of this information;

(*3*) The certified IDR entity must ensure that IIHI is securely destroyed or disposed of in an appropriate and reasonable manner 6 years from either the date of its creation or the first date on which the certified IDR entity had access to it, whichever is earlier;

(*4*) The certified IDR entity must implement policies and procedures to prevent, detect, contain, and correct security violations in the event of a breach of IIHI;

(C) *Breach notification.* The certified IDR entity must, following the discovery of a breach of unsecured IIHI, notify of the breach the provider, facility, or provider of air ambulance services; the plan and issuer; the Secretary, jointly with the Secretary of the Treasury and the Secretary of Health and Human Services; and each individual whose unsecured IIHI has been, or is reasonably believed to have been, subject to the breach, to the extent possible.

(*1*) *Breaches treated as discovered.* For purposes of this paragraph (e)(2)(v)(C), a breach shall be treated as discovered by a certified IDR entity as of the first day on which the breach is known to the certified IDR entity or, by exercising reasonable diligence, would have been known to the certified IDR entity. A certified IDR entity shall be deemed to have knowledge of a breach if the breach is known, or by exercising reasonable diligence would have been known, to any person, other than the person committing the breach, who is an employee, officer, or other agent of the certified IDR entity;

(*2*) *Timing of notification.* A certified IDR entity must provide the notification required by this paragraph (e)(2)(v)(C) without unreasonable delay and in no case later than 60 calendar days after discovery of a breach.

(*3*) *Content of notification.* The notification required by this paragraph (e)(2)(v)(C) must include, to the extent possible:

(*i*) 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;

(*ii*) 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;

(*iii*) 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);

(*iv*) 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

(*v*) 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.

(*4*) *Method for providing notification.* A certified IDR entity must submit the notification required by this paragraph (e)(2)(v)(C) in written form (in clear and understandable language) either on paper or electronically through the Federal IDR portal or electronic mail.

(D) *Application to contractor and subcontractors.* The certified IDR entity must ensure compliance with this paragraph (e)(2)(v) of this section by any contractor or subcontractor with access to IIHI performing any duties related to the Federal IDR process.

(vi) Meet appropriate indicators of fiscal integrity and stability by demonstrating that the certified IDR entity has a system of safeguards and controls in place to prevent and detect improper financial activities by its employees and agents to assure fiscal integrity and accountability for all certified IDR entity fees and administrative fees received, held, and disbursed and by submitting 3 years of financial statements or, if not available, other information to demonstrate fiscal stability of the IDR entity;

(vii) Provide a fixed fee for single determinations and a separate fixed fee for batched determinations within the upper and lower limits for each, as set forth in guidance issued by the Secretary. The certified IDR entity may not charge a fee that is not within the approved limits as set forth in guidance unless the certified IDR entity or IDR entity seeking certification receives written approval from the Secretary to charge a flat rate beyond the upper or lower limits approved by the Secretary for fees. The certified IDR entity or IDR entity seeking certification may update its fees and seek approval from the Secretary to charge a flat fee beyond the upper or lower limits for fees, annually as provided in guidance. In order for the certified IDR entity to receive the Secretary's written approval to charge a flat fee beyond the upper or lower limits for fees as set forth in guidance, it must satisfy both conditions in paragraphs (e)(2)(vii)(A) and (B) of this section as follows:

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

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

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

(*3*) A description of how the alternative flat rate will be used to mitigate the effects of these circumstances; and

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

(viii) Have a procedure in place to retain the certified IDR entity fees described in paragraph (d)(1) of this section paid by both parties in a trust or escrow account and to return the certified IDR entity fee paid by the prevailing party of an IDR payment determination, or half of each party's certified IDR entity fee in the case of an agreement described in paragraph (c)(2)(i) of this section, within 30 business days following the date of the determination;

(ix) Have a procedure in place to retain the administrative fees described in paragraph (d)(2) of this section and to remit the administrative fees to the Secretary in accordance with the timeframe and procedures set forth in guidance published by the Secretary;

(x) Discharge its responsibilities in accordance with paragraph (c) of this section, including not making any determination with respect to which the certified IDR entity would not be eligible for selection pursuant to paragraph (c)(1) of this section; and

(xi) Collect the information required to be reported to the Secretary under paragraph (f) of this section and report the information on a timely basis in the form and manner provided in guidance published by the Secretary.

(3) *Conflict-of-interest standards.* In addition to the general standards set forth in paragraph (e)(2)(iv) of this section, an IDR entity must provide written documentation that the IDR entity satisfies the standards to be a certified IDR entity under this paragraph (e)(3).

(i) The IDR entity must provide an attestation indicating that it does not have a conflict of interest as defined in paragraph (a)(2) of this section;

(ii) The IDR entity must have procedures in place to ensure that personnel assigned to a determination do not have any conflicts of interest regarding any party to the dispute within the 1 year immediately preceding an assignment of dispute determination, similar to the requirements laid out in 18 U.S.C. 207(b). In order to satisfy this requirement, if certified, the IDR entity must ensure that any personnel assigned to a determination do not have any conflicts of interest as defined in paragraph (a)(2) of this section.

(iii) Following certification under this paragraph (e), if a certified IDR entity acquires control of, becomes controlled by, or comes under common control with any entity described in paragraph (e)(3)(i) of this section, the certified IDR entity must notify the Secretary in

writing no later than 3 business days after the acquisition or exercise of control and shall be subject to the revocation of certification under paragraph (e)(6)(ii) of this section.

(4) *Period of certification.* Subject to paragraphs (e)(5) and (6) of this section, each certification (including a recertification) of a certified IDR entity under the process described in paragraph (e)(1) of this section will be effective for a 5-year period.

(5) *Petition for denial or revocation*—(i) *In general.* An individual, provider, facility, provider of air ambulance services, plan, or issuer may petition for a denial of a certification for an IDR entity or a revocation of a certification for a certified IDR entity for failure to meet a requirement of this section using the standard form and manner set forth in guidance to be issued by the Secretary. The petition for denial of a certification must be submitted within the timeframe set forth in guidance issued by the Secretary.

(ii) *Content of petition.* The individual, provider, facility, provider of air ambulance services, plan, or issuer seeking denial or revocation of certification must submit a written petition using the standard form issued by the Secretary including the following information:

(A) The identity of the IDR entity seeking certification or certified IDR entity that is the subject of the petition;

(B) The reason(s) for the petition;

(C) Whether the petition seeks denial or revocation of a certification;

(D) Documentation to support the reasons outlined in the petition; and

(E) Other information as may be required by the Secretary.

(iii) *Process.* (A) The Secretary, jointly with the Secretary of the Treasury and the Secretary of Health and Human Services, will acknowledge receipt of the petition within 10 business days of receipt of the petition.

(B) If the Secretary finds that the petition adequately shows a failure of the IDR entity seeking certification or the certified IDR entity to follow the requirements of this paragraph (e), the Secretary, jointly with the Secretary of the Treasury and the Secretary of Health and Human Services, will notify the IDR entity seeking certification or the certified IDR entity by providing a de-identified copy of the petition. Following the notification, the IDR entity seeking certification or certified IDR entity will have 10 business days to provide a response. After the time period for providing the response has passed, the Secretary, jointly with the Secretary of the Treasury and the Secretary of Health and Human Services, will review the response (if any), determine whether a denial or revocation of a certification is warranted, and issue a notice of the decision to the IDR entity or certified IDR entity and to the petitioner. This decision will be subject to the appeal requirements of paragraph (e)(6)(v) of this section.

(C) Effect on certification under petition. Regarding a petition for revocation of a certified IDR entity's certification, if the Secretary, jointly with the Secretary of the Treasury and the Secretary of Health and Human Services, finds that the petition adequately shows a failure to comply with the requirements of this paragraph (e), following the Secretary's notification of the failure to the certified IDR entity under paragraph (e)(5)(iii)(B) of this section, the certified IDR entity may continue to work on previously assigned determinations but may not accept new determinations until the Secretary issues a notice of the decision to the certified IDR entity finding that a revocation of certification is not warranted.

(6) *Denial of IDR entity certification or revocation of certified IDR entity certification*—(i) *Denial of IDR entity certification.* The Secretary, jointly with the Secretary of the Treasury and the Secretary of Health and Human Services, may deny the certification of an IDR entity under paragraph (e)(1) of this section if, during the process of certification, including as a result of a petition described in paragraph (e)(5) of this section, the Secretary determines the following:

(A) The IDR entity fails to meet the applicable standards set forth under this paragraph (e);

(B) The IDR entity has committed or participated in fraudulent or abusive activities, including, during the certification process, submitting fraudulent data, or submitting information or data the IDR entity knows to be false to the Secretary, the Secretary of the Treasury or the Secretary of Health and Human Services;

(C) The IDR entity has failed to comply with requests for information from the Secretary, the Secretary of the Treasury, or the Secretary of Health and Human Services as part of the certification process;

(D) In conducting payment determinations, including those outside the Federal IDR process, the IDR entity has failed to meet the standards that applied to those determinations or reviews, including standards of independence and impartiality; or

(E) The IDR entity is otherwise not fit or qualified to make determinations under the Federal IDR process.

(ii) *Revocation of certification of a certified IDR entity.* The Secretary, jointly with the Secretary of the Treasury and the Secretary of Health and Human Services, may revoke the certification of a certified IDR entity under paragraph (e)(1) of this section if, as a result of an audit, a petition described in paragraph (e)(5) of this section, or otherwise, the Secretary determines the following:

(A) The certified IDR entity has a pattern or practice of noncompliance with any requirements of this paragraph (e);

(B) The certified IDR entity is operating in a manner that hinders the efficient and effective administration of the Federal IDR process;

(C) The certified IDR entity no longer meets the applicable standards for certification set forth under this paragraph (e);

(D) The certified IDR entity has committed or participated in fraudulent or abusive activities, including submission of false or fraudulent data to the Secretary, the Secretary of the Treasury, or the Secretary of Health and Human Services;

(E) The certified IDR entity lacks the financial viability to provide arbitration under the Federal IDR process;

(F) The certified IDR entity has failed to comply with requests from the Secretary, the Secretary of the Treasury, or the Secretary of Health and Human Services made as part of an audit, including failing to submit all records of the certified IDR entity that pertain to its activities within the Federal IDR process; or

(G) The certified IDR entity is otherwise no longer fit or qualified to make determinations.

(iii) *Notice of denial or revocation.* The Secretary, jointly with the Secretary of the Treasury and the Secretary of Health and Human Services, will issue a written notice of denial to the IDR entity or revocation to the certified IDR entity within 10 business days of the Secretary's decision, including the effective date of denial or revocation, the reason(s) for denial or revocation, and the opportunity to request appeal of the denial or revocation.

(iv) *Request for appeal of denial or revocation.* To request an appeal, the IDR entity or certified IDR entity must submit a request for appeal to the Secretary within 30 business days of the date of the notice under paragraph (e)(6)(iii) of this section of denial or revocation and in the manner prescribed by the instructions to the notice. During

this time period, the Secretary, jointly with the Secretary of the Treasury and the Secretary of Health and Human Services, will not issue a notice of final denial or revocation and a certified IDR entity may continue to work on previously assigned determinations but may not accept new determinations. If the IDR entity or certified IDR entity does not timely submit a request for appeal of the denial or revocation, the Secretary, jointly with the Secretary of the Treasury and the Secretary of Health and Human Services, will issue a notice of final denial or revocation to the IDR entity or certified IDR entity (if applicable) and the petitioner.

(v) *Denial or final revocation.* Upon notice of denial or final revocation, the IDR entity shall not be considered a certified IDR entity and therefore shall not be eligible to accept payment determinations under the Federal IDR process. Moreover, after a notice of final revocation, the IDR entity may not re-apply to be a certified IDR entity until on or after the 181st day after the date of the notice of denial or final revocation.

(f) *Reporting of information relating to the Federal IDR process*—(1) *Reporting of information.* Within 30 business days of the close of each month, for qualified IDR items and services furnished on or after January 1, 2022, each certified IDR entity must, in a form and manner specified by the Secretary, report:

(i) The number of notices of IDR initiation submitted under paragraph (b)(2) of this section to the certified IDR entity during the immediately preceding month;

(ii) The size of the provider practices and the size of the facilities submitting notices of IDR initiation under paragraph (b)(2) of this section during the immediately preceding month, as required to be provided to the certified IDR entity under paragraph (c)(4)(i)(A)(*2*) of this section;

(iii) The number of such notices of IDR initiation with respect to which a determination was made under paragraph (c)(4)(ii) of this section;

(iv) The number of times during the month that the out-of-network rate determined (or agreed to) under this section has exceeded the qualifying payment amount, specified by qualified IDR items and services;

(v) With respect to each notice of IDR initiation under paragraph (b)(2) of this section for which such a determination was made, the following information:

(A) A description of the qualified IDR items and services included with respect to the notification, including the relevant billing and service codes;

(B) The relevant geographic region for purposes of the qualifying payment amount for the qualified IDR items and services with respect to which the notification was provided;

(C) The amount of the offer submitted under paragraph (c)(4)(i) of this section 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 qualifying payment amount;

(D) Whether the offer selected by the certified IDR entity under paragraph (c)(4) of this section was the offer submitted by the plan or issuer (as applicable) or by the provider or facility (as applicable);

(E) The amount of the selected offer expressed as a dollar amount and as a percentage of the qualifying payment amount;

(F) The rationale for the certified IDR entity's decision, including the extent to which the decision relied on the criteria in paragraph (c)(4)(iv) of this section;

(G) The practice specialty or type of each provider or facility, respectively, involved in furnishing each qualified IDR item or service;

(H) The identity for each plan or issuer, and provider or facility, with respect to the notification. Specifically, each certified IDR entity must provide each party's name and address, as applicable; and

(I) 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.

(vi) The total amount of certified IDR entity fees paid to the certified IDR entity under paragraph (d)(1) of this section during the month.

(2) [Reserved]

(g) *Extension of time periods for extenuating circumstances*—(1) *General.* The time periods specified in this section (other than the time for payment, if applicable, under paragraph (c)(4)(ix) of this section) may be extended in extenuating circumstances at the Secretary's discretion if:

(i) An extension is necessary to address delays due to matters beyond the control of the parties or for good cause; and

(ii) The parties attest that prompt action will be taken to ensure that the determination under this section is made as soon as administratively practicable under the circumstances.

(2) *Process to request an extension.* The parties may request an extension by submitting a request for extension due to extenuating circumstances through the Federal IDR portal if the extension is necessary to address delays due to matters beyond the control of the parties or for good cause.

(h) *Applicability date.* The provisions of this section are applicable with respect to plan years beginning on or after January 1, 2022, except that the provisions regarding IDR entity certification at paragraphs (a) and (e) of this section are applicable beginning on October 7, 2021.

■ 14. Section 2590.717–2 is added to read as follows:

§ 2590.717–2 Independent dispute resolution process for air ambulance services.

(a) *Definitions.* Unless otherwise stated, the definitions in § 2590.716–3 apply.

(b) *Determination of out-of-network rates to be paid by health plans and health insurance issuers; independent dispute resolution process*—(1) *In general.* Except as provided in paragraphs (b)(2) and (3) of this section, in determining the out-of-network rate to be paid by group health plans and health insurance issuers offering group health insurance coverage for out-of-network air ambulance services, plans and issuers must comply with the requirements of § 2590.716–8, except that references in § 2590.716–8 to the additional circumstances in § 2590.716–8(c)(4)(iii)(C) shall be understood to refer to paragraph (b)(2) of this section.

(2) *Additional information.* Additional information submitted by a party, provided the information is credible, relates to the circumstances described in paragraphs (b)(2)(i) through (vi) of this section, with respect to a qualified IDR service of a nonparticipating provider of air ambulance services or health insurance issuer of group or individual health insurance coverage that is the subject of a payment determination. This information must also clearly demonstrate that the qualifying payment amount is materially different from the appropriate out-of-network rate.

(i) The quality and outcomes measurements of the provider that furnished the services.

(ii) The acuity of the condition of the participant or beneficiary receiving the service, or the complexity of furnishing the service to the participant or beneficiary.

(iii) The training, experience, and quality of the medical personnel that furnished the air ambulance services.

(iv) Ambulance vehicle type, including the clinical capability level of the vehicle.

(v) Population density of the point of pick-up (as defined in 42 CFR 414.605)

for the air ambulance (such as urban, suburban, rural, or frontier).

(vi) Demonstrations of good faith efforts (or lack thereof) made by the nonparticipating provider of air ambulance services or the plan or issuer to enter into network agreements with each other and, if applicable, contracted rates between the provider of air ambulance services and the plan or issuer, as applicable, during the previous 4 plan years.

(3) *Reporting of information relating to the IDR process.* In applying the requirements of § 2590.716–8(f), within 30 business days of the close of each month, for services furnished on or after January 1, 2022, the information the certified IDR entity must report, in a form and manner specified by the Secretary, with respect to the Federal IDR process involving air ambulance services is:

(i) The number of notices of IDR initiation submitted under the Federal IDR process to the certified IDR entity that pertain to air ambulance services during the immediately preceding month;

(ii) The number of such notices of IDR initiation with respect to which a final determination was made under § 2590.716–8(c)(4)(ii) of this part (as applied by paragraph (b)(1) of this section);

(iii) The number of times the payment amount determined (or agreed to) under this subsection has exceeded the qualifying payment amount, specified by services;

(iv) With respect to each notice of IDR initiation under § 2590.716–8(b)(2) of this part (as applied by paragraph (b)(1) of this section) for which a determination was made, the following information:

(A) A description of each air ambulance service included in such notification, including the relevant billing and service codes;

(B) The point of pick-up (as defined in 42 CFR 414.605) for the services included in such notification;

(C) The amount of the offers submitted under § 2590.716–8(c)(4)(i) (as applied by paragraph (b)(1) of this section) by the group health plan or health insurance issuer (as applicable) and by the nonparticipating provider of air ambulance services, expressed as a dollar amount and as a percentage of the qualifying payment amount;

(D) Whether the offer selected by the certified IDR entity under § 2590.716–8(c)(4)(ii) of this part (as applied by paragraph (b)(1) of this section) to be the payment amount applied was the offer submitted by the plan or issuer (as applicable) or by the provider of air ambulance services;

(E) The amount of the selected offer expressed as a dollar amount and as a percentage of the qualifying payment amount;

(F) The rationale for the certified IDR entity's decision, including the extent to which the decision relied on the criteria in paragraph (b)(2) of this section;

(G) Air ambulance vehicle type, including the clinical capability level of such vehicle (to the extent this information has been provided to the certified IDR entity);

(H) The identity for each plan or issuer and provider of air ambulance services, with respect to the notification. Specifically, each certified IDR entity must provide each party's name and address, as applicable; and

(I) For each determination, 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.

(v) The total amount of certified IDR entity fees paid to the certified IDR entity under paragraph § 2590.716–8(d)(1) of this part (as applied by paragraph (b)(1) of this section) during the month for determinations involving air ambulance services.

(c) *Applicability date.* The provisions of this section are applicable with respect to plan years beginning on or after January 1, 2022.

Department of Health and Human Services

45 CFR Subtitle A, Subchapter B

For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR parts 147 and 149 as set forth below:

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 15. The authority citation for part 147 continues to read as follows:

Authority: 42 U.S.C. 300gg through 300gg–63, 300gg–91, 300gg–92, and 300gg–111 through 300gg–139, as amended, and section 3203, Pub. L. 116–136, 134 Stat. 281.

■ 16. Section 147.136 is amended by:

■ a. Revising paragraphs (a)(1), (c)(2)(i), and (d)(1)(i)(A) and (B);

■ b. Adding paragraph (d)(1)(i)(C);

■ c. Adding Examples 3 through 7 to paragraph (d)(1)(ii); and

■ d. Revising paragraph (g).

The revisions and additions read as follows:

§ 147.136 Internal claims and appeals and external review processes.

(a) *Scope and definitions*—(1) *Scope*—(i) *In general.* This section sets forth requirements with respect to internal claims and appeals and external review processes for group health plans and health insurance issuers. Paragraph (b) of this section provides requirements for internal claims and appeals processes. Paragraph (c) of this section sets forth rules governing the applicability of State external review processes. Paragraph (d) of this section sets forth a Federal external review process for plans and issuers not subject to an applicable State external review process. Paragraph (e) of this section prescribes requirements for ensuring that notices required to be provided under this section are provided in a culturally and linguistically appropriate manner. Paragraph (f) of this section describes the authority of the Secretary to deem certain external review processes in existence on March 23, 2010 as in compliance with paragraph (c) or (d) of this section.

(ii) *Application to grandfathered health plans and health insurance coverage.* The provisions of this section generally do not apply to coverage offered by health insurance issuers and group health plans that are grandfathered health plans, as defined under § 147.140. However, the external review process requirements under paragraphs (c) and (d) of this section, and related notice requirements under paragraph (e) of this section, apply to grandfathered health plans or coverage with respect to adverse benefit determinations involving items and services within the scope of the requirements for out-of-network emergency services, nonemergency services performed by nonparticipating providers at participating facilities, and air ambulance services furnished by nonparticipating providers of air ambulance services under PHS Act sections 2799A–1 and 2799A–2 and §§ 149.110 through 149.130.

* * * * *

(c) * * *

(2) * * *

(i) The State process must provide for the external review of adverse benefit determinations (including final internal adverse benefit determinations) by issuers (or, if applicable, plans) that are based on the issuer's (or plan's) requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit, as well as a consideration of whether a plan or issuer is complying with the surprise

billing and cost-sharing protections under PHS Act sections 2799A–1 and 2799A–2 and §§ 149.110 through 149.130.

* * * * *

(d) * * *

(1) * * *

(i) * * *

(A) An adverse benefit determination (including a final internal adverse benefit determination) by a plan or issuer that involves medical judgment (including, but not limited to, those based on the plan's or issuer's requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit; its determination that a treatment is experimental or investigational; its determination whether a participant, beneficiary, or enrollee is entitled to a reasonable alternative standard for a reward under a wellness program; its determination whether a plan or issuer is complying with the nonquantitative treatment limitation provisions of PHS Act section 2726 and §§ 146.136 and 147.160, which generally require, among other things, parity in the application of medical management techniques), as determined by the external reviewer. (A denial, reduction, termination, or a failure to provide payment for a benefit based on a determination that a participant, beneficiary, or enrollee fails to meet the requirements for eligibility under the terms of a group health plan or health insurance coverage is not eligible for the Federal external review process under this paragraph (d));

(B) An adverse benefit determination that involves consideration of whether a plan or issuer is complying with the surprise billing and cost-sharing protections set forth in PHS Act sections 2799A–1 and 2799A–2 and §§ 149.110 through 149.130; and

(C) A rescission of coverage (whether or not the rescission has any effect on any particular benefit at that time).

(ii) * * *

Example 3. (i) *Facts.* A group health plan generally provides benefits for services in an emergency department of a hospital or independent freestanding emergency department. Individual *C* receives pre-stabilization emergency treatment in an out-of-network emergency department of a hospital. The group health plan determines that protections for emergency services under § 149.110 do not apply because the treatment did not involve ''emergency services'' within the meaning of § 149.110(c)(2)(i). *C* receives an adverse benefit determination and the plan imposes cost-sharing requirements that are greater than the requirements that would apply if the same services were provided in an in-network emergency department.

(ii) *Conclusion.* In this *Example 3,* the plan's determination that treatment received by *C* did not include emergency services involves medical judgment and consideration of whether the plan complied with § 149.110. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section.

Example 4. (i) *Facts.* A group health plan generally provides benefits for anesthesiology services. Individual *D* undergoes a surgery at an in-network health care facility and during the course of the surgery, receives anesthesiology services from an out-of-network provider. The plan decides the claim for these services without regard to the protections related to items and services furnished by out-of-network providers at in-network facilities under § 149.120. As a result, *D* receives an adverse benefit determination for the services and is subject to cost-sharing liability that is greater than it would be if cost sharing had been calculated in a manner consistent with the requirements of § 149.120.

(ii) *Conclusion.* In this *Example 4,* whether the plan was required to decide the claim in a manner consistent with the requirements of § 149.120 involves considering whether the plan complied with § 149.120, as well as medical judgment, because it requires consideration of the health care setting and level of care. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section.

Example 5. (i) *Facts.* A group health plan generally provides benefits for services in an emergency department of a hospital or independent freestanding emergency department. Individual *E* receives emergency services in an out-of-network emergency department of a hospital, including certain post-stabilization services. The plan processes the claim for the post-stabilization services as not being for emergency services under § 149.110(c)(2)(ii) based on representations made by the treating provider that *E* was in a condition to receive notice from the provider about cost-sharing and surprise billing protections for these services, and subsequently gave informed consent to waive those protections. *E* receives an adverse benefit determination and is subject to cost-sharing requirements that are greater than the cost-sharing requirements that would apply if the services were processed in a manner consistent with § 149.110.

(ii) *Conclusion.* In this *Example 5,* whether *E* was in a condition to receive notice about the availability of cost-sharing and surprise billing protections and give informed consent to waive those protections involves medical judgment and consideration of whether the plan complied with the requirements under § 149.110(c)(2)(ii). Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section.

Example 6. (i) *Facts.* Individual *F* gives birth to a baby at an in-network hospital. The baby is born prematurely and receives certain neonatology services from a nonparticipating provider during the same visit as the birth. *F* was given notice about cost-sharing and surprise billing protections for these services, and subsequently gave informed consent to waive those protections. The claim for the neonatology services is coded as a claim for routine post-natal services and the plan decides the claim without regard to the requirements under § 149.120(a) and the fact that those protections may not be waived for neonatology services under § 149.120(b).

(ii) *Conclusion.* In this *Example 6,* medical judgment is necessary to determine whether the correct code was used and compliance with § 149.120(a) and (b) must also be considered. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section. The Departments also note that, to the extent the nonparticipating provider balance bills Individual *F* for the outstanding amounts not paid by the plan for the neonatology services, such provider would be in violation of PHS Act section 2799B–2 and its implementing regulations at 45 CFR 149.420(a).

Example 7. (i) *Facts.* A group health plan generally provides benefits to cover knee replacement surgery. Individual *G* receives a knee replacement surgery at an in-network facility and, after receiving proper notice about the availability of cost-sharing and surprise billing protections, provides informed consent to waive those protections. However, during the surgery, certain anesthesiology services are provided by an out-of-network nurse anesthetist. The claim for these anesthesiology services is decided by the plan without regard to the requirements under § 149.120(a) or to the fact that those protections may not be waived for ancillary services such as anesthesiology services provided by an out-of-network provider at an in-network facility under § 149.120(b). *G* receives an adverse benefit determination and is subject to cost-sharing requirements that are

greater than the cost-sharing requirements that would apply if the services were provided in a manner consistent with § 149.120(a) and (b).

(ii) *Conclusion.* In this *Example 7,* consideration of whether the plan complied with the requirements in § 149.120(a) and (b) is necessary to determine whether cost-sharing requirements were applied appropriately. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section.

* * * * *

(g) *Applicability date.* The provisions of this section generally are applicable to group health plans and health insurance issuers for plan years (in the individual market, policy years) beginning on or after January 1, 2017. The external review scope provision at paragraph (d)(1)(i)(B) of this section is applicable for plan years (in the individual market, policy years) beginning on or after January 1, 2022. The external review provisions described in paragraphs (c) and (d) of this section are applicable to grandfathered health plans and grandfathered individual market policies, with respect to the types of claims specified under paragraph (a)(1)(ii) of this section, for plan years (in the individual market, policy years) beginning on or after January 1, 2022.

PART 149—SURPRISE BILLING AND TRANSPARENCY REQUIREMENTS

■ 17. The authority citation for part 149 is amended to read as follows:

Authority: 42 U.S.C. 300gg–92 and 300gg–111 through 300gg–139, as amended.

■ 18. Section 149.10 is amended by revising paragraph (b) to read as follows:

§ 149.10 Basis and scope.

* * * * *

(b) *Scope.* This part establishes standards for group health plans, health insurance issuers offering group or individual health insurance coverage, health care providers and facilities, and providers of air ambulance services with respect to surprise medical bills, transparency in health care coverage, and additional patient protections. This part also establishes an independent dispute resolution process, and standards for certifying independent dispute resolution entities. This part also establishes a Patient-Provider Dispute Resolution Process and standards for certifying Selected Dispute Resolution entities.

■ 17. Section 149.20 is amended by adding paragraphs (a)(3) and (4) and revising paragraph (b) introductory text to read as follows:

§ 149.20 Applicability.

(a) * * *

(3) The requirements in subpart F of this part apply to certified IDR entities, health care providers, health care facilities, and providers of air ambulance services and group health plans and health insurance issuers offering group or individual health insurance coverage (including grandfathered health plans as defined in § 147.140 of this subchapter) except as specified in paragraph (b) of this section.

(4) The requirements in subpart G of this part apply to Selected Dispute Resolution Entities, health care providers, providers of air ambulance services, health care facilities and uninsured (or self-pay) individuals, as defined in subpart G.

(b) *Exceptions.* The requirements in subparts B, D, E, and F of this part do not apply to the following:

* * * * *

■ 18. Section 149.450 is amended by revising paragraphs (a)(1) and (a)(2)(i) to read as follows:

§ 149.450 Complaint process for balance billing and good faith estimates regarding providers and facilities.

(a) *Scope and definitions*—(1) *Scope.* This section establishes a process for HHS to receive and resolve complaints regarding information that a health care provider, provider of air ambulance services, or health care facility may be failing to meet the requirements under subpart E or subpart G of this part, which may warrant an investigation.

(2) * * *

(i) Complaint means a communication, written, or oral, that indicates there has been a potential violation of the requirements under this subpart or subpart G of this part, whether or not a violation actually occurred.

* * * * *

■ 20. Subpart F, consisting of §§ 149.510 and 149.520. is added to read as follows:

Subpart F—Independent Dispute Resolution Process

§ 149.510 Independent dispute resolution process.

(a) *Scope and definitions*—(1) *Scope.* This section sets forth requirements with respect to the independent dispute resolution (IDR) process (referred to in this section as the Federal IDR process) under which a nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services (as applicable), and a group health plan or health insurance issuer offering group or individual health insurance coverage completes a requisite open negotiation period and at least one party submits a notification under paragraph (b) of this section to initiate the Federal IDR process under paragraph (c) of this section, and under which an IDR entity (as certified under paragraph (e) of this section) determines the amount of payment under the plan or coverage for an item or service furnished by the provider or facility.

(2) *Definitions.* Unless otherwise stated, the definitions in § 149.30 of this part apply to this section. Additionally, for purposes of this section, the following definitions apply:

(i) *Batched items and services* means multiple qualified IDR items or services that are considered jointly as part of one payment determination by a certified IDR entity for purposes of the Federal IDR process. In order for a qualified IDR item or service to be included in a batched item or service, the qualified IDR item or service must meet the criteria set forth in paragraph (c)(3) of this section.

(ii) *Breach* means the acquisition, access, use, or disclosure of individually identifiable health information (IIHI) in a manner not permitted under paragraph (e)(2)(v) of this section that compromises the security or privacy of the IIHI.

(A) Breach excludes:

(*1*) Any unintentional acquisition, access, or use of IIHI by personnel, a contractor, or a subcontractor of a certified IDR entity that is acting under the authority of that certified IDR entity, if the acquisition, access, or use was made in good faith and within the scope of that authority and that does not result in further use or disclosure in a manner not permitted under paragraph (e)(2)(v) of this section.

(*2*) Any inadvertent disclosure by a person who is authorized to access IIHI at a certified IDR entity to another person authorized to access IIHI at the same certified IDR entity, and the information received as a result of the disclosure is not further used or disclosed in a manner not permitted under paragraph (e)(2)(v) of this section.

(*3*) A disclosure of IIHI in which a certified IDR entity has a good faith belief that an unauthorized person to whom the disclosure was made would not reasonably have been able to retain such information.

(B) Except as provided in paragraph (a)(2)(ii)(A) of this definition, access, use, or disclosure of IIHI in a manner not permitted under paragraph (e)(2)(v)

of this section is presumed to be a breach unless the certified IDR entity demonstrates that there is a low probability that the security or privacy of the IIHI has been compromised based on a risk assessment encompassing at least the following factors:

(*1*) The nature and extent of the IIHI involved, including the types of identifiers and the likelihood of re-identification;

(*2*) The unauthorized person who used the IIHI or to whom the disclosure was made;

(*3*) Whether the IIHI was actually acquired or viewed; and

(*4*) The extent to which the risk to the IIHI has been mitigated.

(iii) *Certified IDR entity* means an entity responsible for conducting determinations under paragraph (c) of this section that meets the certification criteria specified in paragraph (e) of this section and that has been certified by the Secretary, jointly with the Secretaries of Labor and the Treasury.

(iv) *Conflict of interest* means, with respect to a party to a payment determination, or certified IDR entity, a material relationship, status, or condition of the party, or certified IDR entity that impacts the ability of the certified IDR entity to make an unbiased and impartial payment determination. For purposes of this section, a conflict of interest exists when a certified IDR entity is:

(A) A group health plan; a health insurance issuer offering group health insurance coverage, individual health insurance coverage, or short-term, limited-duration insurance; a carrier offering a health benefits plan under 5 U.S.C. 8902; or a provider, a facility, or a provider of air ambulance services;

(B) An affiliate or a subsidiary of a group health plan; a health insurance issuer offering group health insurance coverage, individual health insurance coverage, or short-term limited-duration insurance; a carrier offering a health benefits plan under 5 U.S.C. 8902; or a provider, a facility, or a provider of air ambulance services;

(C) An affiliate or subsidiary of a professional or trade association representing group health plans; health insurance issuers offering group health insurance coverage, individual health insurance coverage, or short-term limited duration insurance; carriers offering a health benefits plan under 5 U.S.C. 8902; or providers, facilities, or providers of air ambulance services.

(D) A certified IDR entity, that has, or that has any personnel, contractors, or subcontractors assigned to a determination who have, a material familial, financial, or professional relationship with a party to the payment determination being disputed, or with any officer, director, or management employee of the plan, issuer, or carrier offering a health benefits plan under 5 U.S.C. 8902; the plan or coverage administrator, plan or coverage fiduciaries, or plan, issuer or carrier employees; the health care provider, the health care provider's group or practice association; the provider of air ambulance services, the provider of air ambulance services' group or practice association, or the facility that is a party to the dispute.

(v) *Credible information* means information that upon critical analysis is worthy of belief and is trustworthy.

(vi) *IDR entity* means an entity that may apply or has applied for certification to conduct determinations under paragraph (c) of this section, and that currently is not certified by the Secretary, jointly with the Secretaries of Labor and the Treasury, pursuant to paragraph (e) of this section.

(vii) *Individually identifiable health information (IIHI)* means any information, including demographic data, that relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and

(A) That identifies the individual; or

(B) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

(viii) *Material difference* means a substantial likelihood that a reasonable person with the training and qualifications of a certified IDR entity making a payment determination would consider the submitted information significant in determining the out-of-network rate and would view the information as showing that the qualifying payment amount is not the appropriate out-of-network rate.

(ix) *Material familial relationship* means any relationship as a spouse, domestic partner, child, parent, sibling, spouse's or domestic partner's parent, spouse's or domestic partner's sibling, spouse's or domestic partner's child, child's parent, child's spouse or domestic partner, or sibling's spouse or domestic partner.

(x) *Material financial relationship* means any financial interest of more than five percent of total annual revenue or total annual income of a certified IDR entity or an officer, director, or manager thereof, or of a reviewer or reviewing physician employed or engaged by a certified IDR entity to conduct or participate in any review in the Federal IDR process. The terms annual revenue and annual income do not include mediation fees received by mediators who are also arbitrators, provided that the mediator acts in the capacity of a mediator and does not represent a party in the mediation.

(xi) *Material professional relationship* means any physician-patient relationship, any partnership or employment relationship, any shareholder or similar ownership interest in a professional corporation, partnership, or other similar entity; or any independent contractor arrangement that constitutes a material financial relationship with any expert used by the certified IDR entity or any officer or director of the certified IDR entity.

(xii) *Qualified IDR item or service* means an item or service:

(A) That is an emergency service furnished by a nonparticipating provider or nonparticipating facility subject to the protections of 26 CFR 54.9816–4T, 29 CFR 2590.716–4, or § 149.110, as applicable, for which the conditions of § 149.410(b) are not met, or an item or service furnished by a nonparticipating provider at a participating health care facility, subject to the requirements of 26 CFR 54.9816–5T, 29 CFR 2590.717–5, or § 149.120, as applicable, for which the conditions of § 149.420(c)–(i) are not met, or air ambulance services furnished by a nonparticipating provider of air ambulance services subject to the protections of 26 CFR 54.9817–1T, 29 CFR 2590.717–1, or § 149.130, as applicable, and for which the out-of-network rate is not determined by reference to an All-Payer Model Agreement under section 1115A of the Social Security Act or a specified State law as defined in § 149.30;

(B) With respect to which a provider or facility (as applicable) or group health plan or health insurance issuer offering group or individual health insurance coverage submits a notification under paragraph (b)(2) of this section;

(C) That is not an item or service that is the subject of an open negotiation under paragraph (b)(1) of this section; and

(D) That is not an item or service for which a notification under paragraph (b)(2) of this section is submitted during the 90-calendar-day period under paragraph (c)(4)(vi)(B) of this section, but that may include such an item or service if the notification is submitted during the subsequent 30-business-day period under paragraph (c)(4)(vi)(C) of this section.

(xiii) *Unsecured IIHI* means IIHI that is not rendered unusable, unreadable, or indecipherable to unauthorized persons through the use of a technology or methodology specified by the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor.

(b) *Determination of payment amount through open negotiation and initiation of the Federal IDR process*—(1) *Determination of payment amount through open negotiation*—(i) *In general.* With respect to an item or service that meets the requirements of paragraph (a)(2)(xii)(A) of this section, the provider, facility, or provider of air ambulance services or the group health plan or health insurance issuer offering group or individual health insurance coverage may, during the 30-business-day period beginning on the day the provider, facility, or provider of air ambulance services receives an initial payment or notice of denial of payment regarding the item or service, initiate an open negotiation period for purposes of determining the out-of-network rate for such item or service. To initiate the open negotiation period, a party must send a notice to the other party (open negotiation notice) in accordance with paragraph (b)(1)(ii) of this section.

(ii) *Open negotiation notice*—(A) *Content.* The open negotiation notice must include information sufficient to identify the item(s) and service(s) (including the date(s) the item(s) or service(s) were furnished, the service code, and initial payment amount, if applicable), an offer of an out-of-network rate, and contact information for the party sending the open negotiation notice.

(B) *Manner.* The open negotiation notice must be provided, using the standard form developed by the Secretary, in writing within 30 business days beginning on the day the provider, facility, or provider of air ambulance services receives an initial payment or a notice of denial of payment from the plan or issuer regarding the item or service. The day on which the open negotiation notice is first sent by a party is the date the 30-business-day open negotiation period begins. This notice may be provided to the other party electronically (such as by email) if the following two conditions are satisfied—

(*1*) The party sending the open negotiation notice has a good faith belief that the electronic method is readily accessible by the other party; and

(*2*) The notice is provided in paper form free of charge upon request.

(2) *Initiating the Federal IDR process*—(i) *In general.* With respect to an item or service for which the parties do not agree upon an out-of-network rate by the last day of the open negotiation period under paragraph (b)(1) of this section, either party may initiate the Federal IDR process. To initiate the Federal IDR process, a party must submit a written notice of IDR initiation to the other party and to the Secretary, using the standard form developed by the Secretary, during the 4-business-day period beginning on the 31st business day after the start of the open negotiation period.

(ii) *Exception for items and services provided by certain nonparticipating providers and facilities.* A party may not initiate the Federal IDR process with respect to an item or service if, with respect to that item or service, the party knows (or reasonably should have known) that the provider or facility provided notice and received consent under 45 CFR 149.410(b) or 149.420(c) through (i).

(iii) *Notice of IDR initiation*—(A) *Content.* The notice of IDR initiation must include:

(*1*) Information sufficient to identify the qualified IDR items or services under dispute (and whether the qualified IDR items or services are designated as batched items and services as described in paragraph (c)(3) of this section), including the date(s) and location the item or service was furnished, the type of item or service (such as whether the qualified IDR item or service is an emergency service as defined in 26 CFR 54.9816–4T(c)(2)(i), 29 CFR 2590.716–4(c)(2)(i), or § 149.110(c)(2)(i), as applicable, an emergency service as defined in 26 CFR 54.9816–4T(c)(2)(ii), 29 CFR 2590.716–4(c)(2)(ii), or § 149.110(c)(2)(ii), as applicable, or a nonemergency service; and whether any service is a professional service or facility-based service), corresponding service codes, place of service code, the amount of cost sharing allowed, and the amount of the initial payment made for the qualified IDR item or service, if applicable;

(*2*) Names of the parties involved and contact information, including name, email address, phone number, and mailing address;

(*3*) State where the qualified IDR item or service was furnished;

(*4*) Commencement date of the open negotiation period under paragraph (b)(1) of this section;

(*5*) Preferred certified IDR entity;

(*6*) An attestation that the items and services under dispute are qualified IDR items or services;

(*7*) Qualifying payment amount;

(*8*) Information about the qualifying payment amount as described in § 149.140(d); and

(*9*) General information describing the Federal IDR process as specified by the Secretary.

(B) Manner. The initiating party must provide written notice of IDR initiation to the other party. The initiating party may satisfy this requirement by furnishing the notice of IDR initiation to the other party electronically (such as by email) if the following two conditions are satisfied—

(*1*) The initiating party has a good faith belief that the electronic method is readily accessible by the other party; and

(*2*) The notice is provided in paper form free of charge upon request.

(C) Notice to the Secretary. The initiating party must also furnish the notice of IDR initiation to the Secretary by submitting the notice through the Federal IDR portal. The initiation date of the Federal IDR process will be the date of receipt by the Secretary.

(c) *Federal IDR process following initiation*—(1) *Selection of certified IDR entity*—(i) *In general.* The plan or issuer or the provider, facility, or provider of air ambulance services receiving the notice of IDR initiation under paragraph (b)(2) of this section may agree or object to the preferred certified IDR entity identified in the notice of IDR initiation. If the party in receipt of the notice of IDR initiation fails to object within 3 business days, the preferred certified IDR entity identified in the notice of IDR initiation will be selected and will be treated as jointly agreed to by the parties, provided that the certified IDR entity does not have a conflict of interest. If the party in receipt of the notice of IDR initiation objects, that party must notify the initiating party of the objection and propose an alternative certified IDR entity. The initiating party must then agree or object to the alternative certified IDR entity; if the initiating party fails to agree or object to the alternative certified IDR entity, the alternative certified IDR entity will be selected and will be treated as jointly agreed to by the parties. In order to select a preferred certified IDR entity, the plan or issuer and the provider, facility, or provider of air ambulance services must jointly agree on a certified IDR entity not later than 3 business days after the initiation date of the Federal IDR process. If the plan or issuer and the provider, facility, or provider of air ambulance services fail to agree upon a certified IDR entity within that time, the Secretary shall select a certified IDR entity in accordance with paragraph (c)(1)(iv) of this section.

(ii) *Requirements for selected certified IDR entity.* The certified IDR entity

selected must be an IDR entity certified under paragraph (e) of this section, that:

(A) Does not have a conflict of interest as defined in paragraph (a)(2) of this section;

(B) Ensures that assignment of personnel to a payment determination and decisions regarding hiring, compensation, termination, promotion, or other similar matters related to personnel assigned to the dispute are not made based upon the likelihood that the assigned personnel will support a particular party to the determination being disputed other than as outlined under paragraph (c)(4)(iii) of this section; and

(C) Ensures that any personnel assigned to a payment determination do not have any conflicts of interests as defined in paragraph (a)(2) of this section regarding any party to the dispute within the 1 year immediately preceding an assignment of dispute determination, similar to the requirements laid out in 18 U.S.C. 207(b).

(iii) *Notice of certified IDR entity selection.* Upon the selection of a certified IDR entity, in accordance with paragraph (c)(1)(i) of this section, the plan or issuer or the provider or emergency facility that submitted the notice of IDR initiation under paragraph (b)(2) of this section must notify the Secretary of the selection as soon as reasonably practicable, but no later than 1 business day after such selection, through the Federal IDR portal. In addition, if the non-initiating party believes that the Federal IDR process is not applicable, the non-initiating party must also provide information regarding the Federal IDR process's inapplicability through the Federal IDR portal by the same date that the notice of certified IDR entity selection must be submitted.

(A) *Content.* If the parties have agreed on the selection of a certified IDR entity or the party in receipt of the notice of IDR initiation has not objected to the other party's selection, the notice of the certified IDR entity selection must include the following information:

(*1*) Name of the certified IDR entity;

(*2*) The certified IDR entity number; and

(*3*) Attestation by both parties, or by the initiating party if the non-initiating party fails to object to the selection of the certified IDR entity, that the selected certified IDR entity meets the requirements of paragraph (c)(1)(ii) of this section.

(B) {Reserved]

(iv) *Failure to select a certified IDR entity.* If the plan or issuer and the provider, facility, or provider of air ambulance services fail to select a certified IDR entity in accordance with paragraph (c)(1)(i) of this section, the initiating party must notify the Secretary of the failure no later than 1 business day after the date of such failure (or in other words, 4 business days after initiation of the Federal IDR process) by electronically submitting the notice as described in paragraph (c)(1)(iii) of this section but indicating that the parties have failed to select a certified IDR entity. In addition, if the non-initiating party believes that the Federal IDR process is not applicable, the non-initiating party must also provide information regarding Federal IDR process's inapplicability through the Federal IDR portal by the same date that the notice of failure to select must be submitted. Upon notification of the failure of the parties to select a certified IDR entity, the Secretary will select a certified IDR entity that charges a fee within the allowed range of certified IDR entity fees through a random selection method not later than 6 business days after the date of initiation of the Federal IDR process and will notify the plan or issuer and the provider or facility of the selection. If there are insufficient certified IDR entities that charge a fee within the allowed range of certified IDR entity fees available to arbitrate the dispute, the Secretary, jointly with the Secretary of the Treasury and Secretary of Labor, will select a certified IDR entity that has received approval, as described in paragraph (e)(2)(vi)(B) of this section, to charge a fee outside of the allowed range of certified IDR entity fees.

(v) *Review by certified IDR entity.* After selection by the parties (including when the initiating party selects a certified IDR entity and the other party does not object), or by the Secretary under paragraph (c)(1)(iv) of this section, the certified IDR entity must review the selection and attest that it meets the requirements of paragraph (c)(1)(ii) of this section. If the certified IDR entity is unable to attest that it meets the requirements of paragraph (c)(1)(ii) of this section within 3 business days of selection, the parties, upon notification, must select another certified IDR entity under paragraph (c)(1) of this section, treating the date of notification of the failure to attest to the requirements of (c)(1)(ii) as the date of initiation of the Federal IDR process for purposes of the time periods in paragraphs (c)(1)(i) and (iv) of this section. Additionally, the certified IDR entity selected must review the information submitted in the notice of IDR initiation to determine whether the Federal IDR process applies. If the Federal IDR process does not apply, the certified IDR entity must notify the Secretary and the parties within 3 business days of making that determination.

(2) *Authority to continue negotiations*—(i) *In general.* If the parties to the Federal IDR process agree on an out-of-network rate for a qualified IDR item or service after providing the notice of IDR initiation to the Secretary consistent with paragraph (b)(2) of this section, but before the certified IDR entity has made its payment determination, the amount agreed to by the parties for the qualified IDR item or service will be treated as the out-of-network rate for the qualified IDR item or service. To the extent the amount exceeds the initial payment amount (or initial denial of payment) and any cost sharing paid or required to be paid by the participant or beneficiary, payment must be made directly by the plan or issuer to the nonparticipating provider, facility, or nonparticipating provider of air ambulance services not later than 30 business days after the agreement is reached. In no instance may either party seek additional payment from the participant or beneficiary, including in instances in which the out-of-network rate exceeds the qualifying payment amount. The initiating party must send a notification to the Secretary and to the certified IDR entity (if selected) electronically, through the Federal IDR portal, as soon as possible, but no later than 3 business days after the date of the agreement. The notification must include the out-of-network rate for the qualified IDR item or service and signatures from authorized signatories for both parties.

(ii) *Method of allocation of the certified IDR entity fee.* In the case of an agreement described in paragraph (c)(2)(i) of this section, the certified IDR entity is required to return half of each parties' certified IDR entity fee, unless directed otherwise by both parties. The administrative fee under paragraph (d)(2) of this section will not be returned to the parties.

(3) *Treatment of batched items and services*—(i) *In general.* Batched items and services may be submitted and considered jointly as part of one payment determination by a certified IDR entity only if the batched items and services meet the requirements of this paragraph (c)(3)(i). Batched items and services submitted and considered jointly as part of one payment determination under this paragraph (c)(3)(i) are treated as a batched determination and subject to the fee for batched determinations under this section.

(A) The qualified IDR items and services are billed by the same provider or group of providers, the same facility, or the same provider of air ambulance services. Items and services are billed by the same provider or group of providers, the same facility, or the same provider of air ambulance services if the items or services are billed with the same National Provider Identifier or Tax Identification Number;

(B) Payment for the qualified IDR items and services would be made by the same plan or issuer;

(C) The qualified IDR items and services are the same or similar items and services. The qualified IDR items and services are considered to be the same or similar items or services if each is billed under the same service code, or a comparable code under a different procedural code system, such as Current Procedural Terminology (CPT) codes with modifiers, if applicable, Healthcare Common Procedure Coding System (HCPCS) with modifiers, if applicable, or Diagnosis-Related Group (DRG) codes with modifiers, if applicable; and

(D) All the qualified IDR items and services were furnished within the same 30-business-day period, or the same 90-calendar-day period under paragraph (c)(4)(vi)(B) of this section, as applicable.

(ii) *Treatment of bundled payment arrangements.* In the case of qualified IDR items and services billed by a provider, facility, or provider of air ambulance services as part of a bundled payment arrangement, or where a plan or issuer makes or denies an initial payment as a bundled payment, the qualified IDR items and services may be submitted as part of one payment determination. Bundled payment arrangements submitted under this paragraph (c)(3)(ii) are subject to the rules for batched determinations and the certified IDR entity fee for single determinations.

(4) *Payment determination for a qualified IDR item or service*—(i) *Submission of offers.* Not later than 10 business days after the selection of the certified IDR entity, the plan or issuer and the provider, facility, or provider of air ambulance services:

(A) Must each submit to the certified IDR entity:

(*1*) An offer of an out-of-network rate expressed as both a dollar amount and the corresponding percentage of the qualifying payment amount represented by that dollar amount;

(*2*) Information requested by the certified IDR entity relating to the offer.

(*3*) The following additional information, as applicable—

(*i*) For providers and facilities, information on the size of the provider's practice or of the facility (if applicable). Specifically, a group of providers must specify whether the providers' practice 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;

(*ii*) For providers and facilities, information on the practice specialty or type, respectively (if applicable);

(*iii*) For plans and issuers, information on the coverage area of the plan or issuer, the relevant geographic region for purposes of the qualifying payment amount, whether the coverage is fully-insured or partially or fully self-insured (or a FEHB carrier if the item or service relates to FEHB plans); and

(*iv*) The qualifying payment amount for the applicable year for the same or similar item or service as the qualified IDR item or service.

(B) May each submit to the certified IDR entity any information relating to the offer that was submitted by either party, except that the information may not include information on factors described in paragraph (c)(4)(v) of this section.

(ii) *Payment determination and notification.* Not later than 30 business days after the selection of the certified IDR entity, the certified IDR entity must:

(A) Select as the out-of-network rate for the qualified IDR item or service one of the offers submitted under paragraph (c)(4)(i) of this section, taking into account the considerations specified in paragraph (c)(4)(iii) of this section (as applied to the information provided by the parties pursuant to paragraph (c)(4)(i) of this section). The certified IDR entity must select the offer closest to the qualifying payment amount unless the certified IDR entity determines that credible information submitted by either party under paragraph (c)(4)(i) clearly demonstrates that the qualifying payment amount is materially different from the appropriate out-of-network rate, or if the offers are equally distant from the qualifying payment amount but in opposing directions. In these cases, the certified IDR entity must select the offer as the out-of-network rate that the certified IDR entity determines best represents the value of the qualified IDR item or services, which could be either offer.

(B) Notify the plan or issuer and the provider or facility, as applicable, of the selection of the offer under paragraph (c)(4)(ii)(A) of this section, and provide the written decision required under (c)(4)(vi) of this section.

(iii) *Considerations in determination.* In determining which offer to select, the certified IDR entity must consider:

(A) The qualifying payment amount(s) for the applicable year for the same or similar item or service.

(B) Information requested by the certified IDR entity under paragraph (c)(4)(i)(A)(*2*) of this section relating to the offer, to the extent a party provides credible information.

(C) Additional information submitted by a party, provided the information is credible and relates to the circumstances described in paragraphs (c)(4)(iii)(C)(*1*) through (*5*) of this section, with respect to a qualified IDR item or service of a nonparticipating provider, facility, group health plan, or health insurance issuer of group or individual health insurance coverage that is the subject of a payment determination. This information must also clearly demonstrate that the qualifying payment amount is materially different from the appropriate out-of-network rate.

(*1*) The level of training, experience, and quality and outcomes measurements of the provider or facility that furnished the qualified IDR item or service (such as those endorsed by the consensus-based entity authorized in section 1890 of the Social Security Act).

(*2*) The market share held by the provider or facility or that of the plan or issuer in the geographic region in which the qualified IDR item or service was provided.

(*3*) The acuity of the participant, beneficiary, or enrollee receiving the qualified IDR item or service, or the complexity of furnishing the qualified IDR item or service to the participant, beneficiary, or enrollee.

(*4*) The teaching status, case mix, and scope of services of the facility that furnished the qualified IDR item or service, if applicable.

(*5*) Demonstration of good faith efforts (or lack thereof) made by the provider or facility or the plan or issuer to enter into network agreements with each other, and, if applicable, contracted rates between the provider or facility, as applicable, and the plan or issuer, as applicable, during the previous 4 plan years.

(D) Additional information submitted by a party, provided the information is credible and relates to the offer submitted by either party and does not include information on factors described in paragraph (c)(4)(v) of this section.

(iv) *Examples.* The rules of paragraph (c)(4)(iii) of this section are illustrated by the following examples:

(A) *Example 1*—(*1*) *Facts.* A nonparticipating provider and an issuer are parties to a payment determination in the Federal IDR process. The nonparticipating provider submits an offer and additional written information asserting that the provider has made good faith efforts to enter into network agreements with the issuer. The nonparticipating provider fails to provide any documentation of these efforts, such as correspondence or records of conversations with representatives of the issuer.

(*2*) *Conclusion.* In this *Example 1,* the nonparticipating provider has submitted additional information. However, this information is not credible, as the nonparticipating provider has failed to provide any documentation in support of the provider's assertions of good faith efforts to enter into network agreements with the issuer. Therefore, the certified IDR entity cannot consider the information.

(B) *Example 2*—(*1*) *Facts.* A nonparticipating provider and an issuer are parties to a payment determination in the Federal IDR process. The nonparticipating provider submits credible information relating to the provider's level of training, experience, and quality and outcome measurements from 2019. The provider also submits credible information that clearly demonstrates that the provider's level of training and expertise was necessary for providing the service that is the subject of the payment determination to the particular patient. Further, the provider submits credible information that clearly demonstrates that the qualifying payment amount generally presumes the service would be delivered by a provider with a lower level of training, experience, and quality and outcome measurements. This information, taken together, demonstrates that the qualifying payment amount is not an appropriate payment amount and the provider submits an offer that is higher than the qualifying payment amount and commensurate with the provider's level of training, experience, and quality and outcome measurements with respect to the service provided. The issuer submits the qualifying payment amount as its offer with no additional information.

(*2*) *Conclusion.* In this *Example 2,* the nonparticipating provider has submitted information that is credible. Moreover, the credible information clearly demonstrates that the qualifying payment amount does not adequately take into account the provider's level of training, experience, and quality and outcome measurements with respect to the service provided, and that the appropriate out-of-network rate should therefore be higher than the qualifying payment amount. Accordingly, the certified IDR entity must select the provider's offer, as that offer best represents the value of the service that is the subject of the payment determination.

(C) *Example 3*—(*1*) *Facts.* A nonparticipating provider and an issuer are parties to a payment determination in the Federal IDR process. The nonparticipating provider submits credible information to the certified IDR entity relating to the acuity of the patient that received the service, and the complexity of furnishing the service to the patient, by providing details of the service at issue and the training required to furnish the complex service. The provider contends that this information demonstrates that the qualifying payment amount is not an appropriate payment amount, and the provider submits an offer that is higher than the qualifying payment amount and equal to what the provider believes is commensurate with the acuity of the patient and the complexity of the service that is the subject of the payment determination. However, the evidence submitted by the provider does not clearly demonstrate that the qualifying payment amount fails to encompass the acuity and complexity of the service. The issuer submits the qualifying payment amount as its offer, along with credible information that demonstrates how the qualifying payment amount was calculated for this particular service, taking into consideration the acuity of the patient and the complexity of the service.

(*2*) *Conclusion.* The information submitted by the provider to the certified IDR entity is credible with respect to the acuity of the patient and complexity of the service. However, in this example, the provider has not clearly demonstrated that the qualifying payment amount is materially different from the appropriate out-of-network rate, based on the acuity of the patient and the complexity of the service that is the subject of the payment determination. Accordingly, the certified IDR entity must select the offer closest to the qualifying payment amount, which is the issuer's offer.

(D) *Example 4*—(*1*) *Facts.* A nonparticipating provider and an issuer are parties to a payment determination in the Federal IDR process. The issuer submits credible information demonstrating that the patent for the item that is the subject of the payment determination has expired, including written documentation that demonstrates how much the cost of the item was at the time the provider rendered service and how the qualifying payment amount exceeds that cost. The issuer submits an offer that is lower than the qualifying payment amount and commensurate with the cost of the item at the time service was rendered. The nonparticipating provider submits the qualifying payment amount as its offer and also submits credible information demonstrating the provider's level of training, experience, and quality and outcome measurements from 2019, but the provider does not explain how this additional information is relevant to the cost of the item.

(*2*) *Conclusion.* In this *Example 4,* both the nonparticipating provider and issuer submitted information that is credible and that may be considered by the certified IDR entity. However, only the issuer provided credible information that was relevant to the service that is the subject of the payment determination. Moreover, the issuer has clearly demonstrated that the qualifying payment amount does not adequately take into account the complexity of the item furnished—in this case that the item is no longer patent protected. While the provider submitted credible information, the provider failed to show how the information was relevant to the item that is the subject of the payment determination. Accordingly, the certified IDR entity must select the offer that best represents the value of the item, which is the issuer's offer in this example.

(v) *Prohibition on consideration of certain factors.* In determining which offer to select, the certified IDR entity must not consider:

(A) Usual and customary charges (including payment or reimbursement rates expressed as a proportion of usual and customary charges);

(B) The amount that would have been billed by the provider or facility with respect to the qualified IDR item or service had the provisions of 45 CFR 149.410 and 149.420 (as applicable) not applied; or

(C) The payment or reimbursement rate for items and services furnished by the provider or facility payable by a public payor, including under the Medicare program under title XVIII of the Social Security Act; the Medicaid program under title XIX of the Social Security Act; the Children's Health Insurance Program under title XXI of the Social Security Act; the TRICARE program under chapter 55 of title 10, United States Code; chapter 17 of title 38, United States Code; or

demonstration projects under section 1115 of the Social Security Act.

(vi) *Written decision.* (A) The certified IDR entity must explain its determination in a written decision submitted to the parties and the Secretary, in a form and manner specified by the Secretary;

(B) 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 qualifying payment amount was materially different from the appropriate out-of-network rate, based on the considerations allowed under paragraph (c)(4)(iii)(B) through (D) of this section, with respect to the qualified IDR item or service.

(vii) *Effects of determination*—(A) *Binding.* A determination made by a certified IDR entity under paragraph (c)(4)(ii) of this section:

(*1*) Is binding upon the parties, in the absence of fraud or evidence of intentional misrepresentation of material facts presented to the certified IDR entity regarding the claim; and

(*2*) Is not subject to judicial review, except in a case described in any of paragraphs (1) through (4) of section 10(a) of title 9, United States Code.

(B) *Suspension of certain subsequent IDR requests.* In the case of a determination made by a certified IDR entity under paragraph (c)(4)(ii) of this section, the party that submitted the initial notification under paragraph (b)(2) of this section may not submit a subsequent notification involving the same other party with respect to a claim for the same or similar item or service that was the subject of the initial notification during the 90-calendar-day period following the determination.

(C) *Subsequent submission of requests permitted.* If the end of the open negotiation period specified in paragraph (b)(1) of this section occurs during the 90-calendar-day suspension period regarding claims for the same or similar item or service that were the subject of the initial notice of IDR determination as described in paragraph (c)(4)(vi) of this section, either party may initiate the Federal IDR process for those claims by submitting a notification as specified in paragraph (b)(2) of this section during the 30-business-day period beginning on the day after the last day of the 90-calendar-day suspension period.

(viii) *Recordkeeping requirements.* The certified IDR entity must maintain records of all claims and notices associated with the Federal IDR process with respect to any determination for 6 years. The certified IDR entity must make these records available for examination by the plan, issuer, FEHB carrier, provider, facility, or provider of air ambulance services, or a State or Federal oversight agency upon request, except to the extent the disclosure would violate either State or Federal privacy law.

(ix) *Payment.* If applicable, the amount of the offer selected by the certified IDR entity (less the sum of the initial payment and any cost sharing paid or owed by the participant or beneficiary) must be paid directly to the provider, facility, or provider of air ambulance services not later than 30 calendar days after the determination by the certified IDR entity. If the offer selected by the certified IDR entity is less than the sum of the initial payment and any cost sharing paid by the participant or beneficiary, the provider, facility, or provider of air ambulance services will be liable to the plan or issuer for the difference. The provider, facility, or provider of air ambulance services must pay the difference directly to the plan or issuer not later than 30 calendar days after the determination by the certified IDR entity.

(d) *Costs of IDR process*—(1) *Certified IDR entity fee.* (i) With respect to the Federal IDR process described in paragraph (c) of this section, the party whose offer submitted to the certified IDR entity under paragraph (c)(4)(ii)(A) of this section is not selected is responsible for the payment to the certified IDR entity of the predetermined fee charged by the certified IDR entity.

(ii) Each party to a determination for which a certified IDR entity is selected under paragraph (c)(1) of this section must pay the predetermined certified IDR entity fee charged by the certified IDR entity to the certified IDR entity at the time the parties submit their offers under (c)(4)(i) of this section. The certified IDR entity fee paid by the prevailing party whose offer is selected by the certified IDR entity will be returned to that party within 30 business days following the date of the certified IDR entity's determination.

(2) *Administrative fee.* (i) Each party to a determination for which a certified IDR entity is selected under paragraph (c)(1) of this section must, at the time the certified IDR entity is selected under paragraph (c)(1) of this section, pay to the certified IDR entity a non-refundable administrative fee due to the Secretary for participating in the Federal IDR process described in this section.

(ii) The administrative fee amount will be established in guidance published annually by the Secretary in a manner such that the total fees paid for a year are estimated to be equal to the projected amount of expenditures by the Departments of the Treasury, Labor, and Health and Human Services for the year in carrying out the Federal IDR process.

(e) *Certification of IDR entity*—(1) *In general.* In order to be selected under paragraph (c)(1) of this section—(i) An IDR entity must meet the standards described in this paragraph (e) and be certified by the Secretary, jointly with the Secretaries of Labor and the Treasury, as set forth in this paragraph (e) of this section and guidance promulgated by the Secretary. Once certified, the IDR entity will be provided with a certified IDR entity number.

(ii) An IDR entity must provide written documentation to the Secretary regarding general company information (such as contact information, Taxpayer Identification Number, and website), as well as the applicable service area in which the IDR entity intends to conduct payment determinations under the Federal IDR process. IDR entities may choose to submit their application for all States or self-limit to a particular subset of States.

(iii) An IDR entity that the Secretary, jointly with the Secretary of Labor and the Secretary of the Treasury, certifies must enter into an agreement as a condition of certification. The agreement shall include specified provisions encompassed by this section, including, but not limited to, the requirements applicable to certified IDR entities when making payment determinations as well as the requirements regarding certification and revocation (such as specifications for wind down activities and reallocation of certified IDR entity fees, where warranted).

(2) *Requirements.* An IDR entity must provide written documentation to the Secretary through the Federal IDR portal that demonstrates that the IDR entity satisfies the following standards to be a certified IDR entity under this paragraph (e):

(i) Possess (directly or through contracts or other arrangements) sufficient arbitration and claims administration of health care services, managed care, billing and coding, medical and legal expertise to make the payment determinations described in paragraph (c) of this section within the time prescribed in paragraph (c)(4)(ii) of this section.

(ii) Employ (directly or through contracts or other arrangements) a sufficient number of personnel to make the determinations described in

paragraph (c) of this section within the time prescribed by (c)(4)(ii) of this section. To satisfy this standard, the written documentation must include a description of the IDR entity's organizational structure and capabilities, including an organizational chart and the credentials, responsibilities, and number of personnel employed to make determinations described in paragraph (c) of this section.

(iii) Maintain a current accreditation from a nationally recognized and relevant accrediting organization, such as URAC, or ensure that it otherwise possesses the requisite training to conduct payment determinations (for example, providing documentation that personnel employed by the IDR entity have completed arbitration training by the American Arbitration Association, the American Health Law Association, or a similar organization);

(iv) Have a process to ensure that no conflict of interest, as defined in paragraph (a)(2) of this section, exists between the parties and the personnel the certified IDR entity assigns to a payment determination to avoid violating paragraph (c)(1)(ii) of this section, including policies and procedures for conducting ongoing audits for conflicts of interest, to ensure that should any arise, the certified IDR entity has procedures in place to inform the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, of the conflict of interest and to mitigate the risk by reassigning the dispute to other personnel in the event that any personnel previously assigned have a conflict of interest.

(v) Have a process to maintain the confidentiality of IIHI obtained in the course of conducting determinations. A certified IDR entity's responsibility to comply with these confidentiality requirements shall survive revocation of the IDR entity's certification for any reason, and IDR entities must comply with the record retention and disposal requirements described in this section. Under this process, once certified, the certified IDR entity must comply with the following requirements:

(A) *Privacy.* The certified IDR entity may create, collect, handle, disclose, transmit, access, maintain, store, and/or use IIHI, only to perform:

(*1*) The certified IDR entity's required duties described in this section; and

(*2*) Functions related to carrying out additional obligations as may be required under applicable Federal or State laws or regulations.

(B) *Security.* (*1*) The certified IDR entity must ensure the confidentiality of all IIHI it creates, obtains, maintains, stores, and transmits;

(*2*) The certified IDR entity must protect against any reasonably anticipated threats or hazards to the security of this information;

(*3*) The certified IDR entity must ensure that IIHI is securely destroyed or disposed of in an appropriate and reasonable manner 6 years from either the date of its creation or the first date on which the certified IDR entity had access to it, whichever is earlier.

(*4*) The certified IDR entity must implement policies and procedures to prevent, detect, contain, and correct security violations in the event of a breach of IIHI;

(C) *Breach notification.* The certified IDR entity must, following the discovery of a breach of unsecured IIHI, notify of the breach the provider, facility, or provider of air ambulance services; the plan and issuer; the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor; and each individual whose unsecured IIHI has been, or is reasonably believed to have been, subject to the breach, to the extent possible.

(*1*) *Breaches treated as discovered.* For purposes of this paragraph (e)(2)(v)(C), a breach shall be treated as discovered by a certified IDR entity as of the first day on which the breach is known to the certified IDR entity or, by exercising reasonable diligence, would have been known to the certified IDR entity. A certified IDR entity shall be deemed to have knowledge of a breach if the breach is known, or by exercising reasonable diligence would have been known, to any person, other than the person committing the breach, who is an employee, officer, or other agent of the certified IDR entity;

(*2*) *Timing of notification.* A certified IDR entity must provide the notification required by this paragraph (e)(2)(v)(C) without unreasonable delay and in no case later than 60 calendar days after discovery of a breach.

(*3*) *Content of notification.* The notification required by this paragraph (e)(2)(v)(C) must include, to the extent possible:

(*i*) 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;

(*ii*) 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;

(*iii*) 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);

(*iv*) 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

(*v*) 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.

(*4*) *Method for providing notification.* A certified IDR entity must submit the notification required by this paragraph (e)(2)(v)(C) in written form (in clear and understandable language) either on paper or electronically through the Federal IDR portal or electronic mail.

(D) *Application to contractor and subcontractors.* The certified IDR entity must ensure compliance with this paragraph (e)(2)(v) of this section by any contractor or subcontractor with access to IIHI performing any duties related to the Federal IDR process.

(vi) Meet appropriate indicators of fiscal integrity and stability by demonstrating that the certified IDR entity has a system of safeguards and controls in place to prevent and detect improper financial activities by its employees and agents to assure fiscal integrity and accountability for all certified IDR entity fees and administrative fees received, held, and disbursed and by submitting 3 years of financial statements or, if not available, other information to demonstrate fiscal stability of the IDR entity;

(vii) Provide a fixed fee for single determinations and a separate fixed fee for batched determinations within the upper and lower limits for each, as set forth in guidance issued by the Secretary. The certified IDR entity may not charge a fee that is not within the approved limits as set forth in guidance unless the certified IDR entity or IDR entity seeking certification receives written approval from the Secretary to charge a flat rate beyond the upper or lower limits approved by the Secretary for fees. The certified IDR entity or IDR entity seeking certification may update its fees and seek approval from the Secretary to charge a flat fee beyond the upper or lower limits for fees, annually as provided in guidance. In order for the certified IDR entity to receive the Secretary's written approval to charge a flat fee beyond the upper or lower limits for fees as set forth in guidance, it must satisfy both conditions in paragraphs (e)(2)(v)(A) and (B) of this section, as follows:

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

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

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

(*3*) A description of how the alternative flat rate will be used to mitigate the effects of these circumstances; and

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

(viii) Have a procedure in place to retain the certified IDR entity fees described in paragraph (d)(1) of this section paid by both parties in a trust or escrow account and to return the certified IDR entity fee paid by the prevailing party of an IDR payment determination, or half of each party's certified IDR entity fee in the case of an agreement described in paragraph (c)(2)(i) of this section, within 30 business days following the date of the determination;

(ix) Have a procedure in place to retain the administrative fees described in paragraph (d)(2) of this section and to remit the administrative fees to the Secretary in accordance with the timeframe and procedures set forth in guidance published by the Secretary;

(x) Discharge its responsibilities in accordance with paragraph (c) of this section, including not making any determination with respect to which the certified IDR entity would not be eligible for selection pursuant to paragraph (c)(1) of this section; and

(xi) Collect the information required to be reported to the Secretary under paragraph (f) of this section and report the information on a timely basis in the form and manner provided in guidance published by the Secretary.

(3) Conflict-of-interest standards. In addition to the general standards set forth in paragraph (e)(2)(iv) of this section, an IDR entity must provide written documentation that the IDR entity satisfies the standards to be a certified IDR entity under this paragraph (e)(3).

(i) The IDR entity must provide an attestation indicating that it does not have a conflict of interest as defined in paragraph (a)(2) of this section;

(ii) The IDR entity must have procedures in place to ensure that personnel assigned to a determination do not have any conflicts of interest regarding any party to the dispute within the 1 year immediately preceding an assignment of dispute determination, similar to the requirements laid out in 18 U.S.C. 207(b). In order to satisfy this requirement, if certified, the IDR entity must ensure that any personnel assigned to a determination do not have any conflicts of interest as defined in paragraph (a)(2) of this section.

(iii) Following certification under this paragraph (e), if a certified IDR entity acquires control of, becomes controlled by, or comes under common control with any entity described in paragraph (e)(3)(i) of this section, the certified IDR entity must notify the Secretary in writing no later than 3 business days after the acquisition or exercise of control and shall be subject to the revocation of certification under paragraph (e)(6)(ii) of this section.

(4) *Period of certification.* Subject to paragraphs (e)(5) and (6) of this section, each certification (including a recertification) of a certified IDR entity under the process described in paragraph (e)(1) of this section will be effective for a 5-year period.

(5) *Petition for denial or revocation*—(i) *In general.* An individual, provider, facility, provider of air ambulance services, plan, or issuer may petition for a denial of a certification for an IDR entity or a revocation of a certification for a certified IDR entity for failure to meet a requirement of this section using the standard form and manner set forth in guidance to be issued by the Secretary. The petition for denial of a certification must be submitted within the timeframe set forth in guidance issued by the Secretary.

(ii) *Content of petition.* The individual, provider, facility, provider of air ambulance services, plan, or issuer seeking denial or revocation of certification must submit a written petition using the standard form issued by the Secretary including the following information:

(A) The identity of the IDR entity seeking certification or certified IDR entity that is the subject of the petition;

(B) The reason(s) for the petition;

(C) Whether the petition seeks denial or revocation of a certification;

(D) Documentation to support the reasons outlined in the petition; and

(E) Other information as may be required by the Secretary.

(iii) *Process.* (A) The Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor will acknowledge receipt of the petition within 10 business days of receipt of the petition.

(B) If the Secretary finds that the petition adequately shows a failure of the IDR entity seeking certification or the certified IDR entity to follow the requirements of this paragraph (e), the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, will notify the IDR entity seeking certification or the certified IDR entity by providing a de-identified copy of the petition. Following the notification, the IDR entity seeking certification or certified IDR entity will have 10 business days to provide a response. After the time period for providing the response has passed, the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, will review the response (if any), determine whether a denial or revocation of a certification is warranted, and issue a notice of the decision to the IDR entity or certified IDR entity and to the petitioner. This decision will be subject to the appeal requirements of paragraph (e)(6)(v) of this section.

(C) Effect on certification under petition. Regarding a petition for revocation of a certified IDR entity's certification, if the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, finds that the petition adequately shows a failure to comply with the requirements of this paragraph (e), following the Secretary's notification of the failure to the certified IDR entity under paragraph (e)(5)(iii)(B) of this section, the certified IDR entity may continue to work on previously assigned determinations but may not accept new determinations until the Secretary issues a notice of the decision to the certified IDR entity finding that a revocation of certification is not warranted.

(6) *Denial of IDR entity certification or revocation of certified IDR entity certification*—(i) *Denial of IDR entity certification.* The Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, may deny the certification of an IDR entity under paragraph (e)(1) of this section if, during the process of certification, including as a result of a petition described in paragraph (e)(5) of this section, the Secretary determines the following:

(A) The IDR entity fails to meet the applicable standards set forth under this paragraph (e);

(B) The IDR entity has committed or participated in fraudulent or abusive activities, including, during the certification process, submitting fraudulent data, or submitting information or data the IDR entity knows to be false to the Secretary, the Secretary of the Treasury or the Secretary of Labor;

(C) The IDR entity has failed to comply with requests for information from the Secretary, the Secretary of the

Treasury, or the Secretary of Labor as part of the certification process;

(D) In conducting payment determinations, including those outside the Federal IDR process, the IDR entity has failed to meet the standards that applied to those determinations or reviews, including standards of independence and impartiality; or

(E) The IDR entity is otherwise not fit or qualified to make determinations under the Federal IDR process.

(ii) *Revocation of certification of a certified IDR entity.* The Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, may revoke the certification of a certified IDR entity under paragraph (e)(1) of this section if, as a result of an audit, a petition described in paragraph (e)(5) of this section, or otherwise, the Secretary determines the following:

(A) The certified IDR entity has a pattern or practice of noncompliance with any requirements of this paragraph (e);

(B) The certified IDR entity is operating in a manner that hinders the efficient and effective administration of the Federal IDR process;

(C) The certified IDR entity no longer meets the applicable standards for certification set forth under this paragraph (e);

(D) The certified IDR entity has committed or participated in fraudulent or abusive activities, including submission of false or fraudulent data to the Secretary, the Secretary of the Treasury, or the Secretary of Labor;

(E) The certified IDR entity lacks the financial viability to provide arbitration under the Federal IDR process;

(F) The certified IDR entity has failed to comply with requests from the Secretary, the Secretary of the Treasury, or the Secretary of Labor made as part of an audit, including failing to submit all records of the certified IDR entity that pertain to its activities within the Federal IDR process; or

(G) The certified IDR entity is otherwise no longer fit or qualified to make determinations.

(iii) *Notice of denial or revocation.* The Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, will issue a written notice of denial to the IDR entity or revocation to the certified IDR entity within 10 business days of the Secretary's decision, including the effective date of denial or revocation, the reason(s) for denial or revocation, and the opportunity to request appeal of the denial or revocation.

(iv) *Request for appeal of denial or revocation.* To request an appeal, the IDR entity or certified IDR entity must submit a request for appeal to the Secretary within 30 business days of the date of the notice under paragraph (e)(6)(iii) of this section of denial or revocation and in the manner prescribed by the instructions to the notice. During this time period, the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, will not issue a notice of final denial or revocation and a certified IDR entity may continue to work on previously assigned determinations but may not accept new determinations. If the IDR entity or certified IDR entity does not timely submit a request for appeal of the denial or revocation, the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, will issue a notice of final denial or revocation to the IDR entity or certified IDR entity (if applicable) and the petitioner.

(v) *Denial or final revocation.* Upon notice of denial or final revocation, the IDR entity shall not be considered a certified IDR entity and therefore shall not be eligible to accept payment determinations under the Federal IDR process. Moreover, after a notice of final revocation, the IDR entity may not re-apply to be a certified IDR entity until on or after the 181st day after the date of the notice of denial or final revocation.

(f) *Reporting of information relating to the Federal IDR process*—(1) *Reporting of information.* Within 30 business days of the close of each month, for qualified IDR items and services furnished on or after January 1, 2022, each certified IDR entity must, in a form and manner specified by the Secretary, report:

(i) The number of notices of IDR initiation submitted under paragraph (b)(2) of this section to the certified IDR entity during the immediately preceding month;

(ii) The size of the provider practices and the size of the facilities submitting notices of IDR initiation under paragraph (b)(2) of this section during the immediately preceding month, as required to be provided to the certified IDR entity under paragraph (c)(4)(i)(A)(*2*) of this section;

(iii) The number of such notices of IDR initiation with respect to which a determination was made under paragraph (c)(4)(ii) of this section;

(iv) The number of times during the month that the out-of-network rate determined (or agreed to) under this section has exceeded the qualifying payment amount, specified by qualified IDR items and services;

(v) With respect to each notice of IDR initiation under paragraph (b)(2) of this section for which such a determination was made, the following information:

(A) A description of the qualified IDR items and services included with respect to the notification, including the relevant billing and service codes;

(B) The relevant geographic region for purposes of the qualifying payment amount for the qualified IDR items and services with respect to which the notification was provided;

(C) The amount of the offer submitted under paragraph (c)(4)(i) of this section 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 qualifying payment amount;

(D) Whether the offer selected by the certified IDR entity under paragraph (c)(4) of this section was the offer submitted by the plan or issuer (as applicable) or by the provider or facility (as applicable);

(E) The amount of the selected offer expressed as a dollar amount and as a percentage of the qualifying payment amount;

(F) The rationale for the certified IDR entity's decision, including the extent to which the decision relied on the criteria in paragraph (c)(4)(iv) of this section;

(G) The practice specialty or type of each provider or facility, respectively, involved in furnishing each qualified IDR item or service;

(H) The identity for each plan or issuer, and provider or facility, with respect to the notification. Specifically, each certified IDR entity must provide each party's name and address, as applicable; and

(I) 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.

(vi) The total amount of certified IDR entity fees paid to the certified IDR entity under paragraph (d)(1) of this section during the month.

(2) [Reserved]

(g) *Extension of time periods for extenuating circumstances*—(1) *General.* The time periods specified in this section (other than the time for payment, if applicable, under paragraph (c)(4)(ix) of this section) may be extended in extenuating circumstances at the Secretary's discretion if:

(i) An extension is necessary to address delays due to matters beyond the control of the parties or for good cause; and

(ii) The parties attest that prompt action will be taken to ensure that the determination under this section is made as soon as administratively practicable under the circumstances.

(2) *Process to request an extension.* The parties may request an extension by submitting a request for extension due to extenuating circumstances through the Federal IDR portal if the extension is necessary to address delays due to matters beyond the control of the parties or for good cause.

(h) *Applicability date.* The provisions of this section are applicable with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022, except that the provisions regarding IDR entity certification at paragraphs (a) and (e) of this section are applicable beginning on October 7, 2021.

§ 149.520 Independent dispute resolution process for air ambulance services.

(a) *Definitions.* Unless otherwise stated, the definitions in § 149.30 apply.

(b) *Determination of out-of-network rates to be paid by health plans and health insurance issuers; independent dispute resolution process*—(1) *In general.* Except as provided in paragraphs (b)(2) and (3) of this section, in determining the out-of-network rate to be paid by group health plans and health insurance issuers offering group or individual health insurance coverage for out-of-network air ambulance services, plans and issuers must comply with the requirements of § 149.510, except that references in § 149.510 to the additional circumstances in § 149.510(c)(4)(iii)(C) shall be understood to refer to paragraph (b)(2) of this section.

(2) *Additional information.* Additional information submitted by a party, provided the information is credible, relates to the circumstances described in paragraphs (b)(2)(i) through (vi) of this section, with respect to a qualified IDR service of a nonparticipating provider of air ambulance services or health insurance issuer of group or individual health insurance coverage that is the subject of a payment determination. This information must also clearly demonstrate that the qualifying payment amount is materially different from the appropriate out-of-network rate.

(i) The quality and outcomes measurements of the provider that furnished the services.

(ii) The acuity of the condition of the participant, beneficiary, or enrollee receiving the service, or the complexity of furnishing the service to the participant, beneficiary, or enrollee.

(iii) The training, experience, and quality of the medical personnel that furnished the air ambulance services.

(iv) Ambulance vehicle type, including the clinical capability level of the vehicle.

(v) Population density of the point of pick-up (as defined in 42 CFR 414.605) for the air ambulance (such as urban, suburban, rural, or frontier).

(vi) Demonstrations of good faith efforts (or lack thereof) made by the nonparticipating provider of air ambulance services or the plan or issuer to enter into network agreements with each other and, if applicable, contracted rates between the provider of air ambulance services and the plan or issuer, as applicable, during the previous 4 plan years.

(3) *Reporting of information relating to the IDR process.* In applying the requirements of § 149.510(f), within 30 business days of the close of each month, for services furnished on or after January 1, 2022, the information the certified IDR entity must report, in a form and manner specified by the Secretary, with respect to the Federal IDR process involving air ambulance services is:

(i) The number of notices of IDR initiation submitted under the Federal IDR process to the certified IDR entity that pertain to air ambulance services during the immediately preceding month;

(ii) The number of such notices of IDR initiation with respect to which a final determination was made under § 149.510(c)(4)(ii) (as applied by paragraph (b)(1) of this section);

(iii) The number of times the payment amount determined (or agreed to) under this subsection has exceeded the qualifying payment amount, specified by services;

(iv) With respect to each notice of IDR initiation under § 149.510(b)(2) of this part (as applied by paragraph (b)(1) of this section) for which a determination was made, the following information:

(A) A description of each air ambulance service included in such notification, including the relevant billing and service codes;

(B) The point of pick-up (as defined in 42 CFR 414.605) for the services included in such notification;

(C) The amount of the offers submitted under § 149.510(c)(4)(i) (as applied by paragraph (b)(1) of this section) by the group health plan or health insurance issuer (as applicable) and by the nonparticipating provider of air ambulance services, expressed as a dollar amount and as a percentage of the qualifying payment amount;

(D) Whether the offer selected by the certified IDR entity under § 149.510(c)(4)(ii) (as applied by paragraph (b)(1) of this section) to be the payment amount applied was the offer submitted by the plan or issuer (as applicable) or by the provider of air ambulance services;

(E) The amount of the selected offer expressed as a dollar amount and as a percentage of the qualifying payment amount;

(F) The rationale for the certified IDR entity's decision, including the extent to which the decision relied on the criteria in paragraph (b)(2) of this section;

(G) Air ambulance vehicle type, including the clinical capability level of such vehicle (to the extent this information has been provided to the certified IDR entity);

(H) The identity for each plan or issuer and provider of air ambulance services, with respect to the notification. Specifically, each certified IDR entity must provide each party's name and address, as applicable; and

(I) For each determination, 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.

(v) The total amount of certified IDR entity fees paid to the certified IDR entity under paragraph § 149.510(d)(1) (as applied by paragraph (b)(1) of this section) during the month for determinations involving air ambulance services.

(c) *Applicability date.* The provisions of this section are applicable with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022.

■ 21. Subpart G, consisting of §§ 149.610 and 149.620, is added to read as follows:

Subpart G—Protection of Uninsured or Self-Pay Individuals

§ 149.610 Requirements for provision of good faith estimates of expected charges for uninsured (or self-pay) individuals.

(a) *Scope and definitions*—(1) *Scope.* This section sets forth requirements for health care providers and health care facilities related to the issuance of good faith estimates of expected charges for uninsured (or self-pay) individuals (or their authorized representatives), upon request or upon scheduling an item or service.

(2) *Definitions.* For purposes of this section, the following definitions apply:

(i) *Authorized representative* means an individual authorized under State law to provide consent on behalf of the uninsured (or self-pay) individual, provided that the individual is not a provider affiliated with a facility or an employee of a provider or facility represented in the good faith estimate,

unless such provider or employee is a family member of the uninsured (or self-pay) individual.

(ii) *Convening health care provider or convening health care facility (convening provider or convening facility)* means the provider or facility who receives the initial request for a good faith estimate from an uninsured (or self-pay) individual and who is or, in the case of a request, would be responsible for scheduling the primary item or service.

(iii) *Co-health care provider or co-health care facility (co-provider or co-facility)* means a provider or facility other than a convening provider or a convening facility that furnishes items or services that are customarily provided in conjunction with a primary item or service.

(iv) *Diagnosis code* means the code that describes an individual's disease, disorder, injury, or other related health conditions using the International Classification of Diseases (ICD) code set.

(v) *Expected charge* means, for an item or service, the cash pay rate or rate established by a provider or facility for an uninsured (or self-pay) individual, reflecting any discounts for such individuals, where the good faith estimate is being provided to an uninsured (or self-pay) individual; or the amount the provider or facility would expect to charge if the provider or facility intended to bill a plan or issuer directly for such item or service when the good faith estimate is being furnished to a plan or issuer.

(vi) *Good faith estimate* means a notification of expected charges for a scheduled or requested item or service, including items or services that are reasonably expected to be provided in conjunction with such scheduled or requested item or service, provided by a convening provider, convening facility, co-provider, or co-facility.

(vii) *Health care facility (facility)* means an institution (such as a hospital or hospital outpatient department, critical access hospital, ambulatory surgical center, rural health center, federally qualified health center, laboratory, or imaging center) in any State in which State or applicable local law provides for the licensing of such an institution, that is licensed as such an institution pursuant to such law or is approved by the agency of such State or locality responsible for licensing such institution as meeting the standards established for such licensing.

(viii) *Health care provider (provider)* means a physician or other health care provider who is acting within the scope of practice of that provider's license or certification under applicable State law, including a provider of air ambulance services.

(ix) *Items or services* has the meaning given in 45 CFR 147.210(a)(2).

(x) *Period of care* means the day or multiple days during which the good faith estimate for a scheduled or requested item or service (or set of scheduled or requested items or services) are furnished or are anticipated to be furnished, regardless of whether the convening provider, convening facility, co-providers, or co-facilities are furnishing such items or services, including the period of time during which any facility equipment and devices, telemedicine services, imaging services, laboratory services, and preoperative and postoperative services that would not be scheduled separately by the individual, are furnished.

(xi) *Primary item or service* means the item or service to be furnished by the convening provider or convening facility that is the initial reason for the visit.

(xii) *Service code* means the code that identifies and describes an item or service using the Current Procedural Terminology (CPT), Healthcare Common Procedure Coding System (HCPCS), Diagnosis-Related Group (DRG) or National Drug Codes (NDC) code sets.

(xiii) *Uninsured (or self-pay) individual* means:

(A) An individual who does not have benefits for an item or service under a group health plan, group or individual health insurance coverage offered by a health insurance issuer, Federal health care program (as defined in section 1128B(f) of the Social Security Act), or a health benefits plan under chapter 89 of title 5, United States Code; or

(B) An individual who has benefits for such item or service under a group health plan, or individual or group health insurance coverage offered by a health insurance issuer, or a health benefits plan under chapter 89 of title 5, United States Code but who does not seek to have a claim for such item or service submitted to such plan or coverage.

(b) *Requirements of providers and facilities*—(1) *Requirements for convening providers and convening facilities.* A convening provider or convening facility must determine if an individual is an uninsured (or self-pay) individual by:

(i) Inquiring if an individual is enrolled in a group health plan, group or individual health insurance coverage offered by a health insurance issuer, Federal health care program (as defined in section 1128B(f) of the Social Security Act), or a health benefits plan under chapter 89 of title 5, United States Code;

(ii) Inquiring whether an individual who is enrolled in a group health plan, or group or individual health insurance coverage offered by a health insurance issuer or a health benefits plan under chapter 89 of title 5, United States Code is seeking to have a claim submitted for the primary item or service with such plan or coverage; and

(iii) Informing all uninsured (or self-pay) individuals of the availability of a good faith estimate of expected charges upon scheduling an item or service or upon request; information regarding the availability of good faith estimates for uninsured (or self-pay) individuals must be:

(A) Written in a clear and understandable manner, prominently displayed (and easily searchable from a public search engine) on the convening provider's or convening facility's website, in the office, and on-site where scheduling or questions about the cost of items or services occur;

(B) Orally provided when scheduling an item or service or when questions about the cost of items or services occur; and

(C) Made available in accessible formats, and in the language(s) spoken by individual(s) considering or scheduling items or services with such convening provider or convening facility.

(iv) Convening providers and convening facilities shall consider any discussion or inquiry regarding the potential costs of items or services under consideration as a request for a good faith estimate;

(v) Upon the request for a good faith estimate from an uninsured (or self-pay) individual or upon scheduling a primary item or service to be furnished for such an individual, the convening provider or convening facility must contact, no later than 1 business day of such scheduling or such request, all co-providers and co-facilities who are reasonably expected to provide items or services in conjunction with and in support of the primary item or service and request that the co-providers or co-facilities submit good faith estimate information (as specified in paragraphs (b)(2) and (c)(2) of this section) to the convening provider or facility; the request must also include the date that good faith estimate information must be received by the convening provider or facility;

(vi) Provide a good faith estimate (as specified in paragraph (c)(1) of this section) to uninsured (or self-pay)

individuals within the following timeframes:

(A) When a primary item or service is scheduled at least 3 business days before the date the item or service is scheduled to be furnished: Not later than 1 business day after the date of scheduling;

(B) When a primary item or service is scheduled at least 10 business days before such item or service is scheduled to be furnished: Not later than 3 business days after the date of scheduling; or

(C) When a good faith estimate is requested by an uninsured (or self-pay) individual: Not later than 3 business days after the date of the request.

(vii) A convening provider or convening facility must provide an uninsured (or self-pay) individual who has scheduled an item or service with a new good faith estimate if a convening provider, convening facility, co-provider, or co-facility anticipates or is notified of any changes to the scope of a good faith estimate (such as anticipated changes to the expected charges, items, services, frequency, recurrences, duration, providers, or facilities) previously furnished at the time of scheduling; a new good faith estimate must be issued to the uninsured (or self-pay) individual no later than 1 business day before the items or services are scheduled to be furnished.

(viii) If any changes in expected providers or facilities represented in a good faith estimate occur less than 1 business day before the item or service is scheduled to be furnished, the replacement provider or facility must accept as its good faith estimate of expected charges the good faith estimate for the relevant items or services included in the good faith estimate for the items or services being furnished that was provided by the replaced provider or facility.

(ix) For good faith estimates provided upon request of an uninsured (or self-pay) individual, upon scheduling of the requested item or service, the convening provider or convening facility must provide the uninsured (or self-pay) individual with a new good faith estimate for the scheduled item or service within the timeframes specified in paragraphs (b)(1)(vi)(A) and (B) of this section; and

(x) A convening provider or convening facility may issue a single good faith estimate for recurring primary items or services if the following requirements are met, in addition to the requirements under this section:

(A) The good faith estimate for recurring items or services must include, in a clear and understandable manner, the expected scope of the recurring primary items or services (such as timeframes, frequency, and total number of recurring items or services); and

(B) The scope of a good faith estimate for recurring primary items or services must not exceed 12 months. If additional recurrences of furnishing such items or services are expected beyond 12 months (or as specified under paragraph (b)(vii) of this section), a convening provider or convening facility must provide an uninsured (or self-pay) individual with a new good faith estimate, and communicate such changes (such as timeframes, frequency, and total number of recurring items or services) upon delivery of the new good faith estimate to help patients understand what has changed between the initial good faith estimate and the new good faith estimate.

(2) *Requirements for co-providers and co-facilities.* (i) Co-providers and co-facilities must submit good faith estimate information (as specified in paragraph (c)(2) of this section) upon the request of the convening provider or convening facility. The co-provider or co-facility must provide, and the convening provider or convening facility must receive, the good faith estimate information no later than 1 business day after the co-provider or co-facility receives the request from the convening provider or convening facility.

(ii) Co-providers and co-facilities must notify and provide new good faith estimate information to a convening provider or convening facility if the co-provider or co-facility anticipates any changes to the scope of good faith estimate information previously submitted to a convening provider or convening facility (such as anticipated changes to the expected charges, items, services, frequency, recurrences, duration, providers, or facilities).

(iii) If any changes in the expected co-providers or co-facilities represented in a good faith estimate occur less than 1 business day before that the item or service is scheduled to be furnished, the replacement co-provider or co-facility must accept as its good faith estimate of expected charges the good faith estimate for the relevant items or services included in the good faith estimate for the item or service being furnished that was provided by the replaced provider or facility.

(iv) In the event that an uninsured (or self-pay) individual separately schedules or requests a good faith estimate from a provider or facility that would otherwise be a co-provider or co-facility, that provider or facility is considered a convening provider or convening facility for such item or service and must meet all requirements in paragraphs (b)(1) and (c)(1) of this section for issuing a good faith estimate to an uninsured (or self-pay) individual.

(c) *Content requirements of a good faith estimate issued to an uninsured (or self-pay) individual.* (1) A good faith estimate issued to an uninsured (or self-pay) individual must include:

(i) Patient name and date of birth;

(ii) Description of the primary item or service in clear and understandable language (and if applicable, the date the primary item or service is scheduled);

(iii) Itemized list of items or services, grouped by each provider or facility, reasonably expected to be furnished for the primary item or service, and items or services reasonably expected to be furnished in conjunction with the primary item or service, for that period of care including:

(A) Items or services reasonably expected to be furnished by the convening provider or convening facility for the period of care; and

(B) Items or services reasonably expected to be furnished by co-providers or co-facilities (as specified in paragraphs (b)(2) and (c)(2) of this section);

(iv) Applicable diagnosis codes, expected service codes, and expected charges associated with each listed item or service;

(v) Name, National Provider Identifier, and Tax Identification Number of each provider or facility represented in the good faith estimate, and the State(s) and office or facility location(s) where the items or services are expected to be furnished by such provider or facility;

(vi) List of items or services that the convening provider or convening facility anticipates will require separate scheduling and that are expected to occur before or following the expected period of care for the primary item or service. The good faith estimate must include a disclaimer directly above this list that includes the following information: Separate good faith estimates will be issued to an uninsured (or self-pay) individual upon scheduling or upon request of the listed items or services; notification that for items or services included in this list, information such as diagnosis codes, service codes, expected charges and provider or facility identifiers do not need to be included as that information will be provided in separate good faith estimates upon scheduling or upon

request of such items or services; and include instructions for how an uninsured (or self-pay) individual can obtain good faith estimates for such items or services;

(viii) A disclaimer that informs the uninsured (or self-pay) individual that there may be additional items or services the convening provider or convening facility recommends as part of the course of care that must be scheduled or requested separately and are not reflected in the good faith estimate;

(ix) A disclaimer that informs the uninsured (or self-pay) individual that the information provided in the good faith estimate is only an estimate regarding items or services reasonably expected to be furnished at the time the good faith estimate is issued to the uninsured (or self-pay) individual and that actual items, services, or charges may differ from the good faith estimate; and

(x) A disclaimer that informs the uninsured (or self-pay) individual of the uninsured (or self-pay) individual's right to initiate the patient-provider dispute resolution process if the actual billed charges are substantially in excess of the expected charges included in the good faith estimate, as specified in § 149.620; this disclaimer must include instructions for where an uninsured (or self-pay) individual can find information about how to initiate the patient-provider dispute resolution process and state that the initiation of the patient-provider dispute resolution process will not adversely affect the quality of health care services furnished to an uninsured (or self-pay) individual by a provider or facility; and

(xi) A disclaimer that the good faith estimate is not a contract and does not require the uninsured (or self-pay) individual to obtain the items or services from any of the providers or facilities identified in the good faith estimate.

(2) [Reserved]

(d) *Content Requirements for Good Faith Estimate Information Submitted by Co-Providers or Co-Facilities to Convening Providers or Convening Facilities.* (1) Good faith estimate information submitted to convening providers or convening facilities by co-providers or co-facilities for inclusion in the good faith estimate (described in paragraph (c)(1) of this section) must include:

(i) Patient name and date of birth;

(ii) Itemized list of items or services expected to be provided by the co-provider or co-facility that are reasonably expected to be furnished in conjunction with the primary item or service as part of the period of care;

(iii) Applicable diagnosis codes, expected service codes, and expected charges associated with each listed item or service;

(iv) Name, National Provider Identifiers, and Tax Identification Numbers of the co-provider or co-facility, and the State(s) and office or facility location(s) where the items or services are expected to be furnished by the co-provider or co-facility; and

(v) A disclaimer that the good faith estimate is not a contract and does not require the uninsured (or self-pay) individual to obtain the items or services from any of the co-providers or co-facilities identified in the good faith estimate.

(2) [Reserved]

(e) *Required Methods for Providing Good Faith Estimates for Uninsured (or Self-Pay) Individuals.* (1) A good faith estimate must be provided in written form either on paper or electronically, pursuant to the uninsured (or self-pay) individual's requested method of delivery, and within the timeframes described in paragraph (b) of this section. Good faith estimates provided electronically must be provided in a manner that the uninsured (or self-pay) individual can both save and print. A good faith estimate must be provided and written using clear and understandable language and in a manner calculated to be understood by the average uninsured (or self-pay) individual.

(2) To the extent that an uninsured (or self-pay) individual requests a good faith estimate in a method other than paper or electronically (for example, by phone or orally in person), the convening provider may orally inform the uninsured (or self-pay) individual of information contained in the good faith estimate using the method requested by the uninsured (or self-pay) individual; however, in order for a convening provider or convening facility to meet the requirements of this section, the convening provider or convening facility must issue the good faith estimate to the uninsured (or self-pay) individual in written form as specified in paragraph (e)(1) of this section.

(f) *Additional compliance provisions.* (1) A good faith estimate issued to uninsured (or self-pay) individual under this section is considered part of the patient's medical record and must be maintained in the same manner as a patient's medical record. Convening providers and convening facilities must provide a copy of any previously issued good faith estimate furnished within the last 6 years to an uninsured (or self-pay) individual upon the request of the uninsured (or self-pay) individual.

(2) Providers or facilities that issue good faith estimates issued under State processes that do not meet the requirements set forth in this section fail to comply with the requirements of this section.

(3) A provider or facility will not fail to comply with this section solely because, despite acting in good faith and with reasonable due diligence, the provider or facility makes an error or omission in a good faith estimate required under this section, provided that the provider or facility corrects the information as soon as practicable. If items or services are furnished before an error in a good faith estimate is addressed, the provider or facility may be subject to patient-provider dispute resolution if the actual billed charges are substantially in excess of the good faith estimate (as described in § 149.620).

(4) To the extent compliance with this section requires a provider or facility to obtain information from any other entity or individual, the provider or facility will not fail to comply with this section if it relied in good faith on the information from the other entity, unless the provider or facility knows, or reasonably should have known, that the information is incomplete or inaccurate. If the provider or facility learns that the information is incomplete or inaccurate, the provider or facility must provide corrected information to the uninsured (or self-pay) individual as soon as practicable. If items or services are furnished before an error in a good faith estimate is addressed, the provider or facility may be subject to patient-provider dispute resolution if the actual billed charges are substantially in excess of the good faith estimate (as described in § 149.620).

(g) *Applicability*—(1) *Applicability date.* The requirements of this section are applicable for good faith estimates requested on or after January 1, 2022 or for good faith estimates required to be provided in connection with items or services scheduled on or after January 1, 2022.

(2) *Applicability with other laws.* Nothing in this section alters or otherwise affects a provider's or facility's requirement to comply with other applicable State or Federal laws, including those governing the accessibility, privacy, or security of information required to be disclosed under this section, or those governing the ability of properly authorized representatives to access uninsured (or self-pay) individuals' information held by providers or facilities, except to the

extent a state law prevents the application of this section.

§ 149.620 Requirements for the patient-provider dispute resolution process.

(a) *Scope and definitions*—(1) *Scope.* This section sets forth requirements for the patient-provider dispute resolution process, under which an uninsured (or self-pay) individual, with respect to eligible items or services under paragraph (b) of this section, may submit notification under paragraph (c) of this section to initiate the patient-provider dispute resolution process. This section sets forth in paragraph (d) of this section the certification requirements for a dispute resolution entity to become a Selected Dispute Resolution (SDR) entity contracted to resolve the patient-provider dispute, and the process for HHS to select SDR entities for patient-provider disputes under paragraph (e) of this section. This section sets forth in paragraph (f) the process and requirements regarding how SDR entities will determine the amount to be paid by an uninsured (or self-pay) individual to a provider or facility. This section also sets forth requirements for an administrative fee under paragraph (g) of this section and minimum requirements under paragraph (h) of this section for states that wish to establish processes for performing patient-provider dispute resolution in place of the Federal process.

(2) *Definitions.* Unless otherwise stated, the definitions in § 149.610(a)(2) apply to this section. Definitions related to confidentiality set forth in § 149.510(a)(2), including the definitions for *breach, individually identifiable health information (IIHI),* and *unsecured IIHI* also apply to this section. Additionally, for purposes of this section, the following definitions apply:

(i) *Billed charge(s)* means the amount billed by a provider or facility for an item or service.

(ii) *Substantially in excess* means, with respect to the total billed charges by a provider or facility, an amount that is at least $400 more than the total amount of expected charges listed on the good faith estimate for the provider or facility.

(iii) *Total billed charge(s)* means the total of billed charges, by a provider or-facility, for all primary items or services and all other items or services furnished in conjunction with the primary items or services to an uninsured (or self-pay) individual, regardless of whether such items or services were included in the good faith estimate.

(b) *Eligibility for patient-provider dispute resolution*—(1) *In general.* In general, an item or service provided by a convening provider, convening facility, co-provider, or co-facility is eligible for the patient-provider dispute resolution process if the total billed charges (by the particular convening provider, convening facility, or co-provider or co-facility listed in the good faith estimate), are substantially in excess of the total expected charges for that specific provider or facility listed on the good faith estimate, as required under § 149.610.

(2) *Special rule for co-provider or co-facility substitution.* If a co-provider or co-facility that provided an estimate of the expected charge for an item or service in the good faith estimate is substituted for a different co-provider or co-facility, an item or service billed by the replacement co-provider or co-facility is eligible for dispute resolution if the billed charge is substantially in excess of the total expected charges included in the good faith estimate for the original co-provider or co-facility. If the replacement provider or facility provides the uninsured (or self-pay) individual with a new good faith estimate in accordance with § 149.610(b)(2), then the determination of whether an item or service billed by the replacement co-provider or co-facility is eligible for dispute resolution is based on whether the total billed charge for the replacement co-provider or co-facility is substantially in excess of the total expected charges included in the good faith estimate provided by the replacement co-provider or co-facility.

(c) *Initiation of the Patient Provider dispute resolution process*—(1) *In general.* With respect to an item or service that meets the requirements in paragraph (b) of this section, an uninsured (or self-pay) individual (or their authorized representative, excluding any providers directly represented in the good faith estimate, providers associated with these providers, non-clinical staff associated with these providers, or individuals employed or associated with a facility that had included services in the good faith estimate) may initiate the patient-provider dispute resolution process by submitting a notification (initiation notice) to HHS as specified in paragraph (c)(2) of this section postmarked within 120 calendar days of receiving the initial bill containing charges for the item or service that is substantially in excess of the expected charges in the good faith estimate. In addition, the uninsured (or self-pay) individual must submit an administrative fee as described in paragraph (g) of this section to the SDR entity in an amount and in a manner that will be clarified in guidance by HHS.

(2) *Initiation notice*—(i) *Content.* The notice to initiate the patient-provider dispute resolution process must include:

(A) Information sufficient to identify the item or service under dispute, including the date the item or service was provided, and a description of the item or service;

(B) A copy of the provider or facility bill for the item and service under dispute (the copy can be a photocopy or an electronic image so long as the document is readable);

(C) A copy of the good faith estimate for the item or service under dispute (the copy can be a photocopy or an electronic image so long as the document is readable);

(D) If not included on the good faith estimate, contact information of the provider or facility involved, including, if available, name, email address, phone number, and mailing address;

(E) The State where the items or services in dispute were furnished; and

(F) The uninsured (or self-pay) individual's communication preference, through the Federal IDR portal, or electronic or paper mail.

(ii) *Manner.* The uninsured (or self-pay) individual or their authorized representative must submit the initiation notice, to the Secretary by submitting the notice via the Federal IDR portal, electronically, or on paper, in the form and manner specified by the Secretary. The date of initiation of the patient-provider dispute resolution process will be the date the Secretary receives such initiation notice. In addition, the uninsured (or self-pay) individual must submit an administrative fee as described in paragraph (g) of this section to the SDR entity in an amount and in a manner that will be clarified in guidance by HHS.

(3) *Notification of SDR entity receipt.* Upon receipt of the initiation notice described in paragraph (c)(1) of this section, HHS will select an SDR entity according to the process described in paragraph (e) of this section. Upon selection, the SDR entity will, through the Federal IDR portal, or electronic or paper mail, notify the uninsured (or self-pay) individual, and the provider or facility that a patient-provider dispute resolution request has been received and is under review. Such notice shall also include:

(i) Sufficient information to identify the item or service under dispute;

(ii) The date the initiation notice was received;

(iii) Notice of the additional requirements for providers or facilities specified in paragraphs (c)(5) and (6) of this section while the patient-provider dispute resolution process is pending; and

(iv) Information to the uninsured (or self-pay) individual about the availability of consumer assistance resources that can assist the individual with the dispute.

(4) *Validation of initiation notice.* After the selection of the SDR entity, as described in paragraph (c)(2) of this section, the SDR entity shall review the initiation notice to ensure the items or services in dispute meet the eligibility criteria described in paragraph (b) of this section and the initiation notice contains the required information described in paragraph (c)(2). The SDR entity will notify the uninsured (or self-pay) individual of the outcome of the review, including, if applicable, providing the individual with 21 calendar days to submit supplemental information when the initiation notice is determined to be incomplete or the items or services are determined ineligible for dispute resolution.

(i) If the SDR entity determines that the item or service meets the eligibility criteria, and the initiation notice contains the required information, the SDR entity will notify the uninsured (or self-pay) individual and the provider or facility that the that the item or service has been determined eligible for dispute resolution. The SDR entity shall request the provider or facility provide the information described in paragraph (f)(2) of this section within 10 business days.

(ii) If the SDR entity determines that the item or service does not meet the eligibility criteria or that the initiation notice does not contain the required information, the SDR entity will provide an insufficiency notice to the uninsured (or self-pay) individual of the determination and the reasons for the determination and will notify the uninsured (or self-pay) individual that the individual may submit supplemental information, postmarked within 21 calendar days, to resolve any deficiencies identified. If the insufficiency notice is not made available to an individual in a format that is accessible to individuals with disabilities or with low-English proficiency within 14 calendar days of such a request from the individual, a 14-calendar-day extension will be granted so that the individual will have a total of 35 calendar days to submit supplemental information.

(5) *Prohibitions on collections.* While the patient-provider dispute resolution process is pending, the provider or facility must not move the bill for the disputed item or service into collection or threaten to do so, or if the bill has already moved into collection, the provider or facility should cease collection efforts. The provider or facility must also suspend the accrual of any late fees on unpaid bill amounts until after the dispute resolution process has concluded.

(6) *Prohibitions on retributive action.* The provider or facility must not take or threaten to take any retributive action against an uninsured (or self-pay) individual for utilizing the patient-provider dispute resolution process to seek resolution for a disputed item or service.

(d) *Certification of SDR entities*—(1) *In general.* The Secretary shall contract with and certify only that number of SDR entities the Secretary believes will be necessary to timely resolve the volume of patient-provider disputes. As part of the contract process with HHS, a potential SDR entity must satisfy the Federal IDR entity certification criteria specified in § 149.510(e), subject to the exceptions set forth in paragraphs (d)(2) of this section. In addition, the SDR entity must also meet the conflict-of-interest mitigation policy requirements specified in paragraph (d)(3) of this section. Through this contract process, HHS will assess the dispute resolution entity for compliance with all applicable SDR entity certification requirements.

(2) *Exception for SDR entity certification.* With respect to certified IDR entity requirements that do not apply to an SDR entity, potential SDR entities are not required to make the following submissions:

(i) Information regarding the service area(s) for which the entity will arbitrate cases, however, a potential SDR entity will need to submit information on their ability to operate nationwide through the contract process;

(ii) Fee schedule for batched and non-batched claims;

(iii) Policies and procedures to hold dispute resolution entity fees in a trust or escrow account, however, a potential SDR entity must submit policies and procedures to hold administrative fees, as described in paragraph (g) of this section, and remit them to HHS in a manner specified by HHS.

(3) *Conflict of interest mitigation policies.* A potential SDR entity must also provide additional information on the SDR entity's conflict-of-interest policies and procedures, including outlining a mitigation plan in the event of an entity-level conflict of interest, under which no dispute resolution personnel affiliated with the SDR entity can fairly and impartially adjudicate a case, in compliance with the standards in Federal Acquisition Regulation-subpart 9.5 (48 CFR subpart 9.5). Such conflict of interest mitigation plan could include utilizing a subcontractor without a conflict of interest that meets SDR entity requirements to conduct the patient-provider dispute resolution for the case.

(e) *Selection of an SDR entity.* (1) After the Secretary has received the initiation notice as described in paragraph (c) of this section, the Secretary will assign an SDR entity that is certified and contracted under paragraph (d) of this section to conduct the dispute resolution process for the item or service. Upon receiving an assignment from the Secretary to make a determination for an item or service as described in paragraph (c)(3) of this section, the SDR entity shall ensure that no conflict of interest exists, and in such case, shall notify the uninsured (or self-pay) individual and the provider or facility of the selection of the SDR entity.

(2) Should a conflict of interest exist, the SDR entity must submit notice to the Secretary of such conflict no later than 3 business days following selection by the Secretary. The Secretary will then automatically select a new SDR entity to conduct the patient-provider dispute resolution process for the item or service. In the event that no SDR entities are available to resolve the dispute, the initially-selected SDR entity will be required to initiate their entity-level conflict of interest mitigation plan as described in paragraph (d)(3) of this section. If no other contracted SDR entity, and no subcontracted entity, is able to provide the patient-provider dispute resolution services due to conflicts of interest that cannot be sufficiently mitigated or any other reason, HHS may seek to contract with an additional SDR entity as needed. In the event that HHS needs to contract with an additional SDR entity, the time periods specified in this section may be extended at HHS' discretion to allow for HHS to contract with that SDR entity.

(3) Conflict of interest means, with respect to a party to a payment determination, or SDR entity, a material relationship, status, or condition of the party, or SDR entity that impacts the ability of the SDR entity to make an unbiased and impartial payment determination. For purposes of this section, a conflict of interest exists when an SDR entity is:

(i) A provider or a facility;

(ii) An affiliate or a subsidiary of a provider or facility;

(iii) An affiliate or subsidiary of a professional or trade association representing a provider or facility; or

(iv) An SDR entity, or any personnel assigned to a determination has a material familial, financial, or professional relationship with a party to the payment determination being disputed, or with any officer, director, or management employee of the provider, the provider's group or practice association, or the facility that is a party to the dispute.

(4) Either party to the dispute resolution process (the uninsured (or self-pay) individual, or the provider or facility) may attest that a conflict of interest exists in relation to the SDR entity assigned to a payment dispute, in which case the SDR entity must notify the Secretary of HHS no later than 3 business days receiving the attestation.

(f) *Payment determination for Patient-Provider dispute resolution*—(1) *Determination of payment amount through settlement*—(i) *In general.* If the parties to a dispute resolution process agree on a payment amount (through either an offer of financial assistance or an offer of a lower amount, or an agreement by the uninsured (or self-pay) individual to pay the billed charges in full) after the dispute resolution process has been initiated but before the date on which a determination is made under paragraph (f)(3) of this section, the provider or facility will notify the SDR entity through the Federal IDR Portal, electronically, or in paper form as soon as possible, but no later than 3 business days after the date of the agreement. The settlement notification must contain at a minimum, the settlement amount, the date of such settlement, and documentation demonstrating that the provider or facility and uninsured (or self-pay) individual have agreed to the settlement. The settlement notice must also document that the provider or facility has applied a reduction to the uninsured (or self-pay) individual's settlement amount equal to at least half the amount of the administrative fee paid as set forth in paragraph (g) of this section. Once the SDR entity receives the settlement notice, the SDR entity shall close the dispute resolution case as settled and the agreed upon payment amount will apply for the items or services.

(ii) *Treatment of payments made prior to determination.* Payment of the billed charges (or a portion of the billed charges) by the uninsured (or self-pay) individual (or by another party on behalf of the uninsured (or self-pay) individual) prior to a determination under paragraph (f)(3) of this section does not demonstrate agreement by the uninsured (or self-pay) individual to settle at that amount or any other amount.

(2) *Determination of payment amount through the patient-provider dispute resolution process*—(i) *In general.* With respect to an item or service to which an agreement described in paragraph (f)(1) of this section does not apply, not later than 10 business days after the receipt of the selection notice from the SDR entity described in paragraph (c)(4)(i) of this section, the provider or facility must submit to the SDR entity:

(A) A copy of the good faith estimate provided to the uninsured (or self-pay) individual for the item or service under dispute (the copy can be a photocopy or an electronic image so long as the document is readable);

(B) A copy of the billed charges provided to the uninsured (or self-pay) individual for the item or service under dispute (the copy can be a photocopy or an electronic image so long as the document is readable); and

(C) If available, documentation demonstrating that the difference between the billed charge and the expected charges in the good faith estimate reflects the cost of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided.

(ii) *Timeframe for SDR entity determination.* Not later than 30 business days after receipt of the information described in paragraph (f)(2)(i) of this section, the SDR entity must make a determination regarding the amount to be paid by such uninsured (or self-pay) individual, taking into account the requirements in paragraph (f)(3) of this section.

(3) *Payment determination by an SDR entity*—(i) *In general.* The SDR entity must review any documentation submitted by the uninsured (or self-pay) individual, and the provider or the facility, and make a separate determination for each unique item or service charged as to whether the provider or facility has provided credible information to demonstrate that the difference between the billed charge and the expected charge for the item or service in the good faith estimate reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided.

(ii) *Definition of credible information.* Credible information means information that upon critical analysis is worthy of belief and is trustworthy.

(iii) *Payment determination process.* (A) For an item or service that appears on the good faith estimate:

(*1*) If the billed charge is equal to or less than the expected charge for the item or service in the good faith estimate, the SDR entity must determine the amount to be paid for the item or service as the billed charge.

(*2*) If the billed charge for the item or service is greater than the expected charge in the good faith estimate, and the SDR entity determines that information submitted by the provider or facility does not provide credible information that the difference between the billed charge and the expected charge-for the item or service in the good faith estimate reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, the SDR entity must determine the amount to be paid for the item or service to be equal to the expected charge for the item or service in the good faith estimate.

(*3*) If the billed charge for the item or service is greater than the expected charge in the good faith estimate, and the SDR entity determines that information submitted by the provider or facility provides credible information that the difference between the billed charge and the expected charge for the item or service in the good faith estimate reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, the SDR entity must determine as the amount to be paid for the item or service, the lesser of:

(*i*) The billed charge; or

(*ii*) The median payment amount paid by a plan or issuer for the same or similar service, by a same or similar provider in the geographic area as defined in § 149.140(a)(7) where the services were provided, that is reflected in an independent database as defined in § 149.140(a)(3) using the methodology described in § 149.140(c)(3), except that in cases where the amount determined by an independent database is determined to be less than the expected charge for the item or service listed on the good faith estimate, the amount to be paid will equal to the expected charge for the item or service listed on the good faith estimate. When comparing the billed charge with the amount contained in an independent database, the SDR entity

should account for any discounts offered by the provider or facility.

(B) For an item or service that does not appear on the good faith estimate (new item or service):

(*1*) If the SDR entity determines that the information submitted by the provider or facility does not provide credible information that the billed charge for the new item or service reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, then the SDR entity must determine that amount to be paid for the new item or service to be equal to $0.

(*2*) If the SDR entity determines that the information submitted by the provider or facility provides credible information that the billed charge for the new item or service reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, the SDR entity must select as the amount to be paid for the new item or service, the lesser of:

(*i*) The billed charge; or

(*ii*) The median payment amount paid by a plan or issuer for the same or similar service, by a same or similar provider in the geographic area as defined in § 149.140(a)(7) where the services were provided, that is reflected in an independent database as defined in § 149.140(a)(3) using the methodology described in § 149.140(c)(3). When comparing the billed charge with the amounts contained in an independent database, the SDR entity should account for any discounts offered by the provider or facility.

(C) To calculate the final payment determination amount, the SDR entity must add together the amounts to be paid for all items or services subject to the determination. In cases where the final amount determined by the SDR entity is lower than the billed charges, the SDR entity must reduce the total amount determined by the amount paid by the individual for the administrative fee described in paragraph (g) of this section to calculate the final payment determination amount to be paid by the individual for the items or services. Once the final payment determination amount has been calculated, the SDR entity will inform the uninsured (or self-pay) individual and the provider or facility, through the Federal IDR portal, or by electronic or paper mail, of such determination, the determination amount and the SDR entity's justification for making the determination. After such notification is made, the SDR entity will close the case.

(4) *Effects of determination.* A determination made by an SDR entity under this paragraph (f) will be binding upon the parties involved, in the absence of a fraud or evidence of misrepresentation of facts presented to the selected SDR entity regarding the claim, except that the provider or facility may provide financial assistance or agree to an offer for a lower payment amount than the SDR entity's determination, the uninsured (or self-pay) individual may agree to pay the billed charges in full, or the uninsured (or self-pay) individual and the provider or facility may agree to a different payment amount.

(g) *Costs of patient-provider dispute resolution process*—(1) *Administrative fee to participate in the patient-provider dispute resolution process.* (i) The uninsured (or self-pay) individual shall pay to the SDR entity the administrative fee amount described in section (g)(2) of this section at the initiation of the patient-provider dispute resolution process described in paragraph (c) of this section. The SDR entity shall remit all administrative fees collected to the Secretary upon receiving an invoice from HHS.

(ii) In cases where the SDR entity issues a determination and the provider or facility is the non-prevailing party as described in section (g)(1)(iv) of this section, the provider or facility must pay an amount equal to the administrative fee to the uninsured (or self-pay) individual in the form of a reduction in the payment amount that is applied by the SDR entity to the final payment determination amount as described in paragraph (f)(3) of this section.

(iii) If the SDR entity issues a determination and the provider or facility is the prevailing party as described in paragraph (g)(1)(iv) of this section, the provider or facility is not required to pay an amount equal to the administrative fee to the uninsured (or self-pay) individual in the form of a reduction in the payment amount that is applied by the SDR entity to the final payment determination amount as described in paragraph (f)(3) of this section.

(iv) For purposes of paragraphs (g)(1)(ii) and (iii) of this section, the prevailing party is the provider or facility in cases where the SDR entity determines the amount to be paid as equal to the billed charges; and the prevailing party is the uninsured (or self-pay) individual in cases where the SDR entity determines the-amount to be paid as less than the billed charges.

(v) Allocation of administrative fee in the case of settlement. In case of a settlement described in paragraph (f)(1) of this section, the provider or facility must pay an amount equal to half of the administrative fee to the uninsured (or self-pay) individual in the form of a reduction in the payment amount that is applied to the final settlement amount. The provider or facility will document in the settlement notice described in paragraph (f)(1) that it has applied a payment reduction of at least half of the administrative fee amount to the uninsured (or self-pay) individual's settlement amount.

(2) Establishment of the administrative fee. The amount of the administrative fee described in paragraph (g)(1) of this section will be specified by the Secretary through guidance.

(h) *Deferral to State patient-provider dispute resolution processes*—(1) *In general.* If the Secretary determines that a-state law provides a process to determine the amount to be paid by an uninsured (or self-pay) individual to a provider or facility, and that such process meets or exceeds the requirements in paragraph (h)(2) of this section, the Secretary shall defer to the State process and direct any patient-provider dispute resolution requests received from uninsured (or self-pay) individuals in such state to the State process to adjudicate the dispute resolution initiation request.

(2) *Minimum Federal requirements.* A State process described in paragraph (h)(1) of this section shall at a minimum:

(i) Be binding, unless the provider or facility offer for the uninsured (or self-pay) individual to pay a lower payment amount than the determination amount;

(ii) Take into consideration a good faith estimate, that meets the minimum standards established in § 149.160, provided by the provider or facility to the uninsured (or self-pay) individual;

(iii) If the State has a fee charged to uninsured (or self-pay) individuals to participate in the patient-provider dispute resolution process, the fee must be equal to or less than the Federal administrative fee-established in paragraph (g) of this section; and

(iv) Have in place conflict-of-interest standards that at a minimum meets the requirements set forth in paragraphs (d) and (e) of this section.

(3) *HHS determination of State process.* HHS will review the State process to determine whether it meets or exceeds the minimum Federal requirements set forth in paragraph

(h)(2) of this section—HHS will communicate with the state and determine whether such process meets or exceeds such requirements. HHS will notify the state in writing of such determination.

(4) *HHS review of State process.* HHS will review changes to the State process on an annual basis (or at other times if HHS receives information from the state that would indicate the state process no longer meets the minimum Federal requirements) to ensure the state process continues to meet or exceed the minimum Federal standards set forth in this section.

(5) *State process termination.* In the event that the State process is terminated, or HHS determines that the State process no longer meets the minimum Federal requirements described in paragraph (h)(2) of this section, HHS will make the Federal process available to uninsured (or self-pay) individuals in that State to ensure that the state's residents have access to a patient-provider dispute resolution process that meets the minimum Federal requirements.

(i) *Extension of time periods for extenuating circumstances*—(1) *In general.* The time periods specified in this section (other than the time for payment of the administrative fees under paragraph (d)(2) of this section) may be extended in extenuating circumstances at the Secretary's discretion if:

(i) An extension is necessary to address delays due to matters beyond the control of the parties or for good cause; and

(ii) The parties attest that prompt action will be taken to ensure that the determination under this section is made as soon as administratively practicable under the circumstances.

(2) *Process to request an extension.* The time periods specified in this section may be extended in the case of extenuating circumstances at HHS' discretion. The parties may request an extension by submitting a request for extension due to extenuating circumstances through the Federal IDR portal, or electronic or paper mail if the extension is necessary to address delays due to matters beyond the control of the parties or for good cause.

(j) *Applicability date.* The provisions of this section are applicable to uninsured (or self-pay) individuals; providers (including providers of air ambulance services) and facilities; and SDR entities, generally beginning on or after January 1, 2022. The provisions regarding SDR entity certification in paragraphs (a) and (d) of this section, are applicable beginning on October 7, 2021.

[FR Doc. 2021–21441 Filed 9–30–21; 4:15 pm]

BILLING CODE 4510–29–P