

**Requirements Related to Surprise Billing, Part II  
(CMS-9908-IFC); Summary of Interim Final Rules with Request for Comment (IFC)**

On October 7, 2021, the Departments of Treasury, Labor, and Health and Human Services (HHS) and the Office of Personnel Management (OPM) published in the Federal Register proposed Requirements Related to Surprise Billing, Part II (86 *Federal Register* (FR) 55980). The IFC builds on regulations issued in July (the “July 2021 IFC”<sup>1</sup>) to implement provisions of the No Surprises Act to establish a Federal independent dispute resolution (IDR) process for determining out-of-network payment rates; to provide good faith estimates of out-of-network care and services to people who are uninsured or self-pay; to establish a patient provider dispute resolution process for those claims, and to apply existing external review requirements to adverse determinations by a plan or issuer related to the No Surprises Act.

The rules are generally applicable for plan or policy years beginning on or after January 1, 2022; rules regarding certification of IDR entities are applicable October 7, 2021. OPM regulations apply to contract years beginning on or after January 1, 2022; and HHS-only rules related to the provision of good faith estimates and the patient-provider dispute resolution process are applicable beginning on January 1, 2022, except those related to the certification of SDR entities which are applicable October 7, 2021. **Comments are due December 6, 2021.**

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**I. Background**

The No Surprises Act was enacted as part of the Consolidated Appropriations Act, 2021 (CAA).<sup>2</sup> It established protections for enrollees of health plans from surprise medical bills when they receive emergency services, non-emergency services from nonparticipating providers at participating facilities, and air ambulance services from nonparticipating providers of air ambulance services under certain circumstances. It established an IDR process to resolve disputes regarding out-of-network payment rates as well as a patient-provider dispute resolution process to resolve disputes about rates between providers and uninsured or self-pay patients.

The No Surprises Act protects against surprise out of network bills for emergency services including certain post-stabilization services, and for certain non-emergency services furnished by nonparticipating providers at certain participating health care facilities. Under certain conditions and with the enrollee’s notice and consent, the limitations on balance billing and cost-sharing may be waived with respect to post-stabilization and non-emergency services.

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<sup>1</sup>86 FR 36872

<sup>2</sup> P.L. 116-260

The July 2021 IFC implemented the first set of those protections. The No Surprises Act and the July 2021 IFC established limits on cost sharing for certain protected out-of-network services, prohibited balance billing, and required cost sharing to count towards in-network deductibles and out-of-pocket maximums. The rules specify that 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: (1) an amount determined by an applicable All-Payer Model Agreement; (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).

The October 7th regulations build on the July 2021 IFC in codifying requirements of the No Surprises Act. In this IFC:

- The Departments of Labor, Treasury, and HHS, in largely identical regulations:
  - Establish a Federal IDR process to determine the out-of-network rate for certain protected emergency, non-emergency, and air ambulance services including setting the timeframes for open negotiation over payment rates and other timelines, choosing the certified IDR entity, specifying the selection criteria for the IDR to use in making a determination of the appropriate payment rate; certifying IDR entities, and establishing reporting requirements.
  - Apply the existing external review requirements to adverse determinations by a plan or issuer related to the No Surprises Act. Under the IFC, the applicability of existing external review requirements is expanded in two ways: to require health insurance issuers and group health plans to make external review available for adverse benefit determinations related to claims protected by the No Surprises Act; and to expand the scope of these external review rules to apply to grandfathered health plans. In addition, they add several examples of this expanded scope to the regulatory text.
- OPM amends its rules to incorporate the federal IDR process. It adopts the Departments' interim final rules but uses terms that conform to the FEHB program.
- HHS codifies requirements that providers and facilities provide good faith estimates to uninsured or self-pay individuals upon request. HHS notes that since individuals covered by short-term, limited-duration coverage are not considered to be insured, those enrollees are considered uninsured for this purpose.
- HHS establishes a patient-provider dispute resolution process for an uninsured or self-pay patient who receives a bill for an amount substantially in excess of expected charges as described in the good faith estimate to seek a determination of the amount to be paid to the provider or facility. Under the IFC, selected dispute resolution (SDR) entities would function similarly to IDR entities and must meet similar certification requirements.

The Departments intend to issue regulations later this year related to reporting requirements for pharmacy benefits and prescription drug costs. They also note that until the requirement under

the No Surprises Act to provide a good faith estimate to an individual's plan or coverage is fully implemented through rulemaking, HHS will defer enforcement of it. Stakeholders have requested that the Departments delay the applicability of the requirement until plans and issuers, providers and facilities have had enough time to build the infrastructure necessary to support the transfers. The Departments agree that compliance with this requirement 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 data transfer standards.

The Departments will also defer enforcement of the requirement that plans and issuers provide an advanced explanation of benefits. Rules implementing those sections will include a prospective applicability date to give plans, issuers, providers, and facilities a reasonable amount of time to come into compliance and encourage states undertaking primary enforcement of No Surprises Act provisions to take a similar approach. However, the requirements to provide a good faith estimate to uninsured and self-pay patients will be subject to enforcement.

The Departments note the similarities between transparency requirements issued as part of the Transparency in Coverage final rules and the transparency requirements in the No Surprises Act and **seek comment on 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.**

## **II. Federal Independent Dispute Resolution Process**

### **A. Definitions**

The Departments point out that the definitions in 26 CFR 54.9816-3T, 29 CFR 2590.716-3, and 45 CFR 149.30) apply to these rules. In addition, the Departments add new definitions needed for the IDR process; conflict of interest standards; and for the confidentiality, information security, and privacy requirements applicable to IDR entities seeking certification. The IFC adds the following definitions to each of Treasury, Labor, and HHS regulations:

*Batched items and services* are 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. Criteria for batched items or services are described more fully below.

*Breach* means the acquisition, access, use, or disclosure of individually identifiable health information (IIHI) in a manner not permitted and that compromises the security or privacy of the IIHI. A breach does not include (1) unintentional acquisition if in good faith, inadvertent disclosure, or a disclosure to an unauthorized person when the disclosing IDR entity has a good faith belief that the information would not reasonably have been retained. A breach is presumed to have occurred unless the certified IDR entity can demonstrate that there is a low probability that the security or privacy of the IIHI has been compromised based on a risk assessment taking

into account the nature and extent of the IIHI involved, the person to whom the disclosure was made, whether the IIHI was acquired or viewed, and the extent that the risk was mitigated.

*Certified IDR entity* is an entity responsible for conducting determinations under the IDR process and that meet the certification criteria (described more fully below). Uncertified entities that may apply for certification or have applied are referred to as “IDR entities.”

*Conflict of Interest* refers to a material relationship, status, or condition of the party or certified IDR entity that impacts their ability to make an unbiased and impartial payment determination. For purposes of these rules, a conflict of interest exists when a certified IDR entity is a group health plan; a health insurance issuer offering group or individual or short-term, limited-duration insurance; an FEHB carrier; a provider, a facility, or a provider of air ambulance services. A conflict also exists when a certified IDR entity is an affiliate or a subsidiary one of those entities or organizations, or has any personnel assigned to a determination who have a material familial, financial, or professional relationship with a party to the payment determination being disputed.

- *Material familial relationship* is defined to mean a 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, or of a reviewer or reviewing physician conducting or participating in any review in the Federal IDR process.
- *Material professional relationship* is any physician-patient relationship, any partnership or employment relationship, 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.
- *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.

*Credible information* is information that upon critical analysis is worthy of belief and is trustworthy.

*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 that identifies the individual; or can be used to identify the individual.

*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.

*Qualified IDR item or service* is an emergency service furnished by a nonparticipating provider or nonparticipating facility, an item or service furnished by a nonparticipating provider at a participating health care facility, or air ambulance services furnished by a nonparticipating provider of air ambulance services subject to the protections of the No Surprises Act; for which the out-of-network rate is not determined under an All-Payer Model Agreement or a specified State law; with respect to which a provider or facility or group health plan or health insurance issuer initiates the open negotiation or IDR process as more fully described below.

*Unsecured IHI* is IHI that is not rendered unusable, unreadable, or indecipherable to unauthorized persons through the use of a technology or methodology specified by the Secretaries of HHS, the Treasury and Labor.

## **B. The Term “Days”**

The Departments point out that there are a number of timelines described in the No Surprises Act including for the initiation of the Federal IDR process, the selection of a certified IDR entity, submitting documents, and making payment determinations. In many cases, the statute is silent as to whether the days are calendar days or business days. When unspecified, the Departments have the authority to choose the meaning. Unless there is a reason to use calendar days, the Departments have defined the timeline using business days to provide parties with the maximum amount of time permitted to meet various deadlines.

## **C. Open Negotiation and Initiation of the Federal IDR Process**

The statute provides that where there is no All-Payer Model Agreement or specified state law, the provider or facility or plan or issuer may engage in negotiations to determine the total out-of-network rate. If parties fail to reach an agreement through open negotiation, they may initiate the Federal IDR process. Likewise, out-of-network rates for air ambulance services may also be determined through open negotiation and a largely identical IDR process. (The primary difference is in how the certified IDR entity selects an offer and the reporting obligations with respect to air ambulance services.) The process as codified in the IFC is described in greater detail below.

### **1. Open Negotiation.**

The open negotiation period may be initiated by any party during the 30-business day period beginning on the day that the nonparticipating provider, facility, or air ambulance services receives an initial payment or notice of denial. 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 notice must identify the items and services subject to negotiation, the date the services were furnished, the service code, the initial payment amount or notice of denial, and contact information. The information may be provided electronically so long as the issuer has a good faith belief that an electronic notice is readily accessible and makes a paper notice available free of charge upon request. The notice must be sent within 30 business days of the initial payment or notice of denial.

The 30-business day open negotiation period begins on the day on which the open negotiation notice is first sent (assuming most are sent electronically.) The Departments encourage parties to ensure the email address is correct and caution that if the notice is not properly provided to the other party, the period has not begun and any subsequent payment determination may not be enforceable. They are providing a standard notice that parties may use to satisfy the open negotiation notice requirement and solicit comment on challenges or clarifications needed to ensure the full open negotiation period is available.<sup>3</sup>

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

Either party can initiate the Federal IDR process during the 4-business day period following the end of the open negotiation period. The initiating party must submit a notice to the other party and to the Departments through the Federal IDR portal. The Notice of IDR initiation must include (1) identifying information regarding the qualified IDR items or services and whether they are batched items and services; (2) the names and contact information of the parties involved; (3) the state where the items or services were furnished; (4) the start date of the open negotiation period; (5) the initiating party's preferred certified IDR entity; (6) an attestation that the items or services are within the scope of the Federal IDR process; (7) the Qualifying Payment Amount (QPA); (8) information about the QPA; and (9) a general description of the Federal IDR process including key deadlines, dates, and processes. The Departments have developed a form that parties must use to satisfy the general information requirements for the Notice of IDR initiation.<sup>4</sup>

The notice may be provided electronically and must also be submitted to the Departments through the Federal IDR portal. The Federal IDR process begins on that date or another date as specified by the Departments that can be no later than the date of the receipt by both the other party and the Departments.

### **D. Federal IDR Process Following Initiation**

#### 1. Selection of Certified IDR Entity.

The parties to the Federal IDR process can jointly select a certified IDR entity no later than 3 business days following the date of the IDR initiation. If the party receiving a Notice of IDR Initiation does not object to the preferred certified IDR entity identified in the Notice within 3 business days of the date of initiation of the Federal IDR process, that certified IDR entity is selected unless it has a conflict of interest. If the party receiving the Notice timely objects, it must notify the initiating party of the objection, provide a reason for the objection, and identify an alternative certified IDR entity. If both parties agree on a certified IDR entity or fail to agree on a certified IDR entity, the initiating party must notify the Department no later than 1 business day after the end of the 3-business day period.

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<sup>3</sup> See [Open Negotiation Notice \(dol.gov\)](https://www.dol.gov/open-notice).

<sup>4</sup> See [surprise-billing-part-ii-information-collection-documents-attachment-3.pdf \(dol.gov\)](https://www.dol.gov/surprise-billing-part-ii-information-collection-documents-attachment-3.pdf)

The Departments will provide a list on the Federal IDR portal of certified IDR entities. Selected IDR entities may not have a conflict of interest and personnel assigned to the dispute also cannot have a conflict of interest nor be selected based on a likelihood that they will support a particular party. Personnel may not be a party to the determination nor an employee or agent of a party to the dispute during the 1-year period immediately preceding the assignment.

Additional safeguards to ensure that personnel staff do not have a conflict of interest require the certified IDR entity to attest that its procedure ensures no conflicts of interest; submit policies and procedures as part of the certification process for conducting audits of conflicts of interest; inform the Department of conflicts of interest that arise; and mitigate any risk of those conflicts by reassigning personnel.

If the parties agree on a certified IDR entity, the initiating party must provide a notice of the certified IDR entity selection to the Departments as soon as reasonably practicable, but not later than 1 business day after such selection. The notice, which may be made through the Federal portal must include the name and identifying information for the selected certified IDR entity as well as an attestation by both parties that the entity has no conflict of interest. If the parties are unable to agree on a certified IDR entity, the Departments will make a random selection of an entity that charges a fee within the allowed range no later than 6 business days after the initiation of the process and notify the parties of the selection. **The Departments seek comment on this approach, including the use of a random selection method for the Departments to use when choosing a certified IDR entity.**

The selected entity must certify that it meets the conflict of interest requirements and attest to doing so with a notification to the Departments within 3 business days after which the Departments will notify the parties. It must also review the material submitted to determine whether or not the IDR process applies to the items or services in dispute. Upon notification, the parties have 3 business days to select a different certified IDR entity.

## 2. Authority to Continue Negotiation.

If the parties agree to a payment amount before the Federal IDR process has been completed, the agreed-upon amount will be treated as the out-of-network rate and the dispute is considered resolved. Under this circumstance, the initiating party must notify the Departments and the certified IDR of such agreement no later than 3 business days after the date of the agreement and the plan or issuer must pay the balance of the agreed upon rate no later than 30 days after the agreement is reached. Each party must pay half of the entity fee.

## 3. Treatment of Batched Items and Services.

Under the IFC, multiple claims for qualified IDR items and services may be submitted and considered jointly if they are: (1) billed by the same provider, group of providers, facility, or air ambulance services provider; (2) from the same group health plan or health insurance issuer; (3) for the same or similar items or services (for example, they are billed under the same service

code or a comparable code under a different coding system; and (4) were furnished within the same 30-business day period or 90-calendar-day suspension period (described below).

In the case of items or services billed as part of a bundled arrangement, those items or services may be submitted and considered as part of one payment determination and will be subject to a fee for a single determination.

The Departments note that some batched items and services will have different QPAs. For example, if one group of batched claims include claims from individual insurance as well as from group coverage. In this case, the parties must provide the relevant information for each QPA and the certified IDR entity must consider each QPA separately.

**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 providers and facilities are 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 which 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.

##### *a. Submission of Offers.*

Each party to a determination must submit to the certified IDR entity:

- No later than 10 business days after the selection of the certified IDR entity, an offer for a payment amount expressed as both a dollar amount and as a percentage of the QPA.
- Information requested by the certified IDR entity related to the offer.
- For providers and facilities, information about the size of their practices and facilities, and practice specialty or types. **The Departments seek comment on whether additional guidance is needed to address how contract employees should be incorporated in these data.**
- For plans and issuers, information about the coverage area and geographic region and whether the coverage is insured, partially insured or self-insured.
- For FEHB carriers, if the item or service relates to FEHB.

Parties may submit other information so long as the information doesn't include information that is prohibited from being considered in the Federal IDR process as described more fully below.



*b. Selection of an Offer for Services other than Air Ambulance Services.*

No later than 30 business days after the selection of the certified IDR entity, the certified IDR entity must select one of the offers submitted. In selecting the offer, the certified IDR entity must assume that the QPA is the appropriate payment amount and unless other credible information suggests that the QPA is materially different from the appropriate payment, select the offer closest to the QPA. If both offers are equidistant from the QPA, the IDR must choose the amount that best reflects the value of the item or service.

In addition to the QPA and other requested information, the certified IDR entity must consider information submitted by the parties relating to the following circumstances insofar that the information is credible and that it is not already taken into account in the QPA:

- The level of training, experience, quality and outcomes of the provider or facility.
- The market share held by the provider, facility, or plan within the geographic region in which the item or service was provided.
- The acuity of the individual, or the complexity of furnishing the item or service to the individual.
- The teaching status, case mix, and scope of services of the facility furnishing the item or service.
- 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 during the previous 4 plan years.

The Departments provide the following examples in the regulatory text of these additional considerations:

*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.

*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.

*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.

*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.

The Departments provide their rationale for codifying a presumption that the QPA is the appropriate payment amount unless other considerations suggest it is materially different from the appropriate payment. Based on their interpretation of the statutory construction, the agencies

believe that a certified IDR entity must look first to the QPA and that typically the QPA will be the reasonable out-of-network rate. In addition, they describe policy considerations which support the reliance on the QPA as reflecting standard market rates as well as the oversight and enforcement applicable to the calculation of the QPA to ensure that it reflects its intended rate. Finally, they describe their view that reliance on the QPA as the likely payment amount is appropriate and promotes efficiency and predictability as long as the parties have the ability to rebut the presumption with credible information.

The Departments clarify that it is not the role of certified IDR entities to ensure that the QPA has been calculated correctly, make determinations of medical necessity, nor review denials of coverage. They note that for batched items and services, the certified IDR entity can select different offers when the QPAs for the items or services within the batch are different.

The Departments intend to provide additional guidance to certified IDR entities to clarify how each of the additional factors should be considered.

*c. Selection of Offer for Air Ambulance Services.*

Under the IFC, the process for a certified IDR entity to select an offer for air ambulance services is essentially the same as for all other services. The additional considerations for air ambulance services payment determinations are:

- The quality and outcomes measurements of the provider that furnished the services.
- 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.
- The training, experience, and quality of the medical personnel that furnished the air ambulance services.
- Ambulance vehicle type, including the clinical capability level of the vehicle.
- Population density of the point of pick-up for the air ambulance (such as urban, suburban, rural, or frontier).
- 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 during the previous 4 plan years.

*d. Prohibition on Consideration of Certain Factors.*

Certain factors may not be considered by the certified IDR entity:

- Usual and customary charges nor rates expressed as a proportion of usual and customary charges.
- The amount that would have been billed if not for the prohibition on balance billing. The Departments interpret this prohibition to also prohibit consideration of the billed charges to the plan or issuer for the qualified IDR item or service.
- Payment or reimbursement rates for the items or services under a public program including Medicare, Medicaid, the Children's Health Insurance Program, TRICARE.

*e. Written Decision.*

The certified IDR entity must submit its decision and rationale for the decision through the Federal IDR portal. If the decision is for an amount that is not closest to the QPA, the rationale must include a detailed explanation of the additional considerations taken into account which demonstrated that the QPA is materially different from the appropriate out-of-network rate.

*f. Effect of Determination.*

The certified IDR entity's determination is binding and not subject to judicial review unless it was determined via corruption, fraud or undue means. During the 90-calendar day period following the determination (referred to as the 90-calendar-day suspension period), the party initiating the IDR process cannot initiate a subsequent dispute involving the same party and claims for same or similar items or services.

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 can 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.

Following a determination, the plan or issuer must make any remaining payment owed to the provider, facility, or air ambulance provider no later than 30 days after the determination.

*g. Recordkeeping Requirement.*

Under the IFC, a certified IDR entity must maintain records of all claims and notices associated with the Federal IDR process for a period of 6 years after a determination. The records must be made available for examination by plans, providers, facilities, providers of air ambulance services, or State or Federal oversight agencies upon request.

*h. Costs of the Federal IDR Process.*

The parties to a determination will be responsible for the following costs:

- At the time that a certified IDR entity is selected by both parties, each party must pay the administrative fee due to the Departments for the cost of carrying out the Federal IDR process. The administrative fee will be set to cover the estimated costs of staffing and contracting relating to certifying and overseeing certified IDR entities, the costs of required reporting, the costs of collecting administrative fees, and the costs of maintaining the Federal IDR portal and will be established in guidance each year. These fees are non-refundable; even if the parties negotiate an out-of-network rate before the certified IDR entity makes a determination the fees are not refunded or reduced.

- Both parties must pay a predetermined certified IDR entity fee when they submit their offer. The certified IDR entity will hold those amounts in escrow until a final determination is made. After the determination is made, the party whose offer is not selected is responsible for the payment so at the end of the process, the Certified IDR entity has 30 business days to return the entity fee to the prevailing party. These fees are non-refundable but if the parties negotiate an out-of-network rate before the certified IDR entity makes a determination, the certified IDR entity will return half of each party's payment. Certified IDR entities must set their fees within a pre-determined range that will be specified by the Departments in forthcoming guidance and will be updated annually.

## 5. Certification of IDR Entities.

The IFC provides that an IDR entity must meet certain standards to become certified by the Departments. Identical standards are codified in Departments of Treasury, Labor and HHS regulations and additional guidance will be promulgated. Once certified, the IDR entity will be provided with a certified IDR entity number and will retain its certification for a period of 5-years subject to its continued ability to satisfy the standards and subject to a petition and revocation process described more fully below.

An IDR entity must provide written documentation to the Departments that include general company information (such as contact information, Taxpayer Identification Number, and website), and identify the service area in which the IDR entity intends to operate. In addition, an IDR entity must provide written documentation demonstrating that it meets the following standards:

- Has experience in arbitration, claims administration, managed care, billing and coding, medical and legal expertise sufficient to make the payment determinations within the required timelines.
- Employs a sufficient number of personnel to make the determinations within the required timelines. 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.
- Maintains current accreditation from a nationally recognized and relevant accrediting organization, such as the Utilization Review Accreditation Committee (URAC), or ensures that it otherwise possesses the requisite training to conduct payment determinations.
- Has a process to ensure that no conflict of interest exists between the parties and the personnel assigned to a payment determination, including policies and procedures for conducting ongoing audits for conflicts of interest.
- Has a process to maintain the confidentiality of IIHI and comply with privacy and information security standards. To maintain privacy, a certified IDR entity may create, collect, handle, disclose, transmit, access, maintain, store, and/or use IIHI, only to perform its duties and to carry out any additional obligations under Federal or State law. To ensure security, an entity must protect against any reasonably anticipated threats or hazards to the security of this information; securely destroy or dispose of IIHI 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; have procedures in place to prevent, detect, contain, and correct security violations in the event of a breach of IIHI. Following the discovery of a breach of unsecured IIHI, a certified IDR entity must notify the provider, facility, or provider of air ambulance services; the plan; the Secretaries of Treasury, Labor, and HHS and each individual whose unsecured IIHI has been, or is reasonably believed to have been, subject to the breach, to the extent possible no later than 60 calendar days after its discovery. The contents of the notification must identify each individual whose information was subject to the breach and include a description of what happened, the types of information involved, what the entity is doing to investigate and mitigate harm to the parties, and contact information for individuals to attain additional information.

- Ensure that staff and contractors are trained to handle IIHI and follow proper protocol for handling breaches.
- Document that a system of safeguards and controls are in place to prevent and detect improper financial activities by its employees and agents to assure fiscal integrity and accountability by submitting 3 years of financial statements or other information to demonstrate fiscal stability.
- Provide a fixed fee for a single determination and for a batched determination within the limits as issued in guidance. An entity could seek a fee outside of those limits and potentially receive written approval from the Secretary. To do so, it must submit a proposal in writing justifying the need for the higher or lower fee.
- Have procedures in place to retain the fees paid by both parties at the initiation of the IDR process in a trust or escrow account that is separate from other funds and return the portion of fees paid by the prevailing party within the required timeline.

**The Departments seek comment on whether any additional or different confidentiality protections are needed.**

With respect to fees, the Departments plan to identify a range of fees informed by IDR processes in states. Presently, it finds that those fees generally range from \$300 to \$600. They will also consider the time and resources that certified IDR entities will need to meet the requirements of the rules and the anticipated volume of payment determinations. **They seek comment on any additional factors that should be considered in determining the range.**

In addition to the general standards listed above, a certified IDR entity must provide written documentation that shows that the entity satisfies standards related to conflict of interest including having procedures in place to ensure that personnel assigned to a determination do not have any conflicts of interest; and notifying the Secretaries in writing if via acquisition or exercise of control it develops a conflict of interest. Such notification must be made no later than 3-business days after such acquisition or exercise of control.

Certified IDR entities must also adhere to audit standards. The Departments state that they intend to perform audits on a select number of certified IDR entities. The selections may be random or

based on complaints and findings may be used to revoke certification or taken into account during re-certification decision making.

#### 6. Petition for Denial or Revocation of IDR Entity Certification.

A provider, facility, provider of air ambulance services, plan or issuer may petition for denial of a certification of an IDR entity for failure to meet the statutory, regulatory and other sub-regulatory requirements of the Departments. The petitioner must submit a written petition identifying the reasons for the petition. The Departments will make a public list available of IDR entities seeking certification to help facilitate the petition process. Petitioners will have 5-business days from an announcement that an IDR entity is seeking certification to submit the written petition.

The Departments will acknowledge receipt of the petition within 10 business days of receiving it. If the petition adequately makes the case for a failure of compliance, the Departments will share a de-identified copy of the petition with the IDR entity (or certified IDR entity). The entity has 10 business days to respond. The Departments will review the response and determine whether a denial or revocation is warranted. The entity may appeal. Pending appeal a certified IDR entity can continue to work on previously assigned determinations but it will not be permitted, however to take on new assignments.

The Departments may deny certification if in the process of certification or as a result of a petition it finds that the entity:

- Fails to meet applicable standards.
- Committed or participated in fraudulent activities.
- Failed to comply with requests for information from the Secretaries as part of the certification process.
- Fails to meet standards for payment determinations such as impartiality.
- Is otherwise not qualified or fit to make such determinations.

Further, the Departments may revoke the certification of an IDR entity if it finds:

- A pattern or practice of noncompliance with standards applicable to IDR entities.
- The entity is operating in a manner that hinders efficient and effective administration of the IDR process (for example, consistently fails to meet deadlines or to check for conflicts of interest).
- It no longer meets standards applicable to IDR entities.
- It committed or participated in fraudulent or abusive activities.
- Lacks financial viability.
- Failed to comply with requests from the Secretaries made as part of an audit.
- Is no longer fit or qualified to make payment determinations.

Within 10 business days of a decision, the Departments will issue a written notice of denial including the effective date of the denial or revocation. An entity may appeal the Departments' decision in which case it may continue to complete any open IDR payment determinations

assigned to it but may not receive any new assignments until a final decision is made. If requesting an appeal, the entity must do so within 30 business days of the date of the notice. Such a request could include information relevant to support its appeal including arguments that negate or mitigate the evidence in the denial, including actions it has taken or intends to take to address the failures.

A final notice of denial or revocation will be provided by the departments if the appeal is not timely submitted, or the Departments reach a final determination of denial or revocation upon appeal.

An IDR entity may again apply for certification beginning on the 181<sup>st</sup> calendar day after the date of the final notice of denial or revocation.

The Departments will monitor the implementation of the Federal IDR process and the petition process. **They seek comment on any additional requirements that may be needed regarding denial and revocation, and whether other steps may be required to prevent patterns and practices of noncompliance.**

#### 7. Reporting of Information.

The No Surprises Act requires the Departments to make certain information related to the Federal IDR process available on a public website for each calendar quarter in 2022 and thereafter. The IFC requires certified IDR entities to report the following information in order for the Departments to carry out the requirements. Within 30 business days of the close of each month, each certified IDR entity must report, for items and services furnished on or after January 1, 2022:

- The number of notices of IDR initiation submitted to the certified IDR entity during the preceding month.
- The size of the provider practices and the facilities submitting those notices.
- The number of those notices for which a payment determination was made.
- The number of times during the month that the out-of-network rate exceeded the QPA, specified by qualified IDR items and services.
- For each notice of IDR initiation for which a determination was made:
  - a description of the items and services including their billing and service codes;
  - the geographic region for the QPA for the qualified IDR items and services;
  - the amount of the offer submitted by the each of the parties expressed as a dollar amount and as a percentage of the QPA;
  - whether the offer selected was the offer submitted by the plan or by the provider or facility;
  - the amount of the selected offer expressed as a dollar amount and as a percentage of the QPA;
  - the rationale for the certified IDR entity's decision;



- the practice specialty or type of each provider or facility involved in furnishing each qualified IDR item or service;
- the identity for each plan, and provider or facility including each party's name and address; 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.
- The total amount of certified IDR entity fees paid to the certified IDR entity during the month.

#### 8. Reporting of Information for Air Ambulance Services.

Similar to the reporting requirements for items and services that are not air ambulance services, the IFC requires reporting from certified IDR entities with respect to air ambulance services. Within 30 business days of the close of each month, each certified IDR entity must report, for air ambulance services furnished on or after January 1, 2022:

- The number of notices of IDR initiation submitted under the Federal IDR that pertain to air ambulance services during the preceding month.
- The number of such notices of IDR initiation with respect to which a final determination was made.
- The number of times the payment amount determined (or agreed to) exceeded the QPA.
- With respect to each notice of IDR initiation for which a determination was made:
  - a description of each air ambulance service including its billing and service codes;
  - the point of pick-up for the services;
  - the amount of the offers submitted by the group health plan or health insurance issuer and by the nonparticipating provider of air ambulance services, expressed as a dollar amount and as a percentage of the qualifying payment amount;
  - whether the offer selected by the certified IDR entity was the offer submitted by the plan or by the provider of air ambulance services;
  - the amount of the selected offer expressed as a dollar amount and as a percentage of the QPA;
  - the rationale for the certified IDR entity's decision;
  - air ambulance vehicle type, including the clinical capability level of the vehicle;
  - the identity for each plan and provider of air ambulance services, including each party's name and address; and
  - for each determination, the number of business days between selection of the certified IDR entity and selection of the payment amount.
- The total amount of certified IDR entity fees paid to the certified IDR entity during the month for determinations involving air ambulance services.

## 9. Extension of Time Periods for Extenuating Circumstances.

The Departments codify that the timelines in the IFC (with one exception) may be extended on a case by case basis at the Departments' discretion. The one exception is for the timeline applicable to payments to providers, facilities, or providers of air ambulance services (30 calendar days after a payment determination has been made) which may not be extended. For all other timelines, a request for an extension may be filed via the Federal IDR portal. Extensions are available at the Departments' discretion if needed to address delays due to matters beyond the control of the parties or for good cause. A request must include an explanation about the extenuating circumstances and why the extension is needed.

### **E. Applicability**

The Departments note that the applicability for the rules in the IFC are parallel to those of the July 2021 IFC. The Federal IDR process applies to group health plans and issuers offering group and individual health insurance coverage including grandfathered and "grandmothered" plans beginning January 1, 2022.<sup>5</sup> Group health plans include both insured as well as self-insured group health plans, and church plans subject to the Internal Revenue Code. Individual health insurance includes coverage offered both inside of and outside of Exchanges, and student health insurance coverage.

Because these rules amend OPM regulations by adding references to the Federal IDR process, FEHB carriers must comply with the rules. The rules do not, however apply to health reimbursement arrangements or other account-based plans, excepted benefit plans, short-term, limited duration insurance, retiree-only plans, nor plan with fewer than two participants who are current employees. OPM regulations apply to contract years beginning on or after January 1, 2022

Rules regarding certification of IDR entities are applicable beginning on October 7, 2021.

### **III. External Review and Section 110 of the No Surprises Act**

Section 110 of the No Surprises Act provides for the external review process in existing rules to apply to any adverse determination related to the surprise billing protections of the No Surprises Act. The IFC implements this requirement by amending the scope of claims eligible for external review to include adverse benefit determinations related to compliance with the surprise billing and cost-sharing protections under the No Surprises Act.

Under statute prior to enactment of the No Surprises Act, non-grandfathered group health plans and health insurance issuers of non-grandfathered group and individual coverage are required to comply with state external review requirements so long as those state requirements include a set

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<sup>5</sup> "Grandmothered" plans (sometimes referred to as transitional plans) are non-grandfathered plans against which CMS will not enforce certain specified market requirements. See: [Insurance Standards Bulletin Series – INFORMATION – Extension of Limited Non-Enforcement Policy through 2022 \(cms.gov\)](https://www.cms.gov/insurstds/bulletin-series-information-extension-limited-non-enforcement-policy-through-2022)

of minimum protections. If the state process does not meet those minimum standards, then the plan or issuer must comply with the Federal external review process.

The IFC amends the both state and federal processes to explicitly require that any adverse determination that involves consideration of whether the plan or issuer is complying with the No Surprises Act is eligible for external review.

The Departments also explain that because grandfathered health plans are subject to the No Surprises Act protections, they too are required to provide for external review of claims covered by the No Surprises Act protections. Accordingly, the IFC incorporates amendments to extend the external review process to grandfathered health plans when such review relates to protections under the No Surprises Act.

The Departments note that requiring grandfathered health plans to comply with internal and external claims and appeals rules is in contrast to the prior law and regulations. Since section 103 of the No Surprises Act does not require compliance with internal appeals processes, there may be cases where grandfathered plans and issuers are not subject to a state requirement to have an internal appeals process and have not otherwise instituted such a process. Those plans must under the No Surprises Act and the IFC, however, allow a claimant to request external review of an adverse benefit determination covered by the protections of the No Surprises Act.

The IFC codifies the addition of a number of new examples numbered 3 through 7 in each Department's regulations to further illuminate the types of adverse benefit determinations that are eligible for external review. These are reproduced below.

*Example 3. 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.

*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. 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.

*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. 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.

*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. 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).

*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. 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).

*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.

Finally, although not discussed in the preamble, the IFC fully incorporates into Treasury regulations, the Internal claims and appeals and external review processes including the amendments discussed above as those provisions had not been in the Treasury regulations prior.

The Departments solicit comment on whether additional examples are needed to elucidate the use of external review for claims protected by the No Surprises Act and whether additional guidance is needed to help grandfathered plans comply with the requirements.

## **IV. Overview of the Interim Final Rules Regarding Protections for the Uninsured**

### **A. Overview**

HHS adds a new subpart G to part 149 of title 45, Code of Federal Regulations, to implement the No Surprises Act requirements on health care providers and facilities to provide good faith estimates of expected charges to uninsured or self-pay individuals upon request or upon scheduling an item or service, and to establish the patient-provider dispute resolution process.

Under the No Surprises Act, providers and facilities must inquire about an individual's health insurance status, or whether an individual is seeking to have a claim submitted to their health insurance coverage for the care they seek, when scheduling the item or service, or if requested by an individual. The provider or facility must provide a good faith estimate of expected charges for the items and services to an uninsured (or self-pay) individual.

The good faith estimate must include expected charges for the items or services that are reasonably expected to be provided together with the primary item or service, including items or services that may be provided by other providers and facilities. If an item or service is not scheduled separately from the surgery itself, it will generally be included in the good faith estimate.

Because providers and facilities will require time to establish systems and procedures for providing and receiving the required information from other providers and facilities that may be involved, for good faith estimates provided to uninsured (or self-pay) individuals during 2022, HHS will exercise enforcement where a good faith estimate does not include expected charges from other providers and facilities that are involved in the patient's care.

As required by the No Surprises Act, HHS establishes a patient-provider dispute resolution process to determine a payment amount when an uninsured (or self-pay) individual is billed an amount substantially in excess of the good faith estimate. HHS defines "substantially in excess" as the billed charges being at least \$400 more than the good faith estimate for any provider or facility listed on the good faith estimate. The patient must initiate the patient-provider dispute resolution process within 120 calendar days of receipt the bill. Other eligibility criteria for the process are described below.

Selected Dispute Resolution (SDR) entities will make payment determinations under the patient-provider dispute resolution process pursuant to timelines for documentation submission and payment determination. Individuals will be charged an administrative fee of \$25 which will ultimately be paid by the party that loses the dispute. The administrative fee will be updated annually in sub-regulatory guidance.

## **B. Good Faith Estimates for Uninsured (or Self-Pay) Individuals (§149.610)**

### **1. Definitions.**

Health care providers and health care facilities must issue 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. (In this section, a reference to uninsured individuals will include a reference to self-pay individuals unless otherwise specified.) Section 149.610 defines a number of relevant terms:

*Authorized representative* means an individual authorized under State law to provide consent on behalf of the uninsured individual. However, an authorized representative may not be a provider affiliated with a facility, or an employee of a provider or facility, represented in the good faith estimate unless the authorized representative is a family member of the uninsured individual.

*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 individual and who is responsible for scheduling the primary item or service. In the case of a request, the convening provider or facility would be the one responsible for scheduling the primary item or service.

*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.

*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.

*Expected charge* means the cash pay rate or rate for an item or service set by a provider or facility for an uninsured individual. The expected charge must reflect any discounts for uninsured individuals, where the good faith estimate is being provided to an uninsured or self-pay individual. For example, these discounts may be adjustments required of charitable hospitals under their Financial Assistance Policy requirements. **HHS seeks comment on whether to require both the list price and the discounted price in the expected charges.** Because 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, expected charge also means the amount the provider or facility would expect to charge a plan or issuer if the provider or facility intended to bill a plan or issuer directly.

*Good faith estimate* means a notice of expected charges for a scheduled or requested item or service. This includes items or services that are reasonably expected to be provided in conjunction with such scheduled or requested item or service and provided by a convening provider, convening facility, co-provider, or co-facility.

*Health care facility (facility)* is defined more broadly than the definition in §149.30 which applies to the balance billing protections for non-emergency services. For good faith estimates, the term means an institution (e.g., a hospital, hospital outpatient department, critical access hospital, ambulatory surgical center, rural health center, federally qualified health center, laboratory, or imaging center) licensed as such an institution pursuant to State 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).

*Health care provider (provider)* means a physician or other health care provider acting within the scope of practice of that provider's license or certification under applicable State law. The term also includes air ambulance providers.

*Items or services* has the meaning given in §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. HHS notes 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 care, emergent trauma, or emergency items or services. However, a good faith estimate is required for an urgent care appointment that is scheduled at least 3 days in advance.

*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 such 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. The period of care 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.

*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.

*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.

*Uninsured (or self-pay) individual* means 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, or a FEHB health benefits plan. The term may also mean an individual who has such benefits for the item or service but who does not seek to submit a claim for the item or service submitted to the plan or coverage.

## 2. Requirements for Providers and Facilities.

### *a. Requirements for convening providers and convening facilities.*

(i) Notice of availability of good faith estimates. A convening provider or convening facility must determine if an individual is an uninsured individual or, if insured, whether they will seek to have a claim submitted for the primary item or service with such plan or coverage. If so, the convening provider or facility must provide the uninsured individuals of notice of the availability of a good faith estimate of expected charges upon scheduling an item or service or upon request.

The notice must be written in a clear and understandable manner; and it must be 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. The notice of availability must be provided orally when scheduling an item or service or when questions about the cost of items or services occur. The notice must be made available in accessible formats, and in the language spoken by the individual. HHS anticipates providing a model notice for this purpose though use of the model notice will not be required. **HHS seeks comment on whether to require the use of a standard notice.** Convening providers and convening facilities must consider any discussion or inquiry regarding the potential costs of items or services under consideration as a request for a good faith estimate.

(ii) Contacting co-providers or co-facilities. If a good faith estimate is requested from an uninsured individual, or if a primary item or service is scheduled to be furnished for such an individual, then no later than 1 business day after such scheduling or such request, the convening provider or facility must contact 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. The convening provider or facility must request that the co-providers or co-facilities submit good faith estimate information to the convening provider or facility. This request must also include the date that good faith estimate information must be received by the convening provider or facility. **HHS seeks comment methods and standardized processes, including use of HIPAA standard transactions, that may facilitate accurate and efficient transmission of good faith estimate information from co-providers or co-facilities to convening providers or convening facilities.**

(iii) Timeframes to provide a good faith estimate. Good faith estimates must be provided to uninsured individuals within the following timeframes:

- Not later than 1 business day after the date of scheduling when a primary item or service is scheduled at least 3 business days before the date of furnishing.
- Not later than 3 business days after the date of scheduling when a primary item or service is scheduled at least 10 business days before such item or service is the date of furnishing; or



- Not later than 3 business days after the date of the request when a good faith estimate is requested.

(iv) Changes in scope of information in the good faith estimate. A new good faith estimate is required if any provider involved (whether convening or co-provider or facility) anticipates or is notified of any changes (e.g., changes in expected charges, items, services, frequency, recurrences, duration, providers, or facilities) to the scope of a good faith estimate previously furnished at the time of scheduling. The new good faith estimate must be issued no later than 1 business day before the items or services are scheduled to be furnished.

(v) Changes in providers or facilities in the good faith estimate less than 1 business day before date of furnishing. If there is a change in an expected provider or facility (whether convening or co-provider or facility) represented in a good faith estimate that occurs 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 for the relevant items or services the good faith estimate for those items or services in the good faith estimate that was provided by the replaced provider or facility. HHS believes this policy is necessary for to ensure that uninsured individuals may access the patient-provider dispute resolution process; however, **it seeks comment on whether the policy may have unintended consequences, such as delays in care should providers refuse to serve as replacements.**

(vi) New good faith estimates under other circumstances. If an uninsured individual requests a good faith estimate for items or services and subsequently schedules the requested items or services, the convening provider or convening facility must provide a new good faith estimate for the scheduled items or services within the timeframes that apply to the provision of good faith estimates (described above).

(x) Single good faith estimate for recurring primary items and services. A convening provider or facility may issue a single good faith estimate for recurring primary items or services (e.g., post-surgery physical therapy visits) if the estimate includes the expected scope of the recurring primary items or services (such as timeframes, frequency, and total number of recurring items or services). Additionally, the scope of a good faith estimate for recurring primary items or services may not exceed 12 months. If the recurring primary items or services are expected beyond 12 months, the convening provider or facility must provide a new good faith estimate, and communicate the changes (e.g., 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.

*b. Requirements for co-providers and co-facilities.*

(i) Deadline to submit information to convening provider or facility. Not later than 1 business day after a co-provider or co-facility receives a request from a convening provider or facility for good faith estimate information, the co-provider or co-facility must submit, and the convening provider or facility must receive, that information.

(ii) Notice of changes to good faith estimate information. Co-providers and co-facilities must notify and provide new good faith estimate information to a convening provider or facility if the co-provider or co-facility anticipates any changes to the scope of good faith estimate information previously submitted (e.g., changes to expected charges, items, services, frequency, recurrences, duration, providers, or facilities).

(iii) Changes in providers or facilities in the good faith estimate less than 1 business day before date of furnishing. Similar to the policy above for convening providers or facilities, if there is a change in the expected co-providers or co-facilities represented in a good faith estimate that occurs 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.

(iv) Co-providers or co-facilities treated as convening providers or facilities. If an uninsured individual separately schedules an item or service, or requests a good faith estimate from a provider or facility, that would otherwise be a co-provider or co-facility, that co-provider or co-facility will be considered a convening provider or facility. In such a case, that co-provider or co-facility must meet all the good faith estimate requirements of a convening provider or facility for that item or service for that individual.

### 3. Content Requirements of a Good Faith Estimate.

A good faith estimate issued to an uninsured individual must include the following information:

- Patient name and date of birth.
- Description of the primary item or service (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 furnished for the primary item or service, and items or services reasonably expected to be furnished in conjunction with the primary item or service. This includes the items or services reasonably expected to be furnished by the convening provider or facility, and by co-providers or co-facilities, for 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 each provider or facility represented in the good faith estimate, and the location(s) where the items or services are expected to be furnished.
- 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. There must be a disclaimer directly above this list that informs the uninsured individual that separate good faith estimates will be provided upon scheduling or upon request of the listed items or services and that includes instructions on how to obtain good faith estimates for the items or services.
- Disclaimers for all of the following:

- There may be additional items or services the convening provider or 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.
- The information 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 individual and that actual items, services, or charges may differ from the good faith estimate.
- Information on rights 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, including instructions for where an uninsured individual can find information about how to initiate the patient-provider dispute resolution process. This disclaimer also requires a statement that the initiation of the patient-provider dispute resolution process will not adversely affect the quality of health care services furnished to an uninsured individual by a provider or facility.
- The good faith estimate is not a contract and does not require the uninsured individual to obtain the items or services from any of the providers or facilities identified in the good faith estimate.

HHS considered adding a requirement that the good faith estimate include contact information for a provider's or facility's financial assistance office; **it seeks comment on whether to do so. It also seeks comment on whether to require the good faith estimate to include additional information and expected charges for items and services anticipated to be provided before or after the period of care for the primary item or service but require separate scheduling by the uninsured individual.** HHS clarifies that the good faith estimate is not required for charges for unanticipated items or services that are not reasonably expected or that could occur due to unforeseen events.

With respect to coding, HHS expects the use of coding that best describes the item or service for each item or service listed in the estimate. Where a single service code captures component parts of an item or service, the component parts would not be separately reported or billed.

The IFC includes an example of how an itemized list of expected items and services could be visualized. **It seeks comment on options for displaying and methods for standardizing the format for itemized items and services as well as on potential benefits and challenges of using a standardized form. Comment is also sought on whether to require additional information explaining concepts within the required disclaimers (such as itemized list of items and services).**

#### 4. Content Requirements for Good Faith Estimate Information Submitted by Co-Providers or Co-Facilities to Convening Providers or Convening Facilities.

Co-providers and co-facilities that submit good faith estimate information to convening providers or convening facilities must include the following:

- Patient name and date of birth.
- 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, NPIs, and TINs of the co-provider or co-facility, and the location(s) where the items or services are expected to be furnished by the co-provider or co-facility.
- A disclaimer that the good faith estimate is not a contract and does not require the uninsured individual to obtain the items or services from any of the co-providers or co-facilities identified in the good faith estimate.

#### 5. Required Methods for Providing Good Faith Estimates for Uninsured Individuals.

HHS requires that good faith estimates must be provided in written form. Based on the preference of the uninsured individual, it may be provided either on paper or electronically. It must be furnished within the timeframes set forth in 149.610(b) (described above). If a good faith estimate is provided electronically, the format must permit the uninsured individual to both save and print it. The estimate must be provided and written using clear and understandable language so it can be understood by the average uninsured individual. HHS believes providers and facilities should 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. It also reminds providers and facilities of their duties under federal and state law regarding language access and prohibiting discrimination.

If the uninsured individual asks for a good faith estimate orally, the convening provider may orally inform the uninsured individual of information contained in the good faith estimate using the method requested by the uninsured individual. Nonetheless, the convening provider or facility must still issue the good faith estimate to the uninsured individual in written form as well. Unless prohibited by state law, the good faith estimate may be provided to the authorized representative of an uninsured individual.

#### 6. Additional Compliance Provisions.

*Medical Record.* A good faith estimate under §149.610 is considered to be part of the patient's medical record and therefore must be maintained in the same manner as a patient's medical record. Convening providers and facilities must provide a copy of any previously issued good faith estimate furnished within the last 6 years to an uninsured individual upon request of the uninsured individual.

*Interaction with State Law Requirements.* A provider or facility that issues a good faith estimate under a state law or process that does not meet the requirements of §149.610 will be out of compliance with the federal requirements. HHS views the federal requirements as a minimum standard.

*Errors or Omissions.* If a provider or facility, despite acting in good faith and with reasonable due diligence, makes an error or omission in a good faith estimate, it may correct the information before the item(s) or services(s) are furnished. However, if the item(s) or service(s) are furnished before the error or omission 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.

*Good Faith Reliance on Information from Other Entities and Individuals.* If a provider or facility must obtain information from any other entity or individual, the provider or facility will not be out of compliance with §149.610 if it relied in good faith on the information from the other entity or individual. However, if the provider or facility knows, or reasonably should have known, that the information is incomplete or inaccurate, it may fail to comply with the requirements for good faith estimates. HHS notes that providers and facilities may file a complaint for enforcement investigation of other providers and facilities that fail to comply with the requirements relating to good faith estimates.

If the provider or facility learns that information is incomplete or inaccurate, it must provide corrected information to the uninsured 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.

## 7. Applicability.

The requirements related to good faith estimates apply for estimates requested on or after January 1, 2022 or for estimates that must be provided in connection with items or services scheduled on or after January 1, 2022. As noted above, HHS will exercise enforcement discretion where a good faith estimate provided to an uninsured individual does not include expected charges from co-providers or co-facilities.

HHS clarifies that providers and facilities must still comply with other applicable state or federal laws, including those relating to accessibility, privacy, or security of information required to be disclosed under §149.610, or governing the ability of properly authorized representatives to access uninsured individuals' information held by providers or facilities, unless otherwise prohibited by state law.

## 8. Applicability of Requirements to Notices Required for Balance Billing in Cases of Non-emergency Services Performed by Nonparticipating Providers at Certain Participating Health Care Facilities (§§149.420(c) and (d)(2)).

HHS notes that the July 2021 IFC included requirements at (§149.420(d)(2)) for good faith estimates of amounts certain nonparticipating providers may charge a participant, beneficiary, or enrollee for an item or service. In that IFC, HHS indicated the provider or facility is expected to apply the same process and considerations used to calculate the good faith estimates under PHS Act 2799B-6(2).

In this IFC, HHS clarifies that the good faith estimate in the notice under §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 (i.e., 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) under §149.610. While HHS acknowledges that the Departments are not at this time codifying requirements regarding requirements on providers and facilities to furnish good faith estimates to plans or issuers, its non-enforcement decision with respect to those requirements does not extend to the requirement to provide a good faith estimate as part of the notice under §149.420(c).

### **C. Requirements for the Patient-Provider Dispute Resolution Process (§149.620)**

HHS establishes the patient-provider dispute resolution process through which uninsured individuals who received a good faith estimate of expected charges for items and services may initiate a process by which an SDR entity may determine the amount to be paid by the individual for the item or service where the billed amount is substantially in excess (which HHS defines as \$400) of the expected charges in the good faith estimate. The IFC defines certain terms for the process; specifies the items and services eligible for the process; establishes requirements for the uninsured individual to begin the process; specifies the information providers and facilities must provide to the SDR entity; and sets the administrative fee for the process (estimated not to exceed \$25 in 2022 payable by the non-prevailing party). HHS also establishes requirements for SDR entities with respect to the process as well as certification requirements for those entities. It also sets minimum requirements for state patient-provider dispute resolution processes that operate in lieu of the federal process.

#### **1. Definitions.**

Generally, the terms defined in §149.610 (relating to good faith estimates) apply to patient-provider dispute resolution process. Terms relating to confidentiality have the definitions given them for purposes of the Federal IDR process under §149.510(a)(2), including definitions for *breach*, *individually identifiable health information (IIHI)*, and *unsecured IIHI*. Additionally, HHS defines the following additional terms:

- *Billed charge(s)* means the amount billed by a provider or facility for an item or service.
- *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.
- *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.

HHS considered a number of alternatives for its definition of substantially in excess, including higher or lower dollar amounts, using a straight percentage-based standard (e.g., 20 percent in excess of the expected charge), a tiered percentage-based standard, or combinations of these

policies. Ultimately, HHS prefers a straight-forward, objective test that is easily understandable for potential parties to a dispute. It was also concerned that setting the threshold too high would limit access of uninsured individuals to the process. It also considered but rejected the use of income-based standards. HHS cites research which it believes supports its definition, including a Federal Reserve report which found that nearly 4 in 10 adults would have difficulty covering an emergency expense of \$400 or more. It believes it has struck a balance that ensures the amounts in dispute are sufficiently large to justify the costs of maintaining and operating the dispute resolution process, that minimizes the burden on providers, facilities and the federal government, and that affords access to the process by uninsured individuals. HHS will monitor the use of the process and may propose adjustments in future years. **HHS seeks comment on its definition.**

## 2. Eligibility for Patient-Provider Dispute Resolution.

Generally, 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 provider or facility for the item or service, are substantially in excess of the total expected charges for that specific provider or facility listed on the good faith estimate.

The preamble also states that an item or service is eligible for dispute resolution based on the total billed charges from the provider or facility *regardless of whether the items or services are included in the good faith estimate*. HHS is concerned that providers and facilities may be incentivized to omit items and services from the good faith estimate to avoid the dispute resolution process, and it believes that any item or service not included in the good faith estimate that results in total billed charges substantially in excess of total expected charges should be eligible for dispute resolution. Thus, 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.

To account for the substitution of a co-provider or co-facility, if a different co-provider or co-facility from the original one included in the good faith estimate furnishes the service, 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. However, if the replacement co-provider or co-facility provides the uninsured individual with a new good faith estimate of estimated charges before furnishing the item or service, then those expected charges are used to determine whether the billed amount by the replacement co-provider or co-facility is substantially in excess of the total expected charges for the item(s) or service(s).

HHS had considered basing eligibility on an item-by-item or service-by-service basis. It rejected this approach due to complexity and potential for gaming. It also considered basing eligibility on the total billed charges for all items and services furnished by all providers and facilities listed on the good faith estimate; it also found this to be too complex.

HHS is concerned that providers and facilities may inflate good faith estimates thereby limiting access by uninsured individuals to the dispute resolution process. It believes it addresses this concern by requiring the estimate to provide an itemized list of items and services in advance, and the associated codes and expected charges. **It seeks comment on other resource to aid individuals in determining the reasonableness of good faith estimates.** HHS also cautions that intentionally providing incomplete or inaccurate expected charges in the estimate violates requirements under PHS Act section 2799B-6 which is subject to enforcement actions under PHS Act section 2799B-4. The IFC modifies existing regulations to include violations of subpart G (good faith estimates and the patient-provider dispute resolution process) under the provisions that permit HHS to receive and resolve complaints.

HHS reiterates that it will exercise enforcement discretion during 2022 where the good faith estimate does not include expected charges for items and services from a co-provider or co-facility. This is intended to afford providers and facilities additional implementation time to develop appropriate communication channels among various co-providers or co-facilities.

**HHS seeks comments from underserved and racial/ethnic minority communities on additional barriers these individuals may face in understanding and exercising rights related to these issues, 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 to help ensure that these rights and tools are available, accessible, and understood such that they can be used equitably by all uninsured individuals in appropriate circumstances.**

### 3. Initiation of the Patient Provider Dispute Resolution Process.

#### *a. Deadline to File; Fee.*

Generally, an uninsured individual may initiate the patient-provider dispute resolution process by submitting an initiation notice to HHS within 120 calendar days of receiving the initial bill that contains charges for the item or service that is substantially in excess of the expected charges in the good faith estimate. HHS chose calendar days because it believes consumers can more easily calculate calendar days as opposed to business days. HHS is also concerned about affording too long of an interval between receipt of the bill and initiation of the process, in part because of requirements HHS imposes on providers or facilities to suspend bill collection efforts (including referral to bill collection) and suspend late fees on unpaid bill amounts until after the dispute resolution process is concluded.

The authorized representative of an uninsured individual may also submit the initiation notice unless the representative is any provider 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. State Consumer Assistance Programs and legal aid organizations may serve as authorized representatives.



The uninsured individual must also submit an administrative fee of \$25 for dispute resolution initiated in 2022. The amount of the fee will be updated in later years through guidance. HHS notes that the upfront payment of the administrative fee may discourage some individuals, it believes that the fee is necessary to discourage unnecessary claims. If the patient prevails in the dispute, the amount of the fee is deducted from the amount payable to the provider or facility involved.

*b. Initiation Notice.*

The notice to initiate the patient-provider dispute resolution process must include the following:

- Information sufficient to identify the item or service under dispute, (i.e., date of service and description).
- A copy of the provider or facility bill for the item and service under dispute and a copy of the good faith estimate.
- Contact information of the provider or facility involved (if not included on the good faith estimate).
- The State where the items or services in dispute were furnished.
- The uninsured individual's communication preference.

The initiation notice must be submitted to HHS via the Federal IDR portal, electronically, or on paper, in the form and manner specified by HHS. The initiation date of the patient-provider dispute resolution process will be the date the HHS receives the initiation notice.

*c. Notification of SDR Entity Receipt.*

Upon receipt of the initiation notice, HHS will select an SDR entity. The SDR entity will notify the uninsured individual and the provider or facility that a patient-provider dispute resolution request has been received and is under review. The notice will also include the following:

- Sufficient information to identify the item or service under dispute.
- The date of receipt of the initiation notice.
- Notice of the additional requirements for providers or facilities while the patient-provider dispute resolution process is pending (described below).
- Information to the uninsured individual about the availability of consumer assistance resources that can assist the individual with the dispute.

*d. Validation of Initiation Notice.*

The SDR entity will review the initiation notice to ensure that the items or services in dispute meet the eligibility criteria and that the initiation notice contains the required information. If the initiation notice is determined to be incomplete or the items or services are determined ineligible for dispute resolution, the SDR entity may provide an insufficiency notice to the individual affording them 21 calendar days to submit supplemental information. 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.

If eligibility criteria and the initiation notice content criteria are met, the SDR entity will notify the parties to the dispute that the item or service has been determined eligible for dispute resolution. The SDR entity will request the provider or facility provide, within 10 business days, copies of the good faith estimate and the total billed charges for the item or service as well as documentation explaining the difference between the two amounts.

*e. Prohibitions on Collections.*

While the patient-provider dispute resolution process is pending, the provider or facility is prohibited from moving the bill for the disputed item or service into collection or threatening to do so. If the bill has already moved into collection, the provider or facility must stop 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.

*f. Prohibitions on Retributive Action.*

Using its general rulemaking authority, HHS prohibits the provider or facility from taking or threatening to take any retributive action against an uninsured individual for utilizing the patient-provider dispute resolution process to seek resolution for a disputed item or service.

4. Certification of SDR Entities.

HHS will only contract with and certify only that number of SDR entities that it believes will be required to timely resolve the volume of patient-provider disputes. It anticipates a maximum of 3 entities that will all operate nationwide though case volume may drive changes to that number over time. While SDR entities will have to satisfy most of the criteria that apply to the Federal IDR entities, there are differences between the requirements for the two entities. For example, potential SDR entities are not required to make the following submissions:

- Information regarding the service area(s) for which the entity will arbitrate cases. (Instead, a potential SDR entity must submit information on their ability to operate nationwide through the contract process.)
- Fee schedule for batched and non-batched claims.
- 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 and remit them to HHS in a manner specified by HHS.

In addition, the SDR entity must also meet conflict-of-interest mitigation policy requirements. Specifically, potential SDR entities must provide additional information on the entity's conflict-of-interest policies and procedures. These must include 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. The conflict-of-interest mitigation plan may include using a subcontractor without a conflict of interest that meets SDR entity requirements to conduct the patient-provider dispute resolution for the case.

HHS defines conflict of interest to mean “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.” HHS states that a conflict of interest under the dispute resolution process exists when an SDR entity any of the following:

- A provider or a facility;
- An affiliate or a subsidiary of a provider or facility;
- An affiliate or subsidiary of a professional or trade association representing a provider or facility; or
- 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.

SDR entities must also comply with all confidentiality requirements that apply to certified IDR entities and comply with state and federal law regarding language access and anti-discrimination. SDR entities may not charge fees to parties to the dispute; instead, they are paid for their services through contracts with HHS.

##### 5. Selection of an SDR Entity.

As noted above, upon receipt of an initiation notice, HHS will assign an SDR entity to conduct the dispute resolution process for the item or service. Upon receiving an assignment from HHS, the SDR entity must ensure that no conflict of interest exists. If there is no conflict of interest, the SDR entity will notify the parties to the dispute of its selection.

If a conflict of interest exists, the SDR entity must notify HHS of the conflict not later than 3 business days after being selected by HHS. HHS will then automatically select a new SDR entity to conduct the patient-provider dispute resolution process for the item or service. If there are no SDR entities available to resolve the dispute, the SDR entity first selected will have to initiate their entity-level conflict of interest mitigation plan. If there are no other contracted SDR entities, or subcontracted entities, that can provide the patient-provider dispute resolution services due to conflicts of interest that cannot be sufficiently mitigated or any other reason, HHS may contract with an additional SDR entity. If HHS must contract with an additional SDR entity, the time periods otherwise applicable for SDR entities and parties to the dispute may be extended at HHS' discretion to allow for HHS to contract with that SDR entity.

Either party to the dispute resolution process may attest that a conflict of interest exists in relation to the SDR entity assigned to a payment dispute. The SDR entity must notify HHS no later than 3 business days receiving the attestation.

## 6. Payment Determination for Patient-Provider Dispute Resolution.

### *a. Determination of Payment Amount Through Settlement*

Parties to a dispute resolution process may agree on a payment amount after the dispute resolution process has been initiated before the date on which the SDR entity makes a determination. The settlement amount could be through an offer of financial assistance or an offer of a lower amount, or an agreement by the uninsured individual to pay the billed charges in full. If the parties agree to settle, not later than 3 business days after the date of the agreement the provider or facility will notify the SDR entity. HHS clarifies that neither party is required to enter into a settlement agreement.

At a minimum, the settlement notification must contain the settlement amount, the date of the settlement, and documentation demonstrating that the provider or facility and uninsured individual have agreed to the settlement. In the case of a settlement, the parties evenly split the cost of the administration fee. The settlement notification must also document that the provider or facility has applied a reduction to the uninsured individual's settlement amount equal to at least half the amount of the administrative fee. Upon receipt of the settlement notice, the SDR entity will close the dispute resolution case as settled, and the agreed upon payment amount will apply for the items or services.

If the uninsured individual (or another party on the individual's behalf) pays the billed charges, in whole or in part, before a determination by a SDR entity, that payment does not demonstrate any agreement by the uninsured individual to settle at that amount or any other amount.

### *b. Determination of Payment Amount Through the Patient-Provider Dispute Resolution Process.*

(i) Information from the provider or facility. If the parties to the dispute do not agree to settle the payment amount, then not later than 10 business days after the receipt of the selection notice from the SDR entity, the provider or facility must submit to the SDR entity the following information:

- A copy of the good faith estimate provided to the uninsured individual for the item or service under dispute.
- A copy of the billed charges provided to the uninsured individual for the item or service under dispute.
- 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. No later than 30 business days after receipt of the provider or facility information described above, the SDR entity must determine the amount to be paid by such uninsured individual. This timeframe is similar to the one for the Federal IDR process.

(iii) Payment determination by an SDR entity. The SDR entity must review documentation submitted by the uninsured individual and the provider or the facility, and it must 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 both (I) reflects the costs of a medically necessary item or service and (II) 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 states that the SDR entity should use the expected charges in the good faith estimate as the presumed appropriate amount unless the provider or facility provides credible information justifying the difference. HHS defines credible information to mean information that upon critical analysis is worthy of belief and is trustworthy. HHS notes that in cases where changes in underlying circumstances occur during treatment that would reasonably result in higher-than-expected charges, the SDR entity may consider additional factors that support the charges for medically necessary items and services.

(iv) Payment determination process. If the billed charge is equal to or less than the expected charge for the item or service in the good faith estimate, the amount payable for the item or service is the billed charge.

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 satisfy the criteria for costs and/or unforeseen circumstances, the amount payable for the item or service is the expected charge for the item or service in the good faith estimate.

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 satisfies the criteria for costs and unforeseen circumstances (based on credible information), the amount payable for the item or service, the lesser of:

- The billed charge; or
- 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 where the services were provided, that is reflected in an independent database (using the methodology for calculating the qualifying payment amount described in §149.140(c)(3)). However, if the amount determined by an independent database is less than the expected charge for the item or service listed on the good faith estimate, the amount payable will equal the expected charge for the item or service listed on the good faith estimate. In comparing the billed charge with the amount in an independent database, the SDR entity should account for any discounts offered by the provider or facility.

HHS acknowledges that notwithstanding a finding by the SDR entity that the provider or facility provided credible information to satisfy the criteria, the amount payable may still be less than the billed amount. It also recognizes that this policy could serve as an incentive for uninsured individuals to initiate the dispute resolution process. However, it reasons that the No Surprises Act intended to provide robust consumer protections in response to abusive billing practices, especially for uninsured individuals.

(v) Payment for new items or services. For new items or services (i.e., those that do not appear on the good faith estimate), the following rules apply:

If the SDR entity determines that the information submitted by the provider or facility does not satisfy the criteria for costs and/or unforeseen circumstances, the SDR amount payable for the new item or service is equal to \$0.

If the SDR entity determines that the information submitted by the provider or facility does satisfy the criteria for costs and unforeseen circumstances, the SDR entity must select as the amount payable for the new item or service, the lesser of:

- The billed charge; or
- 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 where the services were provided, that is reflected in an independent database (using the methodology for calculating the qualifying payment amount 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.

(vi) Calculation of final payment determination. The SDR entity will sum the amounts to be paid for all items or services subject to the determination. If the final amount determined by the SDR entity is lower than the billed charges, the SDR entity calculates the final payment determination amount to be paid by the individual for the items or services by subtracting the administrative fee from the total amount determined. When the final payment determination amount has been calculated, the SDR entity will inform the parties of its determination, the determination amount

and its justification for making the determination. The SDR entity will close the case after this notice to the parties has been made.

*c. Effects of Determination.*

The No Surprises Act is silent on the effects of a determination made by an SDR entity. HHS uses its general rulemaking authority to make such a determination binding upon the parties involved. This applies unless there is fraud or evidence of misrepresentation of facts presented to the selected SDR entity regarding the claim. Nothing in the statute or this IFC prevents the provider or facility from providing financial assistance or agreeing to an offer for a lower payment amount than the SDR entity's determination. Similarly, the uninsured individual may agree to pay the billed charges in full, or the uninsured individual and the provider or facility may agree to a different payment amount.

**HHS seeks comment on its policy that determinations are binding on the parties. It also seeks comment on the application of a similar judicial review policy for SDR entities that applies to IDR entities under the Federal IDR process.**

7. Costs of Patient-Provider Dispute Resolution Process.

As noted earlier, the uninsured individual must pay an administrative fee to the SDR entity when initiating the patient-provider dispute resolution process. HHS will specify the amount of the administrative fee through guidance. The SDR entity must remit all administrative fees collected to HHS upon receipt of an invoice from the Department.

If the provider or facility is the non-prevailing party, the provider or facility must reduce the amount of payment due the provider or facility by the amount of the administrative fee.

If the provider or facility is the prevailing party, the provider or facility is not liable for payment of the administrative fee to the uninsured individual.

The provider or facility is the prevailing party where the SDR entity determines the amount to be paid is equal to the billed charges. The uninsured individual is the prevailing party where the SDR entity determines the amount to be paid is less than the billed charges.

As noted earlier, in the case of a settlement, the parties split the cost of the administrative fee equally. The provider or facility must document in the settlement notice that it has applied a payment reduction of at least half of the administrative fee amount to the uninsured individual's settlement amount.

## 8. Deferral to State Patient-Provider Dispute Resolution Processes.

### *a. Deferral to States.*

If HHS determines that a state law provides a process to determine the amount to be paid by an uninsured individual to a provider or facility, and that the process meets or exceeds minimum federal requirements, then HHS will defer to the state process and direct any patient-provider dispute resolution requests received from uninsured individuals in such state to the state process for adjudication.

### *b. Minimum Federal Requirements.*

A State process must at a minimum:

- Be binding, unless the provider or facility offers the uninsured individual to pay a lower payment amount than the determination amount;
- 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 individual;
- Impose a fee charged to uninsured individuals to participate in the patient-provider dispute resolution process in an amount that does not exceed the federal administrative fee; and
- Have in place conflict-of-interest standards that at a minimum meets the requirements applicable to the federal SDR process.

### *c. HHS Determination and Review of State Process.*

HHS will review the state process to determine whether it meets or exceeds the minimum federal requirements, and it will notify the state in writing of such determination. HHS will review changes to the state process on an annual basis to ensure the state process continues to meet or exceed the minimum federal standards. HHS will also review the state process at other times if it receives information from the state that indicates the state process no longer meets the minimum federal requirements.

### *d. State Process Termination.*

If a state process is terminated, or if HHS determines that the state process no longer meets the minimum federal requirements, HHS will make the federal process available to uninsured individuals in that State to ensure access to a patient-provider dispute resolution process in that state that meets the minimum Federal requirements.

## 9. Extension of Time Periods for Extenuating Circumstances.

Timeframes for the patient-provider dispute resolution process 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 SDR entity determination is made as soon as administratively practicable under the circumstances.

There will be no extension of the time for payment of the administrative fee.

Parties may request an extension by submitting a request for extension due to extenuating circumstances if the extension is necessary to address delays due to matters beyond the control of the parties or for good cause.

#### 10. Applicability Date.

The provisions of the patient-provider dispute resolution process apply to uninsured individuals; providers (including providers of air ambulance services) and facilities; and SDR entities, generally beginning on or after January 1, 2022. However, the provisions relating to certification of SDR entities apply beginning October 7, 2021.

### **V. Waiver of Proposed Rulemaking**

Provisions of the No Surprises Act authorize the Secretaries to promulgate interim final rules as necessary or appropriate. Additionally, section 553(b) of the Administrative Procedures Act (5 U.S.C. 553(b)) authorizes an agency to waive traditional advance notice and comment rulemaking procedures if the agency finds good cause that notice and comment rulemaking procedures are impracticable, unnecessary, or contrary to the public interest and incorporates a statement of its finding and its reasons in the rule issued.

The Secretaries and the Director of OPM have determined that it would be impractical and contrary to the public interest to delay putting the provisions in the IFC in place until after a full notice and comment process has been completed. The following rationale are included in the interim final rule:

- There is a short period of time between enactment of the law (December 27, 2020) and the application of Federal IDR, patient-provider dispute resolution, and external review provisions (plan years beginning on or after January 1, 2022).
- Plans and issuers must account for these changes in setting premium or contribution rates; interim final rules permit them to take into account finalized regulations in determining rates and plan offerings.
- Health care plans and issuers, facilities and providers, as well as air ambulance providers, need the rules in place to determine out-of-network rates for protected services or they will not be able to resort to the Federal IDR process. Failure to promulgate the rules in a timely fashion could result in under compensation for certain providers and could encourage additional industry consolidation.

- Providers, facilities, and air ambulance providers require time to implement requirements related to the open negotiation period and the provision of a good faith estimate of expected charges.
- Entities applying for certification as an IDR or SDR need time to establish policies and procedures, gather the documentation necessary in order to be available on the applicability date of January 1, 2022.

## VI. Economic Impact and Paperwork Burden

The Departments and OPM have examined the effects of the IFC pursuant to Executive Order 13563, Executive Order 12866, the Regulatory Flexibility Act and other authorities. They have determined that the IFC is “economically significant” within the meaning of Executive Order 12866 because they are expected have economic impacts of \$100 million or more in any one year. Accordingly, the Departments provide an analysis of the potential costs, benefits, and transfers associated with these rules. They note that they are unable to quantify some of the benefits, costs, and transfers.

The Departments review the need for the regulations including the impact of surprise medical bills on individuals. They describe surprise billing as a market failure since patients often do not have an option to seek care elsewhere nor make decisions based on complete information. The No Surprises Act and the IFC address those failures. Table 1 (Accounting Statement) summarizes the benefits, costs, and transfers associated with the regulations and is reproduced below:

| <b>Benefits:</b>   |
|--|
| <p>Non-quantified benefits of the Federal IDR process for the population with health coverage:</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• 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.</li> <li>• 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.</li> </ul> <p>Non-quantified benefits of the patient-provider dispute resolution process for uninsured (or self-pay) individuals:</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• 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.</li> <li>• 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.</li> </ul> <p>Non-quantified benefits regarding external review:</p> <ul style="list-style-type: none"> <li>• Increased access to benefits for some individuals.</li> </ul> |

|   |          |             |               |                |
|---|----------|-------------|---------------|----------------|
| <ul style="list-style-type: none"> <li>• 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.</li> <li>• Potential increase in confidence and satisfaction among participants, beneficiaries, and enrollees in their health care benefits.</li> <li>• Improved awareness among plans, issuers, and FEHB carriers of participant, beneficiary, enrollee, FEHB covered individuals, and provider concerns.</li> </ul>  |          |             |               |                |
| <b>Costs to Plans, Issuers, and FEHB Carriers:</b>  |          |             |               |                |
| Costs (in millions)   | Estimate | Year dollar | Discount Rate | Period Covered |
| Annualized Monetized (\$/Year)  | \$517.12 | 2021        | 7 percent     | 2022-2031      |
|   | \$491.44 | 2021        | 3 percent     | 2022-2031      |
| <p>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.</p>   |          |             |               |                |
| <b>Costs to the Government:</b>   |          |             |               |                |
| <p>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 million in fiscal year 2021 and \$567,000 annually going forward.</p>   |          |             |               |                |
| <b>Transfers:</b>   |          |             |               |                |
| <p>Non-quantified transfers associated with the Federal IDR process for the population with health coverage:</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• 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.</li> <li>• Potential transfers from plans, issuers, and FEHB carriers to participants, enrollees, and beneficiaries if the Federal IDR process results in lower premiums.</li> <li>• Potential transfers from participants, enrollees, and beneficiaries to plans, issuers, and FEHB carriers if the Federal IDR process results in higher premiums.</li> <li>• Potential transfers to the Federal Government in the form of reduced Premium Tax Credits if the Federal IDR process results in the lower premiums.</li> <li>• 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.</li> <li>• 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.</li> <li>• 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.</li> <li>• 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</li> </ul> |          |             |               |                |

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.

## A. Regulatory Burden

The Departments estimate that the total cost burden associated with the IFC is \$760.9 million in the first year with \$706.7 million attributable to the patient-provider dispute resolution process, \$38.4 million attributable to the Federal IDR process for non-ambulance items and services, \$11.1 million attributable to the Federal IDR process for air ambulance services, \$4.02 million attributable to the external review process, and \$149,616 attributable to costs associated with certification and recordkeeping requirements for certified IDR entities.

The rules are expected to result in a significant reduction in the incidence of surprise billing.

Estimates of the number of impacted entities and individuals are provided including for health insurance issuers, and group health plans, individuals, physicians, emergency departments and other health care facilities, and air ambulance service providers. The Departments expect that there will be approximately 50 IDR entities seeking certification by the Departments and of those, between one and three will seek to become contracted SDR entities.

The benefits of the IDR process, protections for the uninsured, and the external review requirements are reviewed. HHS notes that it was concerned that requiring uninsured individuals to pay for the cost of the dispute resolution would be prohibitive and that requiring a provider or facility to pay those costs would result in higher charges to uninsured individuals. As a result, under the IFC it will incorporate dispute resolution costs into contracts with SDR entities. Total costs for that process are estimated to be \$10.6 million annually. In addition, HHS anticipates requiring an administrative fee of no more than \$25 for individuals to participate in the process. Statute requires that fee be set so that it does not create barriers for uninsured individuals to participate.

The costs of the IDR process are dependent on the number of claims that will be submitted through the process. The Departments have relied on data from New York's IDR process to extrapolate nationwide. They note that in New York the number of claims submitted into dispute resolution has been rising and **they seek comment on what may be causing that trend and whether it should be expected to continue.**

Based on the New York experience, the Departments estimate 17,000 claims will be submitted to the IDR process each year and 23,111 claims will go through open negotiation before entering the IDR process. The cost of the process for nonparticipating providers and emergency facilities is estimated to be \$38.4 million including \$21.1 million for paperwork requirements for the IDR process and \$10.3 million for the open negotiation process.

The Departments expect that 25% of IDR payment determinations will be conducted by an IDR entity not selected by the parties involved. They also estimate that the average certified IDR entity fee will be \$400 totaling \$6.9 million for all fees.

With respect to air ambulance services, the Departments expect a larger percentage of those claims will be entered into dispute resolution since a substantially higher number of air ambulance providers are out of network. The estimate 4,900 air transport payment determinations each year at a cost of \$11.1 million including \$5.3 million for paperwork requirements. An addition 6,532 claims will go through open negotiation at a cost of \$3.8 million.

The Departments expect that 25% of IDR payment determinations will be conducted by an IDR entity not selected by the parties involved. They also estimate that the average certified IDR entity fee will be \$400 totaling \$2 million for all fees.

Costs associated with extension requests are estimated to be \$1,340 per year and for the IDR certification process, \$149,610 in year one and \$124,491 in subsequent years.

The costs associated with external review are estimated based on a rate of 1.3 external reviews for every 10,000 participants. At that rate, the Departments expect:

- 15,942 requests for external reviews for employment-based plans at a cost of \$3.3 million.
- 4,337 external reviews for individual market and non-Federal government plans at a cost of \$241,850.
- Costs to HHS of the process equal to \$0.2 million.

An estimated 26,000 claims are expected to result in patient-provider dispute resolution cases each year. The costs associated with the requirement to notify uninsured individuals of the availability of good faith estimates is estimated to be \$320 million while the cost of providing those estimates to be \$356 million.

The potential impact on premiums, one possible transfer that could result from the rules is discussed. The Congressional Budget Office estimated that the No Surprises Act would reduce premiums by between 0.5 percent to 1 percent in most years. The CMS Office of the Actuary estimated small increases to premiums of between 0 and .35 percent. The uncertainty about the impact on premiums is discussed as well as how those changes could impact Premium Tax Credits, physician and facility payment rates, and health care costs overall.

The Departments considered a large number of regulatory alternatives including:

- Requiring that a certified IDR only consider other factors beside the QPA when clear and convincing evidence was presented that the payment should differ materially from the QPA. This option was rejected because it was not believed to give enough weight to the statutory requirement that certified entities consider additional factors among other reasons.
- Alternative ways to choose the IDR entity where the parties to a payment dispute fail to choose a certified IDR entity, and the Departments are required to choose the entity. Rather than randomly selecting a certified IDR entity, the Department considered choosing based only on entity fees or based on an entity’s history of choosing a payment closest to the QPA. These alternatives were rejected as potentially penalizing entities that fairly took into account additional information among other reasons.
- Several alternative approaches were considered to meet the requirement to provide good faith estimates for uninsured or self-pay individuals such as requiring only broad outreach efforts, providing for standardized notices, or requiring estimates for each instance of a recurring item or services. Those alternatives were rejected.

A number of additional alternatives are described for different stages of the patient-provider dispute resolution process.

## **B. Paperwork Reduction Act**

With the publication of the IFC, 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. They can be obtained at <https://www.RegInfo.gov>.

In addition, the Departments provide annual burden estimates for a number of components of the ICR including the following more significant items:

### 1. ICRs regarding the IDR Processes.

|  | For Non-Air Ambulance Claims |                                 | For Air Ambulance Claims    |                                |
|--|------------------------------|---------------------------------|-----------------------------|--------------------------------|
|  | Total Annual Burden (Hours)  | Total Estimated Cost (millions) | Total Annual Burden (Hours) | Total Estimated Cost(millions) |
| Annual Burden and Costs to Prepare and Send Notice of Open Negotiation Process               | 51,999                       | \$5.2                           | 14,696                      | \$1.5                          |
| Annual Burden and Costs to Prepare and Send Notice of IDR Initiation                         | 38,999                       | \$3.9                           | 11,022                      | \$1.1                          |
| Annual Burden and Costs to Select a Certified IDR Entity and Notify Departments of Selection | 16,250                       | \$1.5                           | 4,593                       | \$0.4                          |

|   | For Non-Air Ambulance Claims |                                 | For Air Ambulance Claims    |                                |
|---|------------------------------|---------------------------------|-----------------------------|--------------------------------|
|   | Total Annual Burden (Hours)  | Total Estimated Cost (millions) | Total Annual Burden (Hours) | Total Estimated Cost(millions) |
| Annual Burden and Costs to Prepare and Submit Offer | 103,998                      | \$10.1                          | 22,044                      | \$2.2                          |
| Annual Burden and Costs to Maintain Records         | --                           | \$0.5                           | -- <sup>1</sup>             | \$0.1                          |
| HHS Cost and Burden of IDR Process                  | 95,119                       | \$9.5                           | 23,576                      | \$2.4                          |
| DOL Cost and Burden of IDR Process                  | 52,844                       | \$5.2                           | 13,098                      | \$1.3                          |
| OPM Cost and Burden of IDR Process                  | 10,569                       | \$1.1                           | 2,630                       | \$0.3                          |

<sup>1</sup> Table 19 indicates annual burden hours of 2,499 but zero labor costs which suggests an error.

Source: HPA based on Tables 5-22 of *Requirements Related Surprise Billing, Part II*.

**2. ICRs Regarding the Notice of the Right to Good Faith Estimates for Uninsured or Self-Pay Individuals.**

The Departments estimate the cost to different types of providers of informing uninsured individuals about the availability of good faith estimates of expected charges. For all of those groups of providers, the costs are related to drafting notices; displaying notices on websites, in offices and other sites; posting a notice in at least two prominent locations; and printing and materials costs. The total cost for those activities is estimated to be \$320 million comprised of the following:

- For providers associated with health care facilities, a total cost of \$91.8 million among 245,336 providers in this group to provide notice of a right to a good faith estimate;
- For health care facilities, \$102.8 million among 245,336 providers in this group to draft and post a notice of good faith estimate;
- For individual physician practitioners, \$75 million to draft and post the notice of a good faith estimates;
- For wholly owned private practices, \$50 million to draft and post the notice of good faith estimate.

**3. ICRs Regarding the Provision of Good Faith Estimates for Uninsured or Self-Pay Individuals.**

The Departments estimate the costs of providing good faith estimates of expected charges to uninsured or self-pay individuals for the years between 2022 and 2024 to be \$356.7 million. Those costs are based on an estimated 3.5 million uninsured or self-pay individuals being impacted by the requirement and 511,748 providers incurring the burden and costs associated with generating the estimates. Annual burden hours among those providers is estimated to be 3.5 million.

#### 4. ICRs Regarding Patient-Provider Dispute Resolution Process.

Based on the experience in New York, HHS estimates that there will be 26,659 claims that go to the patient-provider dispute resolution process each year. Total annual costs for the process are estimated to be \$29.8 million and annual burden hours for individuals, providers and facilities of 255,534. Major components of that cost include:

- \$7 million for SDR entities to attest to HHS as to whether a conflict of interest exists;
- \$3.3 million for an SDR entity to review eligibility and completeness of the initiation notice and notify the parties involved of the selection of the entity;
- \$14.0 million to assess the information provided to the entity by the provider or facility;  
and
- \$3.0 million of administrative fees paid to HHS.