ACR Detailed Summary
Requirements Related to Surprise Billing; Part II

The Departments of Health and Human Services (HHS), Labor and Treasury, and the U.S. Office of Personnel Management released the interim final rule with comment (IFC) Requirements Related to Surprise Billing; Part II on September 30, 2021. The American College of Radiology® (ACR®) is disappointed that the regulations violate the intent of the No Surprises Act (NSA) by making the Qualified Payment Amount (QPA) the primary determinant of physician payment rates in the independent dispute resolution process.

The details of the QPA calculation were outlined in the first interim final rule released by the departments in July. The ACR raised concerns about flaws in the methodology in its comment letter on the July rule. Comments for the second IFC are due no later than 5:00 PM ET on December 6th.

The Departments are establishing a Federal Independent Dispute Resolution (IDR) portal to administer the Federal IDR process. The Departments' Federal IDR portal will be available at https://www.nsa-idr.cms.gov and will be used throughout the Federal IDR process to maximize efficiency and reduce burden.

Background

The Consolidated Appropriations Act, 2021 (CAA), including the No Surprises Act (NSA), was enacted on December 27, 2020. The NSA provides Federal protections against surprise billing and limits out-of-network cost sharing under many of the circumstances in which unexpected bills arise most frequently. "Surprise billing" occurs when an individual receives an unexpected medical bill from a health care provider or facility after receiving medical services from a provider or facility that, usually unknown to the participant, beneficiary, or enrollee, is a nonparticipating provider or facility with respect to the individual's coverage. The NSA also requires providers and facilities to furnish a good faith estimate of expected charges upon request or upon scheduling an item or service.

These interim final rules implement provisions of the No Surprises Act that provide for a Federal IDR process to permit group health plans and health insurance issuers offering group or individual health insurance coverage and nonparticipating providers, facilities, and providers of air ambulance services to determine the out-of-network rate for items and services that are emergency services, nonemergency services furnished by nonparticipating providers at participating facilities, and air ambulance services furnished by nonparticipating providers of air ambulance services, under certain circumstances. The Federal IDR provisions are used following the end of an unsuccessful open negotiation period to determine the out-of-network rate when an All-Payer Model Agreement or specified state law does not apply.

In response to stakeholder feedback, until rulemaking to fully implement the requirement to provide good faith estimates to an individual's plan or coverage is adopted and applicable, the Department of Health and Human Services (HHS) will defer enforcement of the requirement that providers and facilities provide good faith estimate information for individuals enrolled in a health plan or coverage and seeking to submit a claim for scheduled items or services to their

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

On November 12, 2020, the Departments issued the Transparency in Coverage final rules, which require group health plans and health insurance issuers of group or individual health insurance coverage to make price comparison information available to participants, beneficiaries, and enrollees through an internet-based self-service tool and in paper form, upon request. This information must be available for plan or policy years beginning on or after January 1, 2023, with respect to 500 specified items and services, and with respect to all covered items and services, for plan or policy years beginning on or after January 1, 2024. **As the disclosure requirements under the Transparency in Coverage final rules are substantially similar to those required under the NSA, the Departments seek comment on whether the transparency final rules could be leveraged to meet the NSA requirements 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.**

The NSA also mandates establishment of a process for uninsured or self-pay individuals can avail themselves of a patient-provider dispute resolution process if their billed charges after receiving an item or service are substantially in excess of the expected charges listed in the good faith estimate furnished by the provider or facility.

Independent Dispute Resolution Process

Note: Business days (Monday through Friday, not including Federal holidays) instead of calendar days are used throughout the IFC for the Federal IDR process unless otherwise indicated, regardless of whether a nonparticipating provider or facility, or a plan or issuer's business typically operates on weekend days.

Open Negotiation Period

Upon receipt of an initial payment or notice of denial of payment from a plan, a provider, facility, or provider of air ambulance services (as applicable), plan or issuer (as applicable) may initiate an open negotiation period within 30 business days beginning on the date the provider or facility receives the initial payment or notice of denial of payment. The open negotiation period may continue for up to 30 business days beginning on the date that either party first initiates the open negotiation period. The parties may discontinue the negotiation if they agree on an out-of-network rate before the last day of the 30- business-day open negotiation period. If the parties cannot agree on an out-of-network rate, they must exhaust the 30-business-day open negotiation period before initiating the Federal IDR process.

The rules state that the party initiating the open negotiation must provide written notice to the other party of its intent to negotiate. The open negotiation notice must be in writing (electronically or in paper form) and include the date the item or service was furnished, the service code, the initial payment amount or notice of denial of payment, as applicable, an offer

for the out-of-network rate, and contact information of the party sending the open negotiation notice. The 30-business-day open negotiation period begins on the day on which the open negotiation notice is first sent by a party. The Departments believe that most open negotiation notices will be sent electronically, and as such, the date the notice is sent will also be the date the notice is received.

The Departments caution that if sufficient notice of open negotiation is not provided, the Departments may determine that the 30-business-day open negotiation period has not begun. In such case, any subsequent payment determination from a certified IDR entity may be unenforceable due to the failure of the party sending the open negotiation notice to meet the open negotiation requirement of this IFC. **The Departments solicit comment on whether there are any challenges or additional clarifications needed to ensure the parties are afforded the full open negotiation period, including whether there are any challenges regarding designating the date the notice is sent as the commencement date of the open negotiation period.**

Initiation of the IDR Process

Either party may initiate the Federal IDR process during the 4-business-day period beginning on the 31st business day after the start of the open negotiation period. The parties may select a certified IDR entity, or if the parties do not select a certified IDR entity, the Departments will do so. The NSA and this IFC specify that the certified IDR entity selected cannot have a conflict of interest with either party.

To initiate the Federal IDR process, the initiating party must submit a notice to the other party (electronically or in paper form) and to the Departments through the Federal IDR portal (on the same day as the notice to the non-initiating party). The Notice of IDR Initiation must include:

1. Information sufficient to identify the qualified IDR items or services (and whether the qualified IDR items or services are designated as batched items and services), including the dates and location of the items or services, the type of qualified IDR items or services (such as emergency services, post-stabilization services, professional services, hospital-based services), corresponding service and place-of-service codes, the amount of cost sharing allowed and the amount of the initial payment made by the plan or issuer for the qualified IDR items or services, if applicable;
2. The names and contact information of the parties involved, including email addresses, phone numbers, and mailing addresses;
3. The state where the qualified IDR items or services were furnished;
4. The commencement date of the open negotiation period;
5. The initiating party's preferred certified IDR entity;
6. An attestation that the items or services are qualified IDR items and services within the scope of the Federal IDR process;
7. The QPA;
8. Information about the QPA as defined in the July IFC; and
9. General information describing the Federal IDR process, including key deadlines. This general information will help ensure that the non-initiating party is informed about the process and is familiar with the next steps. The Departments have developed a form that parties must use to satisfy this requirement.

The Departments will acknowledge and confirm the initiation date with both parties upon receipt of the Notice of IDR Initiation. **The Departments solicit comment on both the content of the Notice of IDR Initiation as well as the manner for providing the notices as set forth under this IFC.**

Selection of Certified IDR Entity
The provider and plan involved in the Federal IDR process may jointly select a certified IDR entity no later than 3 business days following the date of the IDR initiation. The non-initiating party may agree or object to the selection of the preferred certified IDR entity identified in the Notice of IDR Initiation. If the non-initiating party fails to object within 3 business days of the date of initiation of the Federal IDR process, the preferred certified IDR entity identified in the Notice of IDR Initiation will be the selected certified IDR entity, provided that the certified IDR entity does not have a conflict of interest. If the non-initiating party objects to the certified IDR entity, that party must provide the initiating party with an explanation of the reason for objecting, and propose an alternative certified IDR entity. The involved parties must come to an agreement within 3 business days and notify the Departments by electronically submitting the notice of the certified IDR entity selection no later than 1 business day after the end of the 3 day period. If the parties fail to mutually agree on a certified IDR entity by the deadline, the Departments must be notified through the Federal IDR portal. **The Departments seek comment on this approach and whether any challenges exist in relying solely upon electronic notifications.**

If the parties are unable to mutually select a certified IDR entity, the Departments will randomly select a certified IDR entity that charges a fee within the allowed range within 6 business days after the IDR process is initiated.

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

With regard to conflicts of interest, IDR entities must attest that they have procedures in place to ensure that no conflicts of interest exist or will exist. Certified IDR entities will have to submit, as part of their application to be certified IDR entities, policies and procedures for conducting ongoing audits for conflicts of interest. Should any conflicts arise, the certified IDR entity must have procedures in place to inform the Departments of the conflict of interest and mitigate the risk by reassigning the dispute to other personnel in the event that any personnel previously assigned have a conflict of interest.

If the parties have agreed on a certified IDR entity, the notice of the certified IDR entity selection must include the name of the certified IDR entity, the certified IDR entity number, and an attestation by both parties (or by the initiating party if the other party has not responded) that the selected certified IDR entity does not have a conflict of interest. The attestation must be

submitted based on conducting a conflicts of interest check using information available (or accessible using reasonable means) to the parties (or the initiating party if the other party has not responded) at the time of the selection.

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

Treatment of Batched Items and Services
In order for items or services to be eligible to be batched in the IDR process, the following conditions must be met:

1. The items and services must be billed with the same National Provider Identifier (NPI) or Taxpayer Identification Number (TIN).
2. The payment for the items and services would be made by the same insurer.
3. The items and services must be the same or similar, defined as "those items and services that are billed under the same service code, or a comparable code under a different procedural code system.
4. The items and services must have been furnished within the same 30-business-day period or the 90-calendar-day suspension period.

The Departments solicit comment on this approach and whether there is a need to prescribe an alternative period for other qualified IDR items and services different from the 30-business-day period and what circumstances should be considered in defining any alternative period.

In cases where the QPA is different for batched items or services (i.e. individual market versus large group insurance plans), the parties must provide the relevant information for each QPA, and the certified IDR entity must consider each QPA for each item or service separately.

Payment Determination
Each party must submit to the certified IDR entity an offer for a payment amount for the qualified IDR item or service in dispute and other information related to the offer as requested by the certified IDR entity within 10 business days of selection of the certified IDR entity and may submit additional information for the certified IDR entity to consider. The payment amounts must include both a dollar amount and the percentage of the QPA.

Providers and facilities must include information on size of their practices and facilities as well as the practice specialty or type. Plans and issuers must provide the coverage area of the plan or issuer, the relevant geographic region for purposes of the QPA, and, for group health plans, whether they are fully-insured, or partially or fully self-insured. FEHB carriers must identify if a particular item or service relates to FEHB plans. Parties may not submit information that relates to usual and customary charges, billed amounts, and public payer rates.

The certified IDR entity must select one of the submitted offers not later than 30 business days after the selection of the certified IDR entity. **The IFC specifies that the certified IDR entity**

must begin with the presumption that the QPA is the appropriate out-of-network rate for the qualified IDR item or service under consideration. The IFC also states that the certified IDR entity must select the offer closest to the QPA unless the certified IDR entity determines that "credible information" submitted by either party clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate.

The IFC defines information as "credible" if "upon critical analysis the information is worthy of belief and is trustworthy". The certified IDR entity may not consider usual and customary charges, the amount that would have been billed (including billed charges that are directed to the plan or issuer) if the protections of the NSA had not applied, or any public payer payment or reimbursement rates. In cases where additional information is submitted, or when the offers are equally distant from the QPA but in opposing directions, the certified IDR entity will select the offer that it believes best represents the value of the items or services. If a certified IDR entity does not choose the offer closest to the QPA, IDR must provide rationale and a detailed explanation of the additional considerations that informed its decision.

The Departments believe this interpretation is consistent with the NSA's emphasis on the QPA, both as the basis of the surprise billing protections also included in the statute and implemented by the July 2021 interim final rules and as the sole factor identified without any qualification by the statute. The IFC notes that the Departments are required to report how payment determinations compare to the associated QPA and believe this is an indication that the QPA is a "benchmark for determining the appropriate out-of-network rate". The Departments are of the view that implementing the Federal IDR process in this manner encourages predictable outcomes, which will reduce the use of the Federal IDR process over time and the associated administrative fees.

The IFC states, "**Anchoring the determination of the out-of-network rate to the QPA will increase the predictability of IDR outcomes, which may encourage parties to reach an agreement outside of the Federal IDR process to avoid the administrative costs, and will aid in reducing prices that may have been inflated due to the practice of surprise billing prior to the No Surprises Act. Finally, anchoring the determination to the QPA will help limit the indirect impact on participants, beneficiaries, and enrollees that would occur from higher out-of-network rates if plans and issuers were to pass higher costs on to individuals in the form of increases in premiums.**"

Additional information certified IDR entities must consider if submitted includes:

- Circumstances, including training, experience, quality and outcomes measurements
- Market shares of parties
- Acuity of patients/complexity of cases
- Teaching status, case mix, scope of services of facility
- Good faith efforts by parties to contract and contracting rate history from the last four years

The IFC states that the provider must "clearly demonstrate that the QPA is materially different from the appropriate out-of-network rate for the qualified IDR item or service". For example, if the contracted rates include risk-sharing, bonus, penalty, or other incentive-based payments that

were excluded from the QPA calculation as required by the July IFC, a party may provide evidence as to why the quality or outcome measures support a payment rate that is higher than the QPA.

The Departments seek comment on whether additional requirements should be considered to address any potentially abusive scenarios, including scenarios in which parties could potentially distort information that informs the enumerated considerations, such as overestimating the teaching experience of providers at the facility or upcoding the costs for items or services, and seek comment on the potential for gaming of the Federal IDR process.

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

Cooling-Off Period

The party that initiated the IDR process may not submit a subsequent Notice of IDR Initiation involving the same other party with respect to a claim that is the same as or similar to the item or service that was the subject of the initial determination during the 90-calendar-day period following the initial determination.

For claims for the same or similar item or service for which the end of the open negotiation period occurs during the 90-calendar-day suspension period, after the end of the 90-calendar-day suspension period, either party may initiate the Federal IDR process for the items and services affected by the suspension within 30 business days following the end of the cooling-off period.

Costs of the Federal IDR Process and Payment

At the time that a certified IDR entity is selected by both of the parties or by the Departments, each party to a determination must pay to the certified IDR entity the non-refundable administrative fee due to the Departments for participating in the Federal IDR process. At the time submission of the offer by each party to a determination, the certified IDR entity fee must be paid to the certified IDR entity. Each party will be able to view the certified IDR entity fees and administrative fees in the Federal IDR portal when engaging in the certified IDR entity selection process.

Certified IDR entities are required to hold these funds in a trust or escrow account until the certified IDR entity makes a determination of the out-of-network rate. Within 30 business days of making the determination, the certified IDR entity must refund to the prevailing party the amount the party submitted for the certified IDR entity fee. The certified IDR entity will retain the certified IDR entity fee submitted by the non-prevailing party, as the non-prevailing party is required to pay the certified IDR entity fee.

In setting the administrative fee, the Departments will consider the estimated costs for the Departments to administer the Federal IDR process for the following calendar year, including the staffing and contracting costs related to certifying and providing oversight to certified IDR entities; the costs of developing and publishing reports as required; the costs of collecting the

administrative fees from certified IDR entities; and the cost of maintaining the Federal IDR portal.

Extension of Time Periods for Extenuating Circumstances
The Departments have the discretion to extend deadlines set forth in the IFC due to extenuating circumstances such as natural disasters. Extension requests will be considered on a case-by-case basis and may be submitted through the IDR portal.

Certification of IDR Entities
The NSA and this IFC also set forth requirements for certification of IDR entities by the Departments. To become certified IDR entities, IDR entities must provide written documentation demonstrating that they meet the eligibility criteria through the IDR portal. An IDR entity that satisfies the standards in the interim final rules and guidance issued by the Departments will be provided a certified IDR entity number and will be certified for a 5-year period.

The Departments will require that certified IDR entities set fees within a fixed ranges in order to reduce the potential for excessive certified IDR entity fees that could result in inflated health care and insurance costs that could ultimately be passed on to consumers. In addition, setting a minimum fee will discourage overuse of the IDR process. The Departments will consider current IDR fees for state-managed IDR processes already in use. These fees generally range from $300-$600 per determination. The fee range will be reviewed and updated annually.

An individual, provider, facility, provider of air ambulance services, plan, or issuer may petition for the denial of a certification of an IDR entity or a revocation of a certification of a certified IDR entity for failure to meet the requirements specified in the IFC.

External review changes under Section 110 of NSA
The Affordable Care Act (ACA) requires health plans to comply with federal or state external review processes which are available for adverse benefit determinations based on medical necessity, appropriateness, setting, level of care, or effectiveness of a covered benefit. The NSA directed the Departments to ensure that ACA external review processes apply to adverse benefit determinations by a plan under the NSA. The IFC broadens the scope of external review requirements to explicitly state that any adverse benefit determination that involves consideration of whether a plan is complying with the NSA is eligible for external review.

The Federal external review process must be available for any adverse benefit determination by a plan or issuer that involves medical judgment, as well as a rescission of coverage. The IFC provides examples of adverse benefit determinations that would be eligible for external review related to NSA protections The Departments intend to ensure that this provision is implemented in a manner that affords consumers broad protection under section 110 of the No Surprises Act.

Protections for the Uninsured
The definition of uninsured (or self-pay) individuals in this IFC includes individuals enrolled in individual or group health insurance coverage offered by a health insurance issuer, or a health benefits plan, but not seeking to have a claim for such item or service submitted to such plan or coverage. These individuals are often referred to as self-pay individuals and as such, this IFC

includes the term self-pay when discussing uninsured individuals. Uninsured individuals also include individuals who are enrolled in short-term, limited-duration insurance and not also enrolled in other private or public health plans.

Good Faith Estimates

The NSA requires health care providers and health care to provide a good faith estimate of expected charges to an uninsured (or self-pay) individual who schedules an item or service, and to an individual who has not yet scheduled an item or service, but requests a good faith estimate. The timelines for providing the good faith estimates are as follows:

- When an uninsured or self-pay individual schedules a service at least 3 business days before the date of service, the good faith estimate must be provided no later than 1 business day after the service is scheduled.
- If the service is scheduled at least 10 business days before the date of service or if the uninsured or self-pay individual requests a good faith estimate, the information must be provided no later than 3 days after the date of scheduling or the date of request.

The estimate of expected charges must reflect the anticipated billed charges, including any expected discounts or other relevant adjustments that the provider or facility expects to apply to a self-pay individual's billed charges. **HHS seeks comment on whether providers and facilities should be required to include both the list price and discounted price for an item or service when discounts apply. HHS also seeks comment on publicly available resources, methods, and potential standardized formatting or design that could facilitate communication of good faith estimate information in a clear and understandable manner.**

The convening provider or facility must inform uninsured (or self-pay) individuals that good faith estimates of expected charges are available to uninsured (or self-pay) individuals upon scheduling an item or service or upon request. Information regarding the availability of good faith estimates for uninsured (or self-pay) individuals must be provided in writing and orally. HHS will provide a model notice to providers.

The IFC requires that the convening provider or facility contact all applicable co-providers and co-facilities no later than 1 business day after the request for the good faith estimate is received or after the primary item or service is scheduled, and request submission of expected charges for items or services. The co-providers must provide the relevant information to the convening provider in a timely manner to be included in the good faith estimate.

The NSA also provides further protections for uninsured or self-pay individuals by requiring the Secretary of HHS to establish a process (referred to as patient-provider dispute resolution) that may be used by an uninsured or self-pay individual who is billed an amount "substantially in excess" of the charges outlined in the good faith estimate. In these cases, a certified dispute resolution entity would determine the amount to be paid to the provider or facility. HHS clarifies that if an individual requests a good faith estimate as a self-pay individual and then ultimately decides to submit a claim to the individual's plan or issuer for the billed charges, the individual is no longer considered a self-pay individual and would not be eligible to use the patient-provider dispute resolution process.

The good faith estimate must include the following:

- Patient name and date of birth;
- Description of the primary item or service in clear and understandable language;
- If scheduled, the date the item or service will be provided;
- Itemized list of items or services expected to be provided;
- Applicable diagnosis codes, expected service codes, and expected charges associated with each listed item or service;
- Name, NPI, and TIN of each provider or facility represented in the good faith estimate, and the state(s) and office or facility location(s) where the items or services are expected to be furnished by such provider or facility;
- A disclaimer that informs the uninsured (or self-pay) individual that there may be additional items or services the convening provider or convening facility recommends as part of the course of care that must be scheduled or requested separately and are not reflected in the good faith estimate;
- A disclaimer that informs the uninsured (or self-pay) individual that the information provided in the good faith estimate is only an estimate of items or services reasonably expected to be furnished at the time the good faith estimate is issued to the uninsured (or self-pay) individual and that actual items, services, or charges may differ from the good faith estimate;
- A disclaimer that informs the uninsured (or self-pay) individual of their right to initiate the patient-provider dispute resolution process if the actual billed charges are substantially in excess of the expected charges included in the good faith estimate; and
- A disclaimer that the good faith estimate is not a contract and does not require the uninsured (or self-pay) individual to obtain the items or services from any of the providers or facilities identified in the good faith estimate.

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

The IFC does not require the good faith estimate to include charges for unanticipated items or services that are not reasonably expected and that could occur due to unforeseen events.

HHS seeks comment on options for displaying and methods for standardizing the formatting for the itemized lists of items or services, and the required disclaimers. HHS also seeks comment regarding the potential benefits and challenges of using a standardized form that could serve as a base for good faith estimates issued to uninsured or self-pay individuals. HHS also seeks comment regarding whether the notice should be required to include additional information to explain concepts such as itemized lists of items or services, content within the required disclaimers, or other information included within the good faith estimate. HHS is also interested in information regarding publicly available methods for displaying required information in good faith estimates in a clear and understandable manner.

Required Methods for Providing Good Faith Estimates for Uninsured or Self-Pay Individuals

The IFC states that the good faith estimate must be provided in written form either on paper or electronically. Electronic estimates may be provided through the provider's patient portal or e-mail as preferred by the patient. The individual must be able to save and print the good faith estimate and it must be written using "clear and understandable language".

With the goal of reducing disparities in health care and coverage, HHS intends to analyze data related to individuals' use of the patient-provider dispute resolution process and the appeals process, to understand where barriers to coverage or accessible information persist. HHS is seeking comment on how to use data related to these two processes to understand, analyze, and address continued disparities.

HHS is seeking comment on how the required methods for providing a good faith estimate to uninsured (or self-pay) individuals may affect small or rural providers or facilities.

The IFC states that a good faith estimate issued to an uninsured (or self-pay) individual is considered part of the patient's medical record and must be maintained in the same manner as a patient's medical record, and that convening providers and facilities must provide a copy of any previously issued good faith estimate furnished within the last 6 years to an uninsured (or self-pay) individual upon the request of the uninsured (or self-pay) individual.

With regard to state laws on good faith estimates, the IFC states that the rules established in this IFC are to be considered minimum standards for good faith estimates. Providers or facilities that issue good faith estimates under state processes that do not meet the minimum requirements under this IFC fail to comply with the requirements.

Patient-Provider Dispute Resolution

An uninsured (or self-pay) individual who received a good faith estimate of the expected charges for an item or service may seek a determination from a selected dispute resolution (SDR) entity for the amount to be paid by the uninsured (or self-pay) individual to the provider or facility for such item or service. Uninsured (or self-pay) individuals are eligible for the patient-provider dispute resolution process after being furnished an item or service for which they received a good faith estimate if the individual is billed, by the provider or facility, charges that are "substantially in excess" of the good faith estimate.

The IFC defines "substantially in excess" as an amount that is at least $400 more than the total amount of expected charges for the provider or facility listed on the good faith estimate. HHS considered establishing a definition for "substantially in excess" to mean that the total billed charges are greater than the total expected charges in the good faith estimate by a percentage of the total expected charges in the good faith estimate. However, using a percentage would cause the dollar thresholds to vary significantly depending on the size of the charges. The $400 threshold was the least complex method considered by HHS.

HHS seeks comment on the definition for "substantially in excess," including whether the $400 amount should be set higher or lower, whether there is any other specific dollar value

that would be more appropriate, or whether a different method for determining "substantially in excess" should be considered.

HHS believes that Congress intended to create a process that allows uninsured (or self-pay) individuals to dispute the final billed charges, if such charges are substantially in excess of the expected charges in the good faith estimate; and therefore any item or service that was not included in the good faith estimate, yet resulted in total billed charges substantially in excess of the total expected charges in the good faith estimate, should be eligible for patient-provider dispute resolution.

HHS is concerned that a provider or facility may increase the good faith estimate amount specifically to circumvent the ability of the uninsured (or self-pay) individual to access the patient-provider dispute resolution process, resulting in uninsured (or self-pay) individuals being charged higher prices and as a result the uninsured (or self-pay) individual foregoing needed care due to concerns over the potential costs. **HHS seeks comment on what resources are available to assist individuals in determining the reasonableness of the good faith estimates they receive, particularly those who are uninsured (or self-pay) and with low health literacy. In addition, HHS seeks comment on how to raise awareness of such resources.**

HHS seeks comment from underserved and racial/ethnic minority communities on additional barriers individuals from these communities may face in understanding and exercising their rights related to these topics, and how to address them.

Patients must submit a notice to initiate the patient-provider dispute resolution process within 120 calendar days of receiving the initial bill for the item or service that is substantially in excess of the expected charges in the good faith estimate. The initiation notice may be submitted through the Federal IDR portal, electronically, or on paper and must include the following information:

- Information sufficient to identify the items or services under dispute, including the date of service or date the item was provided and a description of the item or service;
- A copy of the bill for the items and services under dispute;
- A copy of the good faith estimate for the items and services under dispute;
- The contact information of the parties involved, including name, email address, phone number and mailing address;
- The state where the items or services in dispute were furnished; and
- The uninsured (or self-pay) individual's communication preference.

Once the initiation notice has been received, HHS will select an SDR entity and the SDR entity will provide notice to the uninsured (or self-pay) individual and the provider or facility through the Federal IDR portal, or electronic or paper mail, that a patient-provider dispute resolution initiation request has been received and is under review. Providers are not permitted to move the bills for the disputed item or service into collections or threaten to do so while the dispute resolution process is pending. If the bill was already sent to collections prior to initiation of the dispute resolution process, collection efforts must cease until the dispute has been settled.

Providers must provide the following information to the SDR entity no later than 10 business days after notification of initiation of the patient-provider dispute resolution process:

- A copy of the good faith estimate provided to the uninsured (or self-pay) individual for the items or services under dispute;
- A copy of the billed charges provided to the uninsured (or self-pay) individual for items or services under dispute; and
- Documentation demonstrating that the difference between the billed charges and the expected charges in the good faith estimate reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided.

The SDR entity must render its decision on the amount to be paid by the uninsured (or self-pay) individual to the provider no later than 30 business days after receipt of the information from the provider.

The IFC 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 between the total billed charges and the good faith estimate. Such justification may be a demonstration that the difference between the billed charges and the expected charges in the good faith estimate for the item or service reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided. Information is considered "credible" if upon critical analysis the information is worthy of belief and consists of trustworthy information.

If the SDR entity determines that the provider or facility has provided credible information that the difference between the billed charge and the expected charge for the item or service in the good faith estimate reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, the SDR entity must select as the amount to be paid by the uninsured (or self-pay) individual to be the lesser of: (1) the billed charge; or (2) the median payment amount for the same or similar service in the geographic area using the QPA calculation methodology.

HHS seeks comment on ways to reduce the incentives for providers and facilities to over include items or services on the good faith estimate, and the circumstances, if any, in which requiring the SDR entity to set a payment amount below the expected charges in the good faith estimate would be appropriate. HHS also seeks comment on the use of the median amount for the same or similar service in the geographic area or whether a different methodology should also be considered.

The IFC states that HHS will pay dispute resolution costs by directly contracting with SDR entities. The patient pays an administrative fee of no more than $25 when initiating the process. The prevailing party in the dispute resolution process is ultimately responsible for the administrative fee. If the patient is the prevailing party, the amount of the administrative fee will be deducted from the amount owed to the provider.

Deferral to State Patient-Provider Dispute Resolution Processes
The IFC states that when a state law is in effect that provides a process for resolving disputes between an uninsured (or self-pay) individual and a provider or facility that HHS believes meets or exceeds the consumer protections contained in this IFC, the state process should continue to apply.

HHS will communicate with the state and determine whether a state law provides for such a dispute resolution process, and ensure that such process meets or exceeds certain minimum Federal requirements.

Minimum standards for the state process include the following:

- The process must be binding, unless the provider or facility offers for the uninsured (or self-pay) individual to pay lower amount than the determination amount.
- The process must take into consideration a good faith estimate, that meets the minimum standards established in this IFC, provided by the provider or facility to the uninsured (or self-pay) individual
- The process must have a fee to participate in the patient-provider dispute resolution process that is equal to or lower than the Federal administrative fee.
- The process must have in place conflict-of-interest standards that at a minimum meet the requirements set forth in this IFC.

Questions on this IFC should be directed to Kathryn Keysor, ACR Senior Director, Economic Policy at kkeysor@acr.org.