

Regulation Summary

No Surprises Act Interim Final Rule Part 2

Background

On September 30, 2021, the Departments of Health and Human Services (HHS), Treasury, and Labor (the Departments) and the Office of Personnel Management (OPM) issued an [interim final rule \(IFR\)](#) implementing part of the *No Surprises Act*. The *No Surprises Act*, which was included in the Consolidated Appropriations Act that passed in December 2021, bans balance billing for out-of-network (OON) services starting January 1, 2022, and establishes a back-stop independent dispute resolution (IDR) process to ensure that clinicians and facilities are paid appropriately for the OON services they deliver.

For [the last two years](#), ACEP has advocated on behalf of you as emergency physicians and your patients to ensure that any legislation that would address surprise medical billing would truly keep patients out of the middle of billing disputes and include a fair payment mechanism that would hold health plans accountable and ensure adequate reimbursement for OON services. Given how damaging initial Congressional proposals would have been for emergency physicians, the final approach that passed under the *No Surprises Act* represented a mostly reasonable solution to this issue.

Unfortunately, as described in the “[ACEP Perspective on the Rule](#)” section below, *ACEP has serious concerns about the IFR* and its drastic departure from Congressional intent in the No Surprises Act legislation that this regulation is intended to implement.

Overall, this summary provides the following—note that where “provider” is referenced, it could pertain to either the billing physician or group, or the facility:

- [ACEP Perspective on the Rule](#)
- [Interim Final Rule vs. Proposed Rule](#)
- [Background Discussion of the IFR](#)
- [Open Negotiation Period](#)
- [Federal Independent Dispute Resolution \(IDR\) Process](#)
 - [Batching](#)
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- [External Review](#)
- [Protections for the Uninsured](#)
- [Rationale for the Rule](#)
- [Cost Estimates of IDR Process](#)

This is the second IFR that the Departments have released implementing the law. The [first IFR](#) was issued on July 1, 2021. ACEP and the Emergency Department Practice Management Association (EDPMA) submitted a [comprehensive response](#) to that rule on August 31. Comments on this second IFR are due 60 days after the rule is officially published in the Federal Register. Comments will likely be due around December 6, 2021.

ACEP Perspective on the Rule

ACEP is *extremely concerned* with how much weight this rule has now given to the qualified payment amount (QPA) in the IDR process. The QPA is the median contracted rate for a given service in the same insurance market in a specific geographic area. It is used for two purposes: to determine cost-sharing for patients for out-of-network services, and as one of the factors an IDR entity (i.e., the arbiter) can use to choose between the offer submitted by a health plan and the offer submitted by a provider. Since the QPA sets the cost-sharing amount for patients, the Departments established a

methodology for calculating QPAs in the first IFR that will set artificially low amounts—which will not reflect market rates. Thus, we specifically requested in [our comments on the first IFR](#) that the Departments avoid making the QPA the primary consideration of arbitration during the IDR process. *We are extremely disappointed that the Departments decided to make the QPA the presumptive factor.*

ACEP and many others worked hard in Congress to ensure a final bill with a robust IDR process, and what the rule has put forth is very much the opposite--as written, it will be very difficult for the arbiter to make a determination that strays from the QPA, potentially setting a de facto benchmark of the median in-network for out of network care. The [justification](#) provided by the Departments in the rule for going this route is particularly disappointing and is far outside the bounds of Congressional intent in the *No Surprises Act*. This rationale includes assertions that are misleading and accusatory in tone. *In all, we believe that this approach will lead to narrower provider networks and lower reimbursement rates-- which will eventually significantly impact access to care. It will also cause many small emergency physician groups to go out of business, resulting in more provider consolidation.*

Further, the Departments do [NOT fairly and accurate describe the root cause of surprise medical billing](#), which we believe directly leads them to implement a policy that benefits health plans at the expense of health care providers.

ACEP also flagged the impact this will have on emergency care and [small groups in particular to the NY Times](#) and issued [this statement](#) opposing the rule.

Interim Final Rule vs. Proposed Rule

- Under traditional rulemaking, federal agencies release a proposed rule and then a final rule after a 30- or 60-day public comment period. However, this rule is an “interim final rule” with comment period. Although the Departments must eventually issue a final rule based on public comments, the policies included in this rule are considered final (and not just proposed) in the interim. Note that IFRs can sometimes be in place for years before a true final rule is ever released.
- The Departments explain that they are issuing an interim final rule instead of a proposed rule to allow enough time before January 1, 2022 for all stakeholders—health plans, patients, and providers—to understand and implement the new requirements.

Background Discussion of the IFR

- The Departments include a background discussion of the *No Surprises Act* and the first IFR that was released on July 1.
- The Departments are not implementing a provision from the law at this time that would require a provider to provide a good faith estimate of expected charges for scheduled services to a patient’s health plan or issuer to inform the advanced explanation of benefits. However, the Departments will still enforce the requirement that providers and facilities, upon request, provide a good faith estimate to uninsured individuals. This requirement is described in detail in the rule.
- Definitions: The IFR includes numerous definitions related to the IDR process, some of which are below.
 - [Batched items and services](#): 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.
 - [Certified IDR entity](#): an entity responsible for conducting determinations under the IDR process and that has been certified by the Departments. Separately, “IDR entity” means an entity that may apply or has applied for certification to conduct determinations.
 - [Conflict of interest](#): a certified IDR entity has a material relationship with a party (a provider or health plan) that impacts the ability of a certified IDR entity to make an unbiased and impartial payment determination. Under specific conflict-of-interest standards, a certified IDR entity cannot be a provider or facility, or a health plan or issuer (or a subsidiary of one).
 - The Departments define certain terms related to confidentiality, information security, and privacy requirements that apply to an IDR entity seeking certification.
 - Certified IDR entities must maintain the confidentiality of individually identifiable health information (IIHI) obtained while making payment determinations and engaging in other activities related to the Federal IDR process. The rule also discusses the potential for breaches to the IIHI.

- Days: *The No Surprises Act* includes numerous timetables, and in most cases, the rule defines days as business days, which excludes weekends and holidays.

Open Negotiation Period

- With respect to services subject to the federal surprise billing protections (and not to a specified state law or all-payer model), when a dispute arises over out-of-network reimbursement, a provider or health plan may engage in open negotiations to determine the total out-of-network rate. If the parties fail to reach an agreement through open negotiation, they may initiate the Federal IDR process.
 - The open negotiation period may be initiated via written notice of intent to negotiate by either party during the 30-business-day period beginning on the day the provider receives either an initial payment or a notice of denial of payment for an item or service.
 - The 30-business-day open negotiation period then follows, beginning on the day on which the open negotiation notice was first sent by a party.
 - Negotiation during the open negotiation period will occur without the involvement of the Departments or a certified IDR entity.
- The Departments caution that if the open negotiation notice is not properly provided to the other party (and no reasonable measures have been taken to ensure actual notice has been provided), the Departments may determine that the 30-business-day open negotiation period has not begun. In such case, any subsequent payment determination from a certified IDR entity may be unenforceable due to the failure of the party sending the open negotiation notice to meet the open negotiation requirement of these interim final rules.
 - To facilitate communication between parties and compliance with this notice requirement, the Departments are concurrently issuing a standard notice that the parties must use to satisfy the open negotiation notice requirement.
 - 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.

Federal Independent Dispute Resolution (IDR) Process

- ***Initiating IDR process:***
 - If the parties have not reached an agreed-upon amount for the out-of-network rate by the last day of the open negotiation period, either party may initiate the Federal IDR process during the 4-business-day period that begins on the 31st business day after the start of the open negotiation period.
 - To initiate IDR, the initiating party must submit a notice to the other party and to the Departments (Notice of IDR Initiation) through the Federal IDR portal.
 - The Notice of IDR Initiation must include specific information about the IDR items or services and the QPA, as well as contact information of the initiating party (the first IFR requires health plans to provide the QPA to the provider along with each initial payment—so providers have this information if they are the initiating party).
- ***Selection of Certified IDR Entity***
 - Health plans or providers that are parties 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.
 - If both parties agree on and select a certified IDR entity, the initiating party must notify the Departments no later than 4 business days after the date of initiation of the Federal IDR process through the Federal IDR portal.
 - If they fail to agree upon a certified IDR entity within the specified timeframe, the initiating party must still provide notification as such through the Federal IDR portal. The Departments will then make a random selection not later than 6 business days after the date of initiation of the Federal IDR process and will notify the parties of the selection.
 - The Departments will make available on the Federal IDR portal a list of certified IDR entities from which parties to the Federal IDR process may select, including basic information 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.
- Under the IFR, the selected certified IDR entity must not have a conflict of interest with either of the parties in question and must meet certain requirements related to dispute resolution.
 - If the certified IDR entity is unable to attest that it meets these requirements for this particular IDR request, the certified IDR entity must notify the Departments through the Federal IDR portal within 3 business days, after which the Departments will notify the parties.
 - Upon notification, the parties will have 3 business days to select another certified IDR entity.
- ***Authority to Continue Negotiation***
 - In instances in which the parties come to an agreement on a payment amount after the Federal IDR process is initiated but prior to a determination by a certified IDR entity, the agreed-upon amount will be treated as the out-of-network rate and will be treated as resolving the dispute.
 - The initiating party must notify the Departments and the certified IDR entity (if selected) by as soon as possible but no later than 3 business days after the date of the agreement.
 - The plan or issuer must pay the balance of the total plan or coverage amount of the agreed-upon out-of-network rate (with any initial payment made counted towards the total plan or coverage payment) to the provider not later than 30 business days after the agreement is reached.
 - Each party must pay half of the certified IDR entity fee (the fee is described in [more detail below](#)).
- ***Batching***
 - Multiple claims for qualified IDR items and services may be submitted and considered jointly by a certified IDR entity (batched items and services) as one payment determination only if certain conditions are met. The items and services must be:
 - Billed by the same provider or group of providers (defined as national Provider Identifier (NPI) or Taxpayer Identification Number (TIN).)
 - Paid for by the same group health plan or health insurance issuer.
 - The same or similar items or services (defined as those items and services that are billed under the same service code, or a comparable code under a different procedural code system).
 - Furnished within the same 30-business-day period.
 - **Exception: There is an exception for the 90-day “cooling off period.” The Departments are allowing all items and services delivered during this 90-calendar-day period to be included in the same batch for the IDR process.**
 - All bundled payments (single payment for multiple services an individual received during an episode of care) are permitted to be submitted and considered as part of one payment determination by a certified IDR entity.
 - If certain services have different QPAs, 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.
 - The Departments seek comment on all aspects of their approach to batching.
- ***Payment Determination***
 - *Submission of Offers*
 - Both the plan and the provider must submit their offer to the IDR entity not later than 10 business days after the selection of the certified IDR entity,
 - The offer must be expressed as both a dollar amount and the corresponding percentage of the QPA, to facilitate the certified IDR entity reporting the offer as a percentage of the QPA to the Departments.
 - Where batched items and services have different QPAs, the parties should provide these different QPAs and may provide different offers for these batched items and services.
 - Providers and facilities must provide certain information to the certified IDR entity relating to the offer:

- the size of their practices and facilities at the time the information is submitted. This will enable certified IDR entities to report on the size of the provider practices and facilities.
 - practice specialty or type.
 - Similarly, plans and issuers must provide:
 - The coverage area of the plan or issuer.
 - The relevant geographic region for purposes of the QPA.
 - For group health plans, whether they are fully-insured, or partially or fully self-insured.
 - Parties to the Federal IDR process must also submit any other information requested by the certified IDR entity relating to the offer.
- *Selection of Offer*
- Not later than 30 business days after the selection of the certified IDR entity, the entity must select one of the offers submitted by the plan and the provider to be the out-of-network rate for the qualified IDR item or service.
 - The amount by which this out-of-network rate exceeds the cost-sharing amount for the qualified IDR item or service will represent the total payment (with any initial payment made counted towards the total payment).
 - **In selecting the offer, the certified IDR entity must presume that the QPA is an appropriate payment amount and select the offer closest to it,** unless credible information submitted by either of the parties clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate, based on [additional circumstances](#).
 - Information is defined as credible if upon critical analysis the information “is worthy of belief and is trustworthy.”
 - A material difference exists where there is substantial likelihood that a reasonable person with the training and qualifications of a certified IDR entity making a payment determination would consider the information important in determining the out of network rate and view the information as showing that the QPA is not the appropriate out-of-network rate under such additional circumstances.
 - If the certified IDR entity does determine that credible information about additional circumstances clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate, the certified IDR entity must select the offer that the certified IDR entity determines best represents the appropriate out-of-network rate for the qualified IDR items or services, which could be either party’s offer.
 - WHY IS THE QPA THE PRESUMPTIVE FACTOR?
 - The Departments state that they believe that the best interpretation of the *No Surprises Act* is that when selecting an offer, the certified IDR entity must look first to the QPA, as it represents a reasonable market-based payment for relevant items and services, and then to other considerations.
 - This presumption that the QPA is the appropriate out-of-network rate can be rebutted by presentation of credible information about additional circumstances. This additional information must clearly demonstrate that the QPA is materially different from the appropriate out-of-network rate.
 - The Departments note that the statutory text in the *No Surprise Act* lists the QPA as the first factor that the certified IDR entity must consider in determining which offer to select.
 - The additional circumstances that the certified IDR entity must consider if relevant and credible information is provided are [described below](#). The certified IDR entity’s consideration of additional circumstances is subject to a prohibition on considering certain factors (i.e., billed charges).
 - Additionally, the statute sets out detailed rules for calculating the QPA, suggesting that an accurate and clear calculation of the QPA is integral to the application of consumer cost-sharing and to the certified IDR entity’s determination of the out-of-network rate.
 - Health plans must also provide specific information on how the QPA is calculated to providers, ensuring that they are aware of how this amount is calculated. They are also

subject to audit requirements that will be enforced by the Departments to ensure that they follow these rules.

- Cost-sharing is based on the recognized amount—which is the QPA for services eligible for the Federal IDR process, indicating that the QPA is a reasonable out-of-network rate.
- The Departments are also required to report how payment determinations compare to the corresponding QPA, reflecting that the QPA is a benchmark for determining the appropriate out-of-network rate.
- The Departments are also of the view that policy considerations support the approach they have taken under the IFR regarding which offer a certified IDR entity must select.
 - Generally, the QPA should reflect standard market rates arrived at through typical contract negotiations and should therefore be a reasonable out-of-network rate under most circumstances.
 - The QPA is generally based on the median of contracted rates, and these contracted rates are established through negotiations between providers and facilities and plans and issuers
- The Departments believe that 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*.
 - It will help limit the indirect impact on participants, beneficiaries, and enrollees that would occur from higher out-of-network rates if health plans were to pass higher costs on to individuals in the form of increases in premiums.
 - It will also help promote efficiency and predictability in the Federal IDR process and will increase the likelihood that a certified IDR entity will generally select the offer closest to the QPA.
- The Departments clarify that it is not the role of the certified IDR entity to determine whether the QPA has been calculated by the plan or issuer correctly, to make determinations of medical necessity, or review denials of coverage.
 - The certified IDR entity is responsible for considering only the information presented by the parties to determine whether either party has presented credible information regarding additional circumstances.
- The IFR also creates a standardized process for IDR entities to consider **additional circumstances**:
 1. The level of training, experience, and quality and outcome measurement: Any credible information presented must clearly demonstrate that the QPA failed to take into account that the experience or level of training of a provider was necessary for providing the qualified IDR item or service to the patient, or that the experience or training made an impact on the care that was provided.
 2. Market share held by the provider or plan: The parties must show that the market share of either the provider or the plan in the geographic region in which the qualified IDR item or service was provided clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate for the qualified IDR item or service.
 3. Patient acuity or the complexity of the service: A certified IDR entity may also conclude that the QPA does not adequately account for patient acuity.
 - **Downcoding Example**: The Departments are aware that some plans and issuers review claims and alter the service code or modifier submitted by the provider to another service code or modifier that the plan determines to be more appropriate (i.e., downcoding). If a plan has altered the service code or modifier(s) for a submitted claim and applies a QPA that uses a different service code or modifier(s) than that submitted by the provider, the provider could submit credible information to the certified IDR entity demonstrating that the QPA applied by the health plan to the claim is based on a service code or modifier that did not properly encompass patient acuity, or the complexity of furnishing the qualified IDR item or service.

4. Teaching status, case mix, and scope of services of the nonparticipating facility: Parties must present evidence regarding these factors that clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate for the qualified IDR item or service. The Departments seek comment on ways to address any potentially abusive scenarios, including scenarios in which parties could potentially distort information, 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.
 5. Previous contractual relationships: Parties can submit creditable information about any demonstrations of good faith efforts (or lack thereof) made by the providers or facilities or the plan or issuer to enter into network agreements and contracted rates between the provider and the plan, during the previous 4 plan years that clearly demonstrate that the QPA is materially different from the appropriate out-of-network rate for the qualified IDR item or service.
 6. Other factors: Beyond these enumerated factors, the certified IDR entity must also generally consider additional information submitted by a party, provided the information is credible and relates to the offer submitted by either party.
 - Exceptions: As required in the statute, the certified IDR entity may NOT consider:
 - Usual and customary charges: This term, also known as usual, customary and reasonable charges, refers to the amount providers in a geographic area usually charge for the same or similar medical service
 - The amount that would have been billed to a health plan, or to a participant, beneficiary, or enrollee, by a provider if the services were not subject to a prohibition on balance billing.
 - Payment or reimbursement rates payable by a public payor, including Medicare, Medicaid, the Children’s Health Insurance Program (CHIP), and Tricare.
 - *Selection of Offer for Air Ambulances*
 - The rule describes the process for a certified IDR entity to select an offer in a dispute related to air ambulance services—which is essentially the same as the process for other providers.
- **Written Decision**
 - Once the certified IDR entity has made a determination, it must provide the underlying rationale for its determination in a written decision submitted to the parties and to the Departments.
 - **Effect of Determination**
 - The determination is binding upon all parties involved, in the absence of fraud or evidence of intentional misrepresentation of material facts to the certified IDR entity by any party regarding the claim.
 - 90-day cooling off period
 - When a certified IDR entity makes a determination, for the next 90 calendar days, the party that submitted the initial Notice of IDR Initiation may not submit a subsequent Notice of IDR Initiation involving the same other party for the same as or similar to original qualified IDR item or service.
 - For claims for the same or similar item or service for which the end of the open negotiation period occurs during the 90-calendar-day suspension period, after the end of the 90-calendar-day suspension period, either party may initiate the Federal IDR process for the items and services affected by the suspension.
 - For these items or services, the initiating party must submit the Notice of IDR Initiation within 30 business days following the end of the 90-calendar-day suspension period, as opposed to the standard 4-business-day period following the end of the open negotiation period. The 30-business-day period begins on the day after the last day of the 90-calendar-day period.

- The plan or issuer must make any additional payment, if applicable, of the amount of the offer selected by the certified IDR entity directly to the provider, not later than 30 calendar days after the determination by the certified IDR entity.
- **Costs of the IDR process**
 - There are two fees—described in separate [guidance](#): the certified IDR entity fee (which goes to the IDR entity), and the administrative fee (which goes to the Departments for running the IDR process.)
 - **Certified IDR Entity Fee (\$200 to \$500 in 2022):** At the time of submission of the offer by each party to a determination, the certified IDR entity fee must be paid to the certified IDR entity.
 - Each party will be able to view the certified IDR entity fees and administrative fees in the Federal IDR portal when engaging in the certified IDR entity selection process.
 - Each party is to pay the entire certified IDR entity fee at the time the parties provide their offer.
 - Certified IDR entities are required to hold these funds in a trust or escrow account until they make a determination of the out-of-network rate.
 - 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 and refund the IDR entity fee paid by the prevailing party within 30 business days of making the determination.
 - In the case of batched determinations, the certified IDR entity may make different payment determinations for each qualified IDR item or service under dispute (between \$268 and \$670).
 - The party with fewest determinations in its favor is considered the non-prevailing party and is responsible for paying the certified IDR entity fee.
 - In the event that each party prevails in an equal number of determinations, the certified IDR entity fee will be split evenly between the parties.
 - If the parties negotiate an out-of-network rate before the certified IDR entity makes a determination, the certified IDR entity is required to return half of each party’s payment for the certified IDR entity fee.
 - **Administrative Fee (set at \$50 in 2022):** The IFR requires each party to pay the administrative fee to the certified IDR entity at the time the certified IDR entity is selected, regardless of whether that certified IDR entity was selected by the parties or by the Departments. The administrative fee is non-refundable regardless of determination outcome.
- **Certification of IDR Entities**
 - For each initiation of IDR, the IDR entity must provide through the Federal IDR portal written documentation to the Departments that demonstrates the entity satisfies certain standards and procedures:
 - General information about their organization.
 - Proof that it possesses and can demonstrate sufficient arbitration and claims administration of health care services, managed care, billing, coding, medical, and legal expertise.
 - That it employs sufficient personnel to make determinations within the 30 business days allowed for determinations.
 - Current accreditation from a nationally recognized and relevant accreditation organization,
 - Process to ensure that no conflicts of interest exist between the parties and the personnel the certified IDR entity assigns to each dispute.
 - Confidentiality standards to protect sensitive information. These standards include provisions regarding privacy, security, and breach notification.
 - To demonstrate financial stability, 3 years of financial statements, or other documentation that demonstrates fiscal stability as directed by the Departments if 3 years of financial statements are unavailable.
 - As a condition of certification, a certified IDR entity must indicate to the Departments the fees it intends to charge for payment determinations, which are limited to a fixed fee amount for single determinations (including determinations for bundled arrangements) and a separate fixed fee amount for batched determinations.
 - The certified IDR entity can propose an alternative fee beyond the upper or lower bounds, but must receive the Departments’ written approval.

- A certified IDR entity must also have procedures in place to retain the certified IDR entity fees paid by both parties at the initiation of the Federal IDR process in a trust or escrow account.
- A certified IDR entities must also adhere to audit standards.
- ***Petition for Denial or Revocation of IDR Entity Certification***
 - An individual, provide, or plan 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 or has a proven conflict of interest.
 - The Departments will make public the list of IDR entities seeking certification, as well as the list of certified IDR entities, to help facilitate the petition process. Petitioners submitting a petition for denial of a certification will have 5 business days from the announcement that an IDR entity is seeking certification to submit the written petition.
 - The Departments lay out various circumstances where they would consider denying the application of an IDR entity and specific criteria for revoking the certification from a certified IDR entity before the end of their 5-year term. IDR entities can appeal these decisions.
- ***Reporting of Information Relating to the Federal IDR Process***
 - The Departments are required to make certain information related to the Federal IDR process available on a public website for each calendar quarter in 2022 and each calendar quarter in subsequent years.
 - To ensure the Departments have the information needed to satisfy this requirement, the IFR requires that, within 30 business days of the close of each month, each certified IDR entity must report certain data and information—including the size of the provider practices submitting IDR initiations, the number of IDR initiations for which a payment determination was made, and—for each case—the offers submitted by each party listed as a percentage of the QPA and which offer was selected.
 - *The certified IDR entity must also report the number of times the out-of-network rate determined exceeded the QPA.* Where the QPA differs within a group of batched items and services, the certified IDR entity also must include whether the out-of-network rate exceeded the applicable QPA.
 - The certified IDR entity must also report certain additional information on the parties involved.
 - The practice specialty or type of each provider involved in furnishing the qualified IDR items or services at issue with respect to the determination.
 - Each party’s name and address.
 - The number of business days taken between the selection of the certified IDR entity and the selection of the payment amount by the certified IDR entity for each determination issued in relation to a Notice of IDR Initiation submitted during the immediately preceding month.
 - The total amount of certified IDR entity fees paid to the certified IDR entity during the immediately preceding month.
- ***Extension of Time Periods for Extenuating Circumstances***
 - The time periods specified in the IFR can be extended in the case of extenuating circumstances at the Departments’ discretion. The Departments may extend time periods on a case-by-case basis if the extension is necessary to address delays due to matters beyond the control of the parties or for good cause. Such extension may be necessary if, for example, a natural disaster impedes efforts by plans, issuers, providers and facilities, and providers to comply with the requirements of the IFR.
- ***Applicability of the Rules Regarding the Federal IDR Process***
 - These rules are effective as of the date of the IFR’s publication in the Federal Register, so that the Departments can begin certifying IDR entities before the Federal IDR process becomes applicable on January 1, 2022.
 - These rules do not apply to short-term limited duration plans, HRAs or other account-based plans, or retiree-only plans.

External Review

- **Expansion of External Review:** The IFR expands 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*. The rule also adds examples of which types of adverse benefit determinations will be eligible for external review. Further, the IFR extends the external review requirement to grandfathered health plans.

Protections for the Uninsured

- **Good Faith Estimates for Uninsured (or Self-Pay) Individuals (ONLY APPLIES TO SCHEDULED CARE; DOES NOT APPLY TO EMERGENCY CARE):**
 - **Applicability:** The *No Surprises Act* requires health care providers and health care facilities, upon **scheduling** an item or service to be furnished to an individual or upon request of an individual, to inquire about such individual's health coverage status and to provide a notification of the good faith estimate of the expected charges for furnishing such item or service with the expected billing and diagnostic codes for any such item or service. In the case that the individual requesting a good faith estimate for an item or service or seeking to schedule an item or service to be furnished, is not enrolled in a certain type of plan or coverage or is not seeking to file a claim with such type of plan or coverage, providers and facilities are required to furnish the good faith estimate to the individual.
 - **Definitions**
 - **Good faith estimate:** a notification of expected charges for a scheduled or requested item or service, including items or services that are reasonably expected to be provided in conjunction with such scheduled or requested item or service, provided by a convening provider, convening facility, co-provider, or co-facility.
 - **Convening provider or convening facility:** the provider or facility who receives the initial request for a good faith estimate from an uninsured (or self-pay) individual and who is or, in the case of a request, would be responsible for scheduling the primary item or service. convening providers and facilities as well as co-providers and co-facilities are responsible for providing good faith estimates to uninsured (or self-pay) individuals.
 - **Co-provider or co-facility:** 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.
 - **Uninsured (or self-pay) individual:** 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
 - HHS understands, and believes that it is appropriate, that consumers may request a good faith estimate without actually scheduling items or services to compare costs and make a decision about from which provider they will seek care, or whether they will submit a claim to insurance or self-pay. These individuals would be considered self-pay for purposes of the requirement on the provider to provide a good faith estimate.
 - **Requirements for Providers and Facilities:** To the extent possible, an uninsured (or self-pay) individual is entitled to receive a clear and understandable document that informs the uninsured (or self-pay) individual of the expected costs associated with the care that they are considering or are scheduled to receive. In order to do so, the expected charges that inform the good faith estimate should be provided by all providers and facilities who are reasonably expected to furnish the items or services that would be billed to the uninsured (or self-pay) individual.
 - **Requirements for Convening Providers**
 - A convening provider is required to verify whether an individual meets the definition of an uninsured (or self-pay) individual, to provide oral and written communication regarding the requirement to provide good faith estimates to uninsured (or self-pay) individuals upon scheduling an item or service or upon request, and to provide timely good faith estimates to uninsured (or self-pay) individuals.
 - HHS believes that conveying information about the availability of good faith estimates prior to or upon scheduling an item or service aligns with and is most relevant when

uninsured (or self-pay) individuals are considering whether to proceed with medical care while interacting with their providers or facilities.

- A convening provider must contact all 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. The co-provider or co-facility is responsible for providing timely information to the convening provider or convening facility—no later than 1 business day after they receive the request for a good faith estimate.
 - In the case of an individual who schedules an item or service to be furnished at least 3 business days before the date of the service, that the notification of the good faith estimate of expected charges must be provided no later than 1 business day after the date of such scheduling. If the service is scheduled 10 business days before the of the service, that the notification of the good faith estimate of expected charges must be provided no later than 3 business days after the date of such scheduling or such request.
 - HHS recognizes that circumstances may arise where the scope of information included in a good faith estimate changes. In such circumstances, the convening provider or convening facility must issue an uninsured (or self-pay) individual with a new good faith estimate no later than 1 business day before the item or service is scheduled to be furnished.
 - HHS expects that any replacement provider considering whether to furnish items or services will review the applicable good faith estimate and use that information to determine whether to furnish the applicable items or services.
 - HHS acknowledges that there are circumstances where recurring items or services are expected to be furnished to an uninsured (or self-pay) individual (for example, an individual may need multiple physical therapy visits that would occur outside of the period of care for a surgical procedure). The convening provider may issue a single good faith estimate for recurring primary items or services if certain requirements are met.
- ***Content of a Good Faith Estimate for an Uninsured (or Self-Pay) Individual:*** The IFR also sets out the content of good faith estimate, including information about the items and services, applicable diagnosis and service codes, and certain disclaimers.
 - Items or services included in the good faith estimate must be itemized (by each applicable service code), and clearly grouped and displayed as corresponding to the respective provider that is expected to furnish those items or services. For each provider represented in the good faith estimate, the total amount of expected charges must be included and displayed.
 - ***Required Methods for Providing Good Faith Estimates for Uninsured (or Self-Pay) Individuals:*** The IFR establishes required methods for providing good faith estimates to uninsured (or self-pay) individuals. Providers must comply with federal civil rights laws that prohibit discrimination—and must take reasonable steps to ensure meaningful access to individuals with limited English proficiency and individuals with disabilities, including provision of appropriate auxiliary aids and services.
 - ***Additional Compliance Provisions***
 - A good faith estimate issued to an uninsured (or self-pay) individual is considered part of the patient’s medical record. Convening providers and facilities must be able to provide a copy of any previously issued good faith estimate furnished within the last 6 years to an uninsured (or self-pay) individual upon the request of the uninsured (or self-pay) individual.
 - While HHS acknowledges that some states have existing state laws related to the furnishing of good faith estimates, HHS is of the view that uninsured (or self-pay) individuals should still have access to a good faith estimate that meets the minimum requirements established in this IFR.
 - There may be circumstances in which a provider, acting in good faith, makes an error or omission in a good faith estimate. This would not be a violation of the regulation provided that the provider corrects the information as soon as practicable. However, if the services are furnished before the error in the good faith estimate is addressed, the provider may be subject to patient-provider dispute resolution if the billed charges are substantially in excess of the good faith estimate.
 - ***Applicability of the Good Faith Estimate Requirements***
 - The effective date of this new requirement to offer good faith estimates of scheduled services is January 1, 2022.

- HHS recognizes that some providers may need to establish efficient and secure communication channels for transmission of good faith. HHS is seeking comment on any existing challenges related to secure transmission of good faith estimate information between providers and facilities.
 - HHS understands that it may take time for providers to develop systems and processes for receiving and providing the required information from co-providers and co-facilities. Therefore, for good faith estimates provided to uninsured (or self-pay) individuals from January 1, 2022 through December 31, 2022, HHS will NOT enforce the requirement that the good faith estimate provided to an uninsured (or self-pay) individual includes expected charges from co-providers or co-facilities.
- ***Patient-Provider Dispute Resolution (ONLY APPLIES TO SCHEDULED CARE; DOES NOT APPLY TO EMERGENCY CARE)***
 - *Scope:* The *No Surprises Act* requires HHS to establish a process called a patient-provider dispute resolution process.
 - The IFR includes specific definitions related to the patient-provider dispute resolution process; specifies the items and services eligible for the process; establishes requirements for what uninsured (or self-pay) individuals must provide to initiate the process; and specifies the information providers and facilities must provide to an SDR entity to inform payment determinations. The IFR also establishes requirements for SDR entities contracted to resolve the patient-provider dispute, including how SDR entities determine the payment amount, and certification standards that HHS will consider when contracting with SDR entities. The IFR also specifies the administrative fee associated with the patient-provider dispute resolution process and the minimum requirements for state patient-provider dispute resolution processes to operate in place of the Federal patient-provider dispute resolution process.
 - *Definitions*
 - Substantially in excess: With respect to the total billed charges by a provider, an amount that is at least \$400 more than the total amount of expected charges for the provider listed on the good faith estimate. HHS goes into extensive detail outlining the rationale for choosing that amount, as well as discusses alternatives it considered implementing.
 - *Eligibility for Patient-Provider Dispute Resolution*
 - ***The patient-provider dispute process applies to uninsured (or self-pay) individuals who received a good faith estimate of the expected charges for scheduled or requested items or services from a provider, and who after being furnished such item or service is billed by such provider charges substantially in excess of such estimate. An uninsured individual would trigger the process.***
 - An item or service is eligible for patient-provider dispute resolution based on the total billed charges from the provider, regardless of whether such items or services are included in a good faith estimate.
 - HHS is very concerned that a provider 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 also recognizes that uninsured (or self-pay) individuals in underserved and racial/ethnic minority communities, including individuals with vision, hearing, or language limitations, individuals with limited English proficiency, lesbian, gay, bisexual, transgender, and queer (LGBTQ+) individuals, and persons with health literacy needs, may face additional barriers to paying for high unexpected health care costs, understanding their rights related to good faith estimates, patient-provider dispute resolution, and how and when to initiate the dispute resolution process. HHS seeks comment from underserved and racial/ethnic minority communities on additional barriers individuals from these communities may face in understanding and exercising their rights related to these topics, and how to address them.
 - *Initiation of Patient-Provider Dispute Resolution*
 - The initiation notice must be submitted to the HHS Secretary and postmarked within 120 calendar days of receiving the initial bill containing charges for the item or service that is substantially in excess of the expected charges in the good faith estimate.

- The initiation notice must include: (1) information sufficient to identify the items or services under dispute, including the date of service or date the item was provided and a description of the item or service; (2) a copy of the bill for the items and services under dispute (the copy can be a photocopy or an electronic image so long as the document is readable); (3) a copy of the good faith estimate for the items and services under dispute (the copy can be a photocopy or an electronic image so long as the document is readable); (4) the contact information of the parties involved, including name, email address, phone number and mailing address; (5) the state where the items or services in dispute were furnished; and (6) the uninsured (or self-pay) individual’s communication preference, through the Federal IDR Portal, or electronic or paper mail.
- In addition to the required information, the uninsured (or self-pay) individual must submit with the initiation notice an administrative fee to the SDR entity. The amount of the administrative fee, as well as the manner in which it must be submitted, will be clarified in guidance by HHS (it is initially set at \$25).
- HHS expects to leverage the Federal IDR portal to facilitate the operation of the patient-provider dispute resolution process.
- Once the initiation notice has been received, HHS will select an SDR entity. After the SDR entity has been selected, the SDR entity will provide notice to the uninsured (or self-pay) individual and the provider through the Federal IDR portal that a patient-provider dispute resolution initiation request has been received and is under review, the SDR entity will also include information identifying the item or service under dispute, and the date the initiation notice was received.
 - The SDR entity will also notify the uninsured (or self-pay) individual, and the provider, that while the dispute resolution process is pending, the provider must not move bills for the disputed items or services into collection or threaten to do so. If the bill has already moved into collection, the provider should cease collection efforts until the dispute has been settled.
- The SDR entity will review the initiation notice submitted by the uninsured (or self-pay) individual to ensure that the disputed items or services meet the eligibility criteria for the patient-provider dispute resolution process and that the initiation notice contains all the required information. The SDR entity will notify the uninsured (or self-pay) individual of the outcome of the review including in cases where the initiation notice is determined to be incomplete or the item or service is determined ineligible for dispute resolution, in which case the uninsured (or self-pay) individual would be provided 21 calendar days to submit any missing information or provide supplemental information to demonstrate the item or service is eligible for the dispute resolution process.
- Once the SDR entity has determined that an item or service is eligible for dispute resolution, the SDR entity must provide notification of the determination to both parties and must request that the provider provide certain information ([described below](#)) within 10 business days.
- *Certification of Selected Dispute Resolution Entities*
 - HHS will compensate SDR entities directly for their services under a contract (and therefore parties will not be required to pay a separate SDR entity fee). HHS believes that 1 to 3 SDR entities will be sufficient in the first year to conduct the dispute resolution process. Unlike the process for certifying IDR entities, HHS intends to contract only with SDR entities that will be able to conduct patient-provider dispute resolution in all applicable states where the patient-provider dispute resolution process will apply. As such, SDR entities will need to submit information on their ability to operate nationwide through the contract process.
 - HHS outlines certain requirements around conflicts of interest and standards around confidentiality, including security, privacy, and breach notification requirements that apply to an IDR entity seeking certification—similar to certified IDR entities.
- *Selection of an SDR Entity for Patient-Provider Dispute Resolution*
 - Upon receiving a request to initiate patient-provider dispute resolution case from an uninsured (or self-pay) individual, HHS will select 1 of the contracted SDR entities to serve as the entity to conduct the dispute resolution process. Selection of an SDR entity that will resolve a particular dispute will occur in round robin fashion to ensure equal allocation of cases to SDR entities, unless conflicts of interest arise (in which case another SDR entity will be selected).

- *Payment Determination for Patient-Provider Dispute Resolution*
 - While the SDR entity payment determination is pending, HHS recognizes that the two parties to the patient-provider dispute resolution process (the uninsured (or self-pay) individual and the provider) may agree to resolve the dispute by settling on a payment amount. In the event that the parties agree to settle on a payment amount, the provider should notify the SDR entity as soon as possible, but no later than 3 business days after the date of the agreement. HHS also clarifies that payment of the billed charges by the uninsured (or self-pay) individual (does not demonstrate agreement by the uninsured (or self-pay) individual to settle at that amount or any other amount.
 - As part of the SDR determination process, the IFR requires that the provider must submit information to the SDR entity not later than 10 business days after the receipt of the notice from the SDR entity initiating the patient-provider dispute resolution process. This information must include:
 - 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.
 - 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 when the good faith estimate was provided.
 - HHS believes it is also necessary and appropriate to provide a means for a provider to submit documentation or an explanation to support the billed charges, such as information related to the patient's relevant medical history that is necessary to demonstrate that the item or service is medically necessary and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider when the good faith estimate was provided.
 - Not later than 30 business days after receipt of the information from the provider, the SDR entity must make a determination on the amount to be paid by such uninsured (or self-pay) individual.
- *Requirements for Determination*
 - The SDR entity should use the expected charges in the good faith estimate as the presumed appropriate amount and unless the provider provides credible information justifying the difference between the total billed charges and the good faith estimate. The provider must demonstrate 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. For this purpose, information is credible if upon critical analysis the information is worthy of belief and consists of trustworthy information.
 - If the SDR entity determines that the provider has provided credible information and the billed charge should have been greater than the good faith estimate, 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 that is reflected in an independent database-- or if the amount reflected in the independent database is less than the expected charge in the good faith estimate, the good faith estimate amount.
 - For new items or services not originally listed on the good faith estimate, if the SDR entity determines the provider did not provide credible information that demonstrates that the billed charge for the new item or service reflects the costs of a medically necessary item or service and is based on unforeseen circumstances, the SDR entity will determine a payment amount equal to \$0.
 - After making a determination for all items or services subject to patient-provider dispute resolution, the SDR entity must add together the amounts to be paid for all items and services. The SDR entity must reduce the final amount by an amount equal to the administrative fee amount paid by the individual to calculate the final payment determination amount to be paid by the uninsured (or self-pay) individual for the items or services subject to the SDR entity determination.
- *Effects of Determination*
 - Determinations made by a certified IDR entity are binding upon the parties involved, in the absence of a fraudulent claim or evidence of misrepresentation of facts presented to the IDR entity involved.

- *Costs of Patient-Provider Dispute Resolution Process*
 - HHS intends to assess an administrative fee on the non-prevailing party (providers, facilities, and uninsured (or self-pay) individuals) to the patient-provider dispute resolution process. Upon the SDR entity determination, if the uninsured (or self-pay) individual is the prevailing party, the SDR entity would apply a reduction, equal to the administrative fee amount paid by the individual, to the final determination amount to be paid by the individual for the items or services.
- *State laws*
 - The Departments will defer to states with their own laws of resolving disputes between an uninsured (or self-pay) individual and a provider that meets or exceeds the consumer protections.
- *Extension of Time Periods for Extenuating Circumstances*
 - These timelines may be extended in the case of extenuating circumstances at HHS' discretion on a case-by-case basis if the extension is necessary to address delays due to matters beyond the control of the parties or for good cause. Such extension may be necessary if, for example, a natural disaster impedes efforts by individuals, providers, and facilities to comply with the terms of the IFR.

Rationale for Rule

- The IFR states that surprise billing is caused by certain providers for which consumers typically do not shop. Since volume does not depend on whether specific providers are in-network, there is less of an incentive for these providers to engage in negotiations with health plans.
- The Departments specifically call out the role of emergency physicians and the Emergency Medical Treatment and Labor Act (EMTALA)—arguing that because of emergency physicians' legal obligation under EMTALA, and the inability of patients to make treatment decisions (including by selecting providers) in emergency settings, there are fewer incentives for emergency providers to contract with issuers.
- Finally, the Departments state that an additional factor contributing to the current environment is the increasing participation of private equity groups in the health care market through the acquisition of physician groups. The Departments seek comment on how private equity ownership structures may be affected by the Federal IDR process.

Cost Estimates of IDR Process

- The Departments do not have data on how many claims will be submitted to the Federal IDR process. For the purposes of the estimating the impact of the rule, the Departments rely on the experience of New York State.
 - In 2018, New York State had 1,014 IDR decisions. In that year, the state of New York accounted for 5.8 percent of the private insurance market.
 - For purposes of their analysis, the Departments assume that, going forward, New York State will continue to see 1,000 IDR cases each year and that the number of Federal IDR cases will be proportional to that in New York State.
 - Accordingly, the Departments estimate that there will be approximately 17,000 claims that are submitted to the Federal IDR process each year.
- The Departments estimate that 140,270 physicians, on average, bill on an out-of-network basis and will be affected by the IFR. The Departments estimate that the cost associated with the Federal IDR process for providers and facilities will be \$38.4 million. This includes an estimated cost of \$21.1 million for paperwork requirements.
- The IFR is expected to have an effect on premiums, although there is uncertainty around how premiums will ultimately be affected.
 - The Congressional Budget Office estimated the provisions in the No Surprises Act are likely to reduce premiums by 0.5 percent to 1 percent in most years.
 - In comparison, the Office of the Actuary (OACT) within CMS estimated the IFR is likely to increase premiums by 0.00 percent to 0.35 percent.
- The Departments argue that in states where arbitrators are directed to base their determinations on billed charges, there have been increased health care costs as a result of the out-of-network payment standard being higher than that in-network rate.
 - However, if certified IDR entities base their determinations on median in-network rates, which are typically lower than billed charges, the IDR process could place downward pressure on health care costs and premiums.

- If certified IDR entities choose amounts that are above median in-network rates, this could result in a potential increase in costs and premium. The Departments base this last conclusion on an [analysis](#) by the USC-Brookings Schaeffer Initiative for Health Policy.
- The Departments state that the IFR may affect provider payments and revenue, noting it is possible that the payments collected by some providers and facilities will be lower than they would have been otherwise.
 - The IFR set standards requiring certified IDR entities to consider the QPA (typically the median in-network rate) when making payment determinations
 - The Departments expect this approach to have a downward impact on health care costs, potentially resulting in transfers from providers and facilities to individuals with health coverage.