Holland & Knight

Summary of Second Interim Final Rule Implementing the *No Surprises Act*

Holland & Knight Alert

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Highlights:

On Sept. 30, the Departments of Health and Human Services (HHS) and Labor (DOL) jointly released a second interim final rule (IFR) with comment period implementing provisions of the No Surprises Act (NSA). This IFR is the second in a series of three.

The policies in this rule are generally effective **Jan. 1, 2022**. Comments are due **Dec. 6, 2021**.

This IFR largely deals with:

1. The provider-payer independent dispute resolution (IDR) process
2. "Good faith" cost estimates for uninsured and self-pay individuals
3. The patient-provider dispute resolution process (for when costs exceed these estimates)

Summary of Major Provisions:

- The certified IDR entity must begin with the presumption that the QPA is the appropriate out-of-network rate and select the offer closest to the QPA unless credible information is submitted by either party that clearly demonstrates that the QPA is "materially different" from the appropriate out-of-network rate.
- The Patient-Provider Dispute Resolution Process may be initiated by an uninsured or self-pay individual if the total billed charge is "substantially in excess" of the expected charges listed in the good faith estimate, which is defined in this IFR as a difference of at least $400.
- For 2022, items or services provided by a co-provider or co-facility will not be eligible for the patient-provider dispute resolution process and HHS will exercise enforcement discretion.
- Under this process, even if the SDR entity ultimately determines that the difference between the billed and expected reflects the costs of medically necessary items or services that could not have reasonably been anticipated, the SDR entity must select the lesser of: (1) the billed charge; or (2) the median payment amount for the same or similar service in the geographic area as reflected in an independent database (or the good faith estimate amount, if higher).
- A portal available at https://www.nsa-idr.cms.gov will administer the federal IDR process and patient-provider dispute resolution process.

For more information:

- Holland & Knight's analysis of Part I of the No Surprises Act Interim Final Rule
- CMS Press release
- CMS Fact sheet
- New CMS Surprise Billing Resource Webpage

Detailed Provisions:

I. Federal Independent Dispute Resolution (IDR) Process

Patient-Provider Dispute Resolution Process Upon receipt of initial payment or notice of denial of payment, disputing parties have 30 business days to initiate, in writing (electronic is acceptable) an "open negotiation" period to negotiate a payment rate. A full 30 calendar days from the initial date of notice day clock must run out before either party can initiate the federal IDR process.

Initiating the Federal IDR Process The IDR process applies to plans and services for which balance billing was prohibited in the July Part I IFR. Within four business days of the 30-day patient-provider dispute resolution process ending, either party may initiate the federal IDR process by sending a notice to the other party and federal government through the Federal IDR portal. The notice must contain certain information outlined on page 55991 of the IFR including a preferred certified IDR entity candidate. The receiving party has three business days to respond. If they disagree with the initiating party's selection of a certified IDR entity, they must propose their own.

Selecting a Certified IDR Entity If the two parties agree, they must inform the Departments of their selection including the name, entity number, and an attestation from both parties that neither has a conflict of interest. If the parties cannot agree on an IDR entity within three business days, they must notify the Departments the following day, and the Departments will select one at random (within six business days). The chosen certified IDR entity must attest through the IDR portal within three business days that they meet all requirements, including no conflicts of interest with either party. In the event they are ineligible for any reason, the selection process starts over.

Submission of Required Information Within 10 business days of a certified IDR entity being selected, both parties must submit: 1) their respective offers, 2) relevant supporting information and documentation, 3) the IDR process administrative fee, and 4) the certified IDR entity fee. Administrative fees are non-refundable, including in cases where a resolution is reached by the parties before the IDR entity renders a decision or where the IDR process is not applicable due to a preempting state law or applicable All-Payer Model Agreement. For 2022, the administrative fee is $50. Certified IDR entity fees must be within a preselected range to be determined annually. Parties must express payment offers as a dollar amount and as a percentage of the QPA. Providers and facilities must provide the number of employees and specialty or facility type. Plans/issuers must provide the relevant geographic region, whether they are fully, partially, or self-insured (for group plans), and (for FEHB carriers) if a particular item/service is relevant to the plan. Both parties must also provide additional information to the IDR entity upon request and may choose to provide supplemental, relevant information related (but not limited) to:

- Market dominance by either party
- Patient acuity or complexity of service (if not already reflected in QPA)
- Facility characteristics (e.g. teaching status, scope of services) critical to delivering item/service
- Risk-sharing or other incentive-based payments excluded from QPA per the July 2021 IFR
- Level of training, experience, and quality of medical personnel
- Good faith efforts (or lack thereof) to enter into in-network arrangements over the last four years
- (For air ambulance services) ambulance vehicle type, including the clinical capability level of the vehicle (excluding fixed or rotary wing as this is already reflected in separate coding)
- (For air ambulance services) population density of the point of pick-up (beyond MSA, non-MSA distinction already accounted for in QPA under July 2021 IFR Part I)

Ensuring the Federal IDR Process Applies IDR entities must first determine whether the federal IDR process applies (e.g. whether an All-Payer Model Agreement or state law applies). If it does not, they must notify the Departments and parties within three business days via the IDR portal.

Determining a Final Payment Amount The certified IDR entity must begin with the presumption that the QPA is the appropriate out-of-network rate and select the offer closest to the QPA unless credible information was submitted by either party that clearly demonstrates that the QPA is "materially different" from the appropriate out-of-network rate, including the factors listed above. Certified IDR entities are prohibited from considering usual and customary charges or rates of other plans or payers or beneficiaries, including public payers. Additionally, the IFR clarifies that it is not the IDR entity's role to determine whether the QPA was calculated correctly, make determinations of medical necessity, or review coverage denials. The certified IDR entity must render a written decision within 30 business days informing both parties of which offer was selected as the final payment amount along with the underlying rationale. This decision must be done through the Federal IDR portal in a form and manner to be specified in future guidance. This decision is binding, unless fraud or misrepresentation of material facts is involved.

Final Payments and Fees IDR entities are required to hold certified IDR entity fees in a trust or escrow account until the OON rate is determined and it is notified by the Departments that it may remit the funds. Any resulting balance between the parties must be paid within 30 calendar days. The patient copay will not change. Within 30 business days of the determination, the certified IDR entity must refund the prevailing party the certified IDR entity fee. The non-prevailing party will owe an additional fee. For 90 calendar days following the determination, the initiating party may not submit initiate a separate IDR process involving the same party and the same or similar services (though they may do so after this "cooling off" period). The certified IDR entity will remit the administrative fee to the Departments at a time and manner specified in future guidance.

Batched Items and Services To streamline, multiple claims for similar qualified IDR items and services may be submitted and considered jointly i.e. "batched" if the following conditions are met:

- They are billed by the same provider, group, or facility (i.e. the same NPI or TIN).
- Payment would be made by same plan/issuer.
- They involve the same or similar items/services based on the definition in the July 2021 IFR.
- Items/services were furnished within the same 30-business-day period.

Batched items and services may have different QPAs, such as when it involves the same service but two different types of plans. When this is the case, the parties should provide relevant information for each QPA, and the IDR entity will consider QPAs for each item or service separately. The IDR entity may make different payment determinations for each item or service. In these cases, the party with fewest determinations in its favor is considered the non-prevailing party and is responsible for paying the certified IDR entity fee. If equal, the fee will be split evenly between the parties.

Internal Resolutions After IDR Process Has Already Been Initiated Should the parties agree on an amount for a qualified IDR item or service after the Federal IDR process has been initiated but prior to a determination by a certified IDR entity, the dispute is considered resolved and the initiating party must notify the Departments and certified IDR entity through the Federal IDR portal within three business days indicating the agreed upon rate with signatures from both parties. Any resulting balance must be paid within 30 business days and each party must pay half of the certified IDR entity fee (i.e. half of the initial fee will be returned to each), unless the parties agree on an alternative allocation. Neither party can request additional payment from the beneficiary.

Requesting Extensions Parties may submit a Request for Extension through the Federal IDR portal. The request should include an explanation about the extenuating circumstances and why an extension is needed. Requests will be considered on a case-by-case basis based on whether matters are beyond the control of the parties and for good cause, such as natural disasters.

Certified IDR Entity Criteria To become certified IDR entities, applicants must provide written documentation demonstrating that they meet the eligibility criteria, which includes:

- Sufficient expertise and staffing to conduct determinations on a timely basis;
- Procedures to regularly check against conflicts of interest and address if one should arise;
- Accreditation by a nationally recognized and relevant accrediting body;
- Procedures to maintain confidentiality of individually identifiable health information (IIHI), including using secure electronic interfaces when transmitting IIHI electronically;
- Maintaining set fees and having procedures to retain and remit said fees;
- Fiscal integrity and stability and an ability to carry out all Federal IDR process requirements.
- Agreement to participate in all audit and oversight activities including data submission.

The Departments will indicate recommended documentation through future guidance.

IDR Entity Fees Annually, the Departments will select an acceptable range for IDR Entity fees, which generally range from $300–$600 per determination. The IDR entity may not charge a higher or lower fee unless it submits a written request with justification and the Departments approve.

IDR Entity Application and Selection Process The Departments will certify IDR entities on a rolling basis. Those interested in becoming certified by Jan. 1, 2022, should apply by Nov. 1, 2021. The Departments will post on the Federal IDR portal a list of entities seeking certification and those already certified along with contact information and website links. Members of the public, providers, facilities, plans, and issuers may petition for denial or revocation of certification of an IDR entity, to which entities will have 10 business days to respond. Selected entities will be provided a certified IDR entity number and will be certified for a period of five years. IDR entities must notify the Departments in writing of any ownership changes or acquisitions within three business days.

Oversight and Transparency Certified IDR entities must maintain records of relevant documentation associated with any Federal IDR process determination for six years and must make these records available to all participating parties and to state or Federal agencies upon request for oversight purposes, except when disclosure would violate state or Federal privacy laws and regulations. Breach notification standards will mirror those for HIPAA, including a risk assessment and breach notification required through the federal IDR portal (no later than 60 calendar days after discovery). Certified IDR entities may be selected for an audit at random or based on a stakeholder complaint, a pattern of non-compliance, and/or potentially fraudulent or unethical behavior. While an audit is being conducted, an IDR entity may work on previously assigned determinations, but may not accept new requests. Findings may result in revocation of certification. Decertified IDR entities who address deficiencies may reapply after 180 calendar days. This IFR also expands the scope of claims eligible for external review to include adverse benefit determinations related to compliance with the NSA.

Data Reporting Certified IDR entities must report required data about the IDR process within 30 business days of the close of each month. The Departments will use data that is already reported through the IDR portal to avoid duplicate reporting. More on the specific data elements can be found on pages 56008-56009 of the IFR and will be released in future guidance.

II. "Good Faith" Cost Estimates for Uninsured/Self-Pay Individuals

Informing the Patient of their Right to a Good Faith Estimate All relevant providers and facilities, including air ambulance service providers, upon scheduling an item or service or upon request of an individual, must assess the individual's coverage/payment status and in the case of an uninsured or self-pay individual, must inform the patient of their right to a good faith estimate of service through oral and written notification. Any discussion or inquiry regarding the potential cost of items or services warrants a good faith estimate. Written notice must be provided in clear language that the individual can understand in an accessible format, prominently displayed in the office and on the provider/facility's website, and must be easily searchable from a public search engine. Written notices should account for any vision, hearing, or language limitations, including individuals with limited English proficiency or other literacy needs. It may be provided on paper or electronically, depending on the individual's preference. HHS intends to provide a model notice, but providers/ facilities can also use their own.

Key Definitions The "convening" provider or facility is that who receives the initial request for a good faith estimate and who is responsible for scheduling the primary item/service in question. ''Co-providers/ facilities" furnish items or services that are customarily provided in conjunction with the primary item or service. They would be expected to provide a quote of those aligned items or services, which the convening provider/facility would incorporate into their good faith estimate. The convening provider or facility must contact all applicable co-providers and co-facilities within one business day after the request for the estimate is received or the primary item/service is scheduled. All co-providers/facilities must respond within one business day. The "period of care" entails the day(s) relevant items or services are furnished, which includes primary items/services as well as any relevant equipment, devices, telemedicine, imaging, laboratory, or preoperative and postoperative services that would not be scheduled separately, plus any items/services expected to be furnished in conjunction with the primary service by co-providers/facilities.

Providing Estimates All estimates must include:

- Patient name and date of birth
- A clear description of each item/service with diagnosis codes, expected service codes, and expected charges associated with each listed item or service (and date of service if scheduled)
- An itemized list of items/services reasonably expected to be furnished in conjunction with the primary item/service grouped by provider/facility along with the NPI/TIN and location of each
- A disclaimer that the good faith estimate is only an estimate of items/services reasonably expected to be furnished at the time and final items, services, or charges may differ.
- A disclaimer that additional recommended items or services may be part of the course of care but are not reflected in the good faith estimate along with a separate list of items/services that require separate scheduling and for which separate estimates would need to be requested.
- A disclaimer informing the patient of their right to initiate the patient-provider dispute resolution process if the actual billed charges are substantially greater than the estimated charges along with instructions of where to find more information and written assurance that initiating such process will not adversely affect the quality of services rendered.
- A disclaimer that the estimate is not a contract and does not require the individual to obtain the items or services from any of the providers or facilities identified.

The good faith estimate must include expected charges for all relevant items or services including any reasonably expected to be provided in conjunction with the main items/services (including those provided by another provider/facility). A single estimate may be provided for recurring items or services provided it includes the scope (i.e. frequency, and total number of items/services, and timeframe, which is not to exceed 12 months). HHS provides a sample estimate on page 56020 of the IFR but notes this format is not mandated.

The estimate must be provided within three business days of a request, three business days of being scheduled (if scheduled 10 business days out), or within 1 business day (if scheduled three business days out) and must include the expected billing and diagnostic codes for items or services.

Enforcement Discretion for Co-Provider Estimates HHS will exercise enforcement discretion in regards to expected charges from co-providers or co-facilities for estimates issued during CY 2022 and encourages states to take a similar approach.

Updated Estimates In instances where a good faith estimate is requested by the individual, a new estimate must be provided upon scheduling. Updated estimates should also be provided to the patient (and to the convening provider/facility if relevant) if the scope of the information in the estimate materially changes for any reason, such as if a new provider will be rendering the services. Updated estimates should be provided at least one business day out from the scheduled date of service. If changes occur less than one business day out, the replacement co-provider or co-facility must accept the expected charges for the relevant items or services as its own estimate.

Oversight and Enforcement Good faith estimates are considered part of a patient's medical record and must be maintained in the same manner. Accordingly, convening providers/facilities must be able to provide a copy of any estimates within the last six years. Providers will not be considered non-compliant if they act in good faith and with reasonable due diligence and correct any inaccuracies as soon as practicable. HHS will exercise enforcement discretion in scenarios where convening providers and facilities are relying on the accuracy of expected charges for items or services for which they do not bill from co-providers or co-facilities, provided they did not know, or reasonably should have known, that the information was incomplete or inaccurate, and that they attempt to correct any inaccuracies as soon as possible. Providers/facilities who experience others' failures to comply with these requirements may file a complaint for enforcement investigation.

III. Patient-Provider Dispute Resolution Process (PPDRP)

Eligible Items and Services Uninsured (or self-pay) individuals may initiate this process if the total billed charge from a provider/facility is "substantially in excess" of the expected charges listed in the good faith estimate, defined as a difference of at least $400 (though it may be adjusted in the future). During the enforcement discretion period for items/services provided by co-providers or co-facilities (i.e. CY 2022), charges for these supplementary items/services would not be eligible for the PPDRP.

Initiating the Process The patient him/herself, an authorized representative, Client Assistance Program, or legal aid organization must submit an initiation notice on behalf of the individual within 120 calendar days of receiving the initial bill. The initiation notice may be submitted through the Federal IDR portal, electronically, or on paper in a form and manner to be specified in future guidance. Providers or facilities directly represented in the good faith estimate are not eligible to initiate the PPDRP on behalf of a patient due to potential conflict of interest.

Initiation notices must include:

- Descriptive information to identify items/services under dispute (i.e. dates of service; location)
- Copy of the bills under dispute (photocopies or electronic images are acceptable)
- Copy of the good faith estimate (photocopies or electronic images are acceptable)
- Contact information of involved parties
- Patient's communication preference (i.e. Federal IDR Portal, electronic mail, or paper mail)

Fees HHS will pay the majority of dispute resolution costs through direct contracts with SDR entities. In addition, a nominal administrative fee will be assessed to the non-prevailing party. The exact amount will be clarified in future guidance but is not expected to exceed $25. The individual will initially pay the fee when it initiates the PPDRP. If the individual prevails, the fee will be removed from the final payment amount they owe.

Suspension of Collection Efforts While the dispute resolution process is pending, the provider or facility must suspend any collection efforts and late fees and is prohibited from taking any retributive action against an individual for utilizing the PPDRP.

Selecting an SDR Entity Once the initiation notice has been received, HHS will select an SDR entity. The entity has three business days to attest it has no conflict of interest with any involved party or inform HHS that it does, in which case HHS would choose another entity.

Collection of Relevant Information The selected SDR entity will notify the relevant parties and provide the patient with available resources. The entity will review the initiation notice to ensure all relevant information is included and determine whether the disputed items or services meet eligibility criteria to proceed. Individuals will have 21 calendar days to respond to any requests for additional information, which may be extended by HHS due to language or other accessibility limitations. The SDR entity will inform all parties if the request is eligible to proceed, upon which time the provider/facility will have ten business days to submit required information including:

- A copy of the good faith estimate provided to the individual for items or services under dispute
- A copy of the billed charges provided to the individual for items or services under dispute
- Documentation demonstrating that the difference between the billed and expected charges reflects the costs of medically necessary items/services based on unforeseen circumstances that could not have reasonably been anticipated and that substantiate the billed charges in general (e.g. a written explanation of circumstance changes; a patient's relevant medical history)

Individuals may also submit additional, relevant information or documentation during this window, although they are not required to submit anything beyond what is required in the initiation notice.

Determining a Final Payment Amount The SDR Entity has 30 calendar days to render a final payment decision. To do so, it must evaluate each item/service separately as follows:

For items/services that did appear on the original good faith estimate:

- If the billed amount was less than estimated, the amount to be paid is the billed amount.
- If the billed amount was higher than estimated, and the difference is not based on the cost of unforeseen but medically necessary items/services, the amount to be paid is the expected charge.
- If the billed amount was higher than estimated, and the difference is based on items/services determined to be medically necessary and unforeseen, the amount to be paid is the lesser of the

billed charge OR the median payment amount for the same or similar service in the geographic area according to an independent database (OR the good faith estimate amount IF it is higher)

For items/services that did not appear on the original good faith estimate:

- If not medically necessary and beyond reasonable anticipation, the amount to be paid is $0.
- If determined to be reasonable and not reasonably anticipated, the amount owed is the lesser of the billed charge or median payment amount (or good faith estimate), as explained above.

After making this determination for each item or service, the SDR entity will add them together to determine the final payment amount. If the final amount is lower than the total billed charges, the SDR entity will reduce the final amount owed by the cost of the administrative fee paid by the individual to initiate the process. The SDR entity would then inform all parties of the final payment amount owed by the individual along with a justification for its decision. It would do so through the Federal IDR portal as well as through preferred communication preferences indicated by the parties. Absent fraud or proven misrepresentation of facts, these decisions are considered binding.

Agreements Reached After PPDRP is Initiated If at any point after the dispute resolution process has been initiated but before the SDR entity makes a decision the two parties agree on a payment amount, they must notify the SDR Entity within three business days. In this notice, they must include the settlement amount, date of agreement, acknowledgement by both parties, and show that the patient is responsible for no more than half of the administrative fee.

Extenuating Circumstances Parties may request through the IDR portal extensions for the timeframes in this section (expect for payment of the administrative fee) based on delays caused by extenuating circumstances beyond the control of the parties or for good cause. They must attest that they will comply as soon as they are able. HHS will consider these on a case-for-case basis.

Certifying SDR Entities Rather than an open call for applicants, HHS intends to certify and directly contract with a small number of entities with a national presence. For the first year, HHS anticipates contracting with up to three SDR entities. Through this contract process, HHS will assess the entity for compliance with all SDR entity certification requirements, which are generally consistent with those for certified IDR entities with a few exceptions. In addition to satisfying the conflict of interest requirements expected of IDR entities, SDR entities will also be expected to include a mitigation plan for an entity-level conflict of interest, which could include hiring a subcontractor. Expectations for documentation required to be certified as an SDR entity will be released through future guidance. SDR entities may but are not required to also apply for certification as an IDR entity.

Compliance HHS is concerned that providers or facilities may be incentivized to overestimate prices in the good faith estimate to avoid dispute resolution and seeks comment on ways to prevent this.

Deferring to State Law In cases where a state law provides a process for resolving disputes between uninsured/self-pay individuals and providers/facilities that meets/exceeds the consumer protections in this rule, the state law will continue to apply. HHS will assess annually and notify states in writing.

IV. Deferral of Enforcement for Advanced Explanation of Benefits Requirements

This IFR does not address requirements for providers/facilities to provide an advanced explanation of benefits. HHS will delay enforcement of this requirement until it addresses it in future rulemaking.