Illinois Health and Hospital Association

October 20, 2021

ILLINOIS HEALTH AND HOSPITAL ASSOCIATION
M E M O R A N D U M

SUBJECT: Detailed Summary: No Surprises Act, Implementing Regulations Part II

As part of the *Consolidated Appropriations Act of 2021*, the No Surprises Act (NSA) outlines new patient protections from surprise medical bills and requirements for healthcare providers and plans. The provisions apply to both state-regulated individual and group health plans and self-funded Employee Retirement Income Security Act (ERISA) plans. Most NSA provisions are effective Jan. 1, 2022 and require the issuance of implementing regulations. IHA's summary of the NSA is on the IHA Finance *website*.

The Office of Personnel Management and the U.S. Departments of Health and Human Services (HHS), Labor, and Treasury (the Departments) are releasing NSA implementing regulations in stages, with the Part II regulations issued Oct. 7, 2022 and summarized in detail below. The Part II regulations focus mainly on the required good faith estimate (GFE) for uninsured and self-pay patients and the Independent Dispute Resolution (IDR) process.

Implementing Regulations, Part I

The Departments published Implementing Regulations, *Part I* in the *Federal Register* on July 13 as an interim final rule with comment period. IHA issued comments on Part I, as well as on the draft standard notice and consent documents released by the Departments with Part I.

Part I addressed several provisions of the NSA, including the ban on balance billing for certain out-of-network services, the notice and consent process necessary to balance bill patients for certain out-of-network services, provider reimbursement for out-of-network services, calculating patient cost sharing, and the complaint process for potential NSA violations. IHA's summary of Part I is *here* and IHA's comment letter is *here*.

Proposed Rule on NSA Enforcement

On Sept. 10, the Departments released proposed rules implementing NSA provisions related to enforcement, air ambulance transport, and agent and broker disclosures. The proposed rule would amend the Public Health Services (PHS) Act to give states the primary enforcement authority over providers, including out-of-state providers furnishing telehealth services. This proposed change aligns state enforcement authority for providers with existing state authority over health insurance issuers and plans.

If a state signals it cannot enforce PHS Act requirements, or the federal government determines a state is not adequately enforcing PHS Act requirements, then the Centers for Medicare & Medicaid Services (CMS) becomes the default federal enforcement entity. The proposed rule establishes the federal process for investigations of alleged noncompliance, as well as enforcement actions CMS may take for continued noncompliance. Confirmed violations come

with a civil monetary penalty of up to $10,000 per violation. IHA submitted comments on this proposed rule, available *here*.

Delayed Enforcement

On Aug. 20, the Departments announced delayed enforcement of NSA provisions specific to insured patients. The Departments will defer enforcement of GFEs and advanced explanation of benefit requirements for insured patients until they are able to go through the notice and comment rulemaking process that includes the establishment of data transfer standards. Providers are still required to provide uninsured and self-pay patients with GFEs beginning Jan. 1, 2022.

Implementing Regulations, Part II

On Oct. 7, the Departments published in the *Federal Register* Requirements Related to Surprise Billing; Part II (*CMS-9908-IFC*) (Interim Final Rule with Comment Period). Part II outlines the required GFE providers must create and share with uninsured and self-pay patients, creates a process for uninsured and self-pay patients to dispute provider charges, establishes the federal independent dispute resolution (IDR) process, and modifies existing external review requirements as part of payer oversight to incorporate provisions related to the NSA.

Please note that this IHA summary is limited to provisions of Part II that specifically affect providers and facilities (i.e., providers). Part II contains additional requirements and policies specific to health plans, health plan issuers (i.e., payers) and air ambulance providers, as well as the selection and certification of IDR and selected dispute resolution (SDR) entities.

Good Faith Estimates for Uninsured/Self-Pay Patients

The NSA requires providers to furnish GFEs to uninsured/self-pay individuals upon their request and at the time of scheduling an item or service. Uninsured/self-pay individuals are defined as individuals that:

- Do not have benefits for an item or service under a group health plan, group or individual health insurance coverage offered by a health insurance issuer, a Federal health care program, or a health benefits plan under *5 USC Ch. 89*;
- Have benefits for an item or service under a group health plan or individual or group health insurance coverage offered by a health insurance issuer, but who do not seek to submit a claim for such item or service; or
- Are enrolled in short-term, limited-duration insurance and not also enrolled in a group health plan, group or individual health insurance coverage offered by a health insurance issuer, Federal health care program, or a health benefits plan under chapter 89 of title 5, United States Code.

Providers must provide a GFE notification that outlines the expected charges for all items or services reasonably expected to be provided in conjunction with a scheduled or requested item or service. The Departments define “expected charges” as cash pay rates or rates for an uninsured/self-pay patient that reflect any discounts available for the individual patient. The

GFE must include items or services provided by the convening provider, as well as all reasonably expected items or services to be provided by any co-providers. The Departments define "convening provider" as the provider or facility responsible for scheduling the primary item or service. A "co-provider" is a provider or facility other than the convening provider that furnishes items and services customarily provided in conjunction with a primary item or service. For example, the convening provider for a surgical service would be the hospital because the hospital scheduled the primary service (the surgery), while the surgeon and anesthesiologist would be co-providers involved with the provision of that surgery.

The GFE must also include expected billing and diagnostic codes for all listed items and services. HHS notes that supplying the expected billing and diagnostic codes allows individuals to compare the supplied GFE with other provider expected charges made public via the *Hospital Price Transparency* requirements.

Providers must provide a GFE to an uninsured/self-pay individual who schedules an item or service no later than one business day after the item or service is scheduled, and at least three business days before the date the item or service is to be furnished. However, if the item or service is scheduled at least ten business days in advance, the provider must furnish the GFE within three business days of scheduling the service.

When an uninsured/self-pay individual requests a GFE of expected charges but has not scheduled the item or service, the treating provider must furnish a GFE to the individual within three business days of the request.

A GFE template is available *here* (file name: Good Faith Estimate Template).

Patient-Provider Dispute Process for Uninsured and Self-Pay Patients

Any item or service rendered by convening providers or co-providers to a patient are eligible for the patient-provider dispute process if the total billed charges are substantially in excess of the total expected charges listed on the GFE. The Departments define "substantially in excess" as total billed charges that are higher than total expected charges by $400 or more.

The Departments recognize that unforeseen factors during the course of treatment may occur, which could involve additional items or services from providers and may result in billed charges higher than the GFE. However, the Departments state that if only the items or services explicitly listed in the GFE are eligible for patient-provider dispute resolution, providers may be incentivized to omit items and services from the GFE in order to avoid dispute resolution. Therefore, patients may initiate dispute resolution even if the total billed charges are excessively higher due to the provision of items or services that were not originally listed on the GFE. Similarly, patients may initiate dispute resolution even if total billed charges are excessively higher due to items or services furnished by co-providers not originally listed on the GFE.

The Departments notes that a replacement co-provider may provide the uninsured/self-pay patient with a new GFE of expected charges. In such cases, determining whether an item or service billed by the replacement co-provider is eligible for dispute resolution depends on

whether the total billed charges for the replacement co-provider are substantially in excess of the total expected charges included in the new GFE.

Patients who believe a provider intentionally provided incomplete or inaccurate expected charges in the GFE may file a complaint with HHS.

Delayed Enforcement

Convening providers must list all reasonably expected items and services to be provided by a co-provider. The Departments acknowledge that providers may need additional implementation time to develop appropriate communication channels among various co-providers. Therefore, HHS will exercise enforcement discretion in situations where the GFE does not include expected charges for items and services from a co-provider from Jan. 1 through Dec. 31, 2022.

The Departments encourage convening providers to include a range of expected charges for such items and services during the period of care. This range of expected charges will not be eligible for the patient-provider dispute resolution process between Jan. 1 and Dec. 31, 2022.

Additionally, the Departments note nothing prevents a co-provider from furnishing required GFE information before Dec. 31, 2022. In such cases, a co-providers are subject to the patient-provider dispute resolution process. Additionally, nothing would prevent the uninsured/self-pay individuals from separately requesting a GFE directly from a co-provider before Dec. 31, 2022. In such cases, again, the patient-provider dispute resolution process would apply.

Initiating the Patient-Provider Dispute Resolution Process

When the total billed charges are $400 or more than expected in the GFE, an uninsured/self-pay individual or their authorized representative may submit an initiation notice to HHS to begin the patient-provider dispute resolution process. The initiation notice must be postmarked within 120 calendar days of receiving the initial bill showing an excessive total billed charge. Once the patient-provider dispute resolution process is initiated, relevant providers may not move nor threaten to move a patient's bill for the disputed item or service into collection. If the bill is already in collection, the provider must cease collection efforts and suspend the accrual of any late fees on unpaid bill amounts until after the dispute resolution process concludes.

HHS outlines specific information that individuals must include with the initiation notice, and requires the use of the Federal IDR portal for all documentation submission and dispute communication. The uninsured/self-pay individual must also submit an administrative fee to cover costs of the selected dispute resolution (SDR) entity, though this fee will be nominal so as not to create a barrier to accessing the dispute resolution process. If the uninsured/self-pay individual prevails in the dispute, the individual will recoup the administrative fee.

The dispute resolution process begins the day HHS receives the initiation notice. In forthcoming guidance, HHS will provide additional information on how uninsured/self-pay individuals can submit the initiation notice and a standard notification *form* (file name: PPDR

Dispute Initiation Form). HHS also intends to provide outreach and education to consumer advocates, consumer assistance programs (CAPs), legal aid organizations, and other stakeholders to assist individuals through this process. In general, a provider may not represent uninsured/self-pay individuals in the dispute resolution process if the provider was represented on the GFE, or is employed by a provider that furnished items or services involved in the dispute.

After receiving the initiation notice, HHS will select an SDR entity. SDR entities will be assigned in round robin fashion to ensure equal allocation of cases unless conflicts of interest arise, in which case the next SDR entity in line will be selected. SDR entities will use the Federal IDR portal to notify relevant parties that an initiation request was received and is under review. This notification will also include:

- Information identifying the item or service under dispute;
- The date the initiation notice was received;
- Information on the availability of consumer assistance resources for the uninsured/self-pay individual;
- Instructions to the provider reiterating that unpaid bills may not be moved to collection or accrue late fees; and
- Instructions that the provider may not take or threaten to take retributive action against uninsured/self-pay individuals utilizing the patient-provider dispute resolution process.

The SDR entity will review the patient's initiation notice for eligibility and completeness, notifying the individual of the outcome of the review and requesting additional information as applicable. Uninsured/self-pay individuals must submit missing or supplemental information within 21 to 35 calendar days (an extension is available when SDR entities are unable to fulfill accessibility accommodation requests in 14 calendar days).

Once the SDR entity determines that an item or service is eligible for the patient-provider dispute resolution process, the SDR entity must provide notification of the determination to both the individual and provider.

Certification of SDR Entities

HHS intends to contract directly with up to three SDR entities for the first year of the program. HHS will compensate SDR entities directly for their services, and will assess them for compliance with all applicable certification requirements. SDR entities must be able to operate nationwide, and will be held to the same general conflict-of-interest standards as IDR entities (outlined below). SDR entities must also have an approved mitigation plan in place for addressing conflicts of interest. Both the uninsured/self-pay individual and the provider may attest that a conflict of interest exists in relation to the SDR entity assigned to a payment dispute, in which case the SDR entity must notify HHS no later than three business days following receipt of the attestation. If all SDR entities and subcontractors have similar conflicts of interest, HHS may seek to contract with an additional SDR entity as needed.

Payment Determination

The individual and provider may settle the payment amount before an SDR determination is made. Should the parties settle on a payment amount before the SDR entity makes a determination, the provider should notify the SDR entity through the Federal IDR portal, electronically, or in paper form, as soon as possible but no later than three business days after the date of the agreement. The settlement notification must contain, at minimum, the settlement amount, the date upon which the settlement was reached, and documentation demonstrating that the provider and uninsured/self-pay individual agreed to the settlement. The provider must also document that it applied a reduction to the uninsured/self-pay individual's settlement amount that is equal to at least half the amount of the administrative fee paid. Once the SDR entity receives the settlement notification, the SDR entity will close the dispute resolution case as settled and the agreed upon payment amount will apply for applicable items or services.

The Departments clarified that payment of the billed charges, or a portion of the billed charges, by the uninsured/self-pay individual does not demonstrate agreement by the individual to settle at that amount or any other amount. Rather, the individual may initiate a dispute even after making payment or entering into a payment plan, and the provider may not use previous payment to prove a settlement has been reached to avoid the patient-provider dispute resolution process.

The provider must submit information to the SDR entity within 10 business days after receiving the initiation notice from the SDR entity. This information must include:

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

The SDR entity will make a determination on the amount the uninsured/self-pay individual must pay within 30 days of receiving information from the provider. HHS instructs SDR entities to use expected charges in the GFE as the presumed appropriate charge amount unless the provider supplies credible information justifying the difference between total billed charges and the GFE. Justifications must demonstrate that the difference between billed and expected charges reflects the cost of medically necessary items or services and be based on unforeseen circumstances that the provider could not have reasonably anticipated. Information is deemed credible if it is found worthy of belief and consists of trustworthy information.

HHS acknowledged that unforeseen factors during the course of treatment may result in the provision of additional items or services that could result in higher total billed amounts. In

cases where changes in the underlying circumstances occur during treatment and would reasonably result in higher than expected charges, the SDR entity may consider additional factors that support charges for medically necessary items or services. Providers should provide documentation, which can include a written explanation, detailing any change in circumstances, how that change resulted in a higher billed charge, and why the billed charge reflects the cost of a medically necessary item or service.

The SDR entity must review all submitted documentation and decide whether the provider demonstrated that the difference between billed and expected charges was medically necessary and reasonably unforeseen. SDRs must make this determination separately for each unique billed item or service. For any item or service where the billed charge is equal to or less than the expected charge, the SDR entity will determine the payment amount to be the billed charge. If the billed charge is higher than the expected charge and the SDR entity determines the provider has not proved the difference reflects medically necessary and reasonably unforeseen items or services, the SDR entity must determine the amount to be paid by the uninsured/self-pay individual to be equal to the expected charge for the item or service listed in the GFE.

If the SDR entity determines that the provider did prove the difference reflects medically necessary and reasonably unforeseen items or services, the SDR entity must select the lesser of the following to be paid by the uninsured/self-pay patient:

(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 if the amount reflected in the independent database is less than the expected charge in the GFE, the GFE amount.

When using an independent database to determine the median payment amount, the requirements and methodology from *Part I* apply. These are the requirements and methodology used to calculate the QPA when a payer does not have sufficient internal information to calculate a QPA based on the median negotiated rate.

The Departments acknowledge that under this approach, providers may receive payment that is less than total billed charges even in circumstances where higher billed charges are justified. HHS also acknowledged that this approach may incentivize uninsured/self-pay individuals to initiate the patient-provider dispute resolution process, even in cases when they know higher billed charges are justified. The Departments state they believe the consumer protections established under the NSA are meant to protect patients from excessive billed charges, even when such billed charges reflect medically necessary and reasonably unforeseen items or services when the GFE was provided. Additionally, the Departments state they believe the median payment amount is a reasonable payment amount because the methodology used to calculate the median payment amount should result in a fair market rate for an item or service.

For new items or services not originally listed on the GFE for which the SDR entity determines the provider did not prove reasonably unforeseen medical necessity, the SDR entity will

determine a payment amount of $0. If the SDR entity determines the provider does prove reasonably unforeseen medical necessity for new items or services that did not appear on the GFE, then the SDR entity must select the lesser of the following to be paid by the uninsured/self-pay patient:

(1) The billed charge; or
(2) The median payment amount for the same or similar service in the geographic area, or that is reflected in an independent database.

After making a determination for all items or services subject to dispute resolution, the SDR will add together the amounts to be paid for all items and services. If this payment amount is lower than the total billed charges, the SDR entity must reduce the final payment amount by the administrative fee paid by the individual to account for the administrative fee charged to the provider. This represents the final payment amount for the uninsured/self-pay patient.

The Departments acknowledge that under this approach, particularly in cases where the provider submits credible information to justify higher billed charges, the SDR entity may still determine a lower payment amount than the billed charge and the provider would end up paying an administrative fee in a large portion of patient-provider dispute resolution cases. The Departments justify this by explaining their view that the intent behind the NSA is to protect uninsured/self-pay patients from unexpected billed charges that are substantially in excess of the expected charges in the GFE. As a result, the Departments believe uninsured/self-pay individuals should be held harmless in cases where the process results in a lower payment amount.

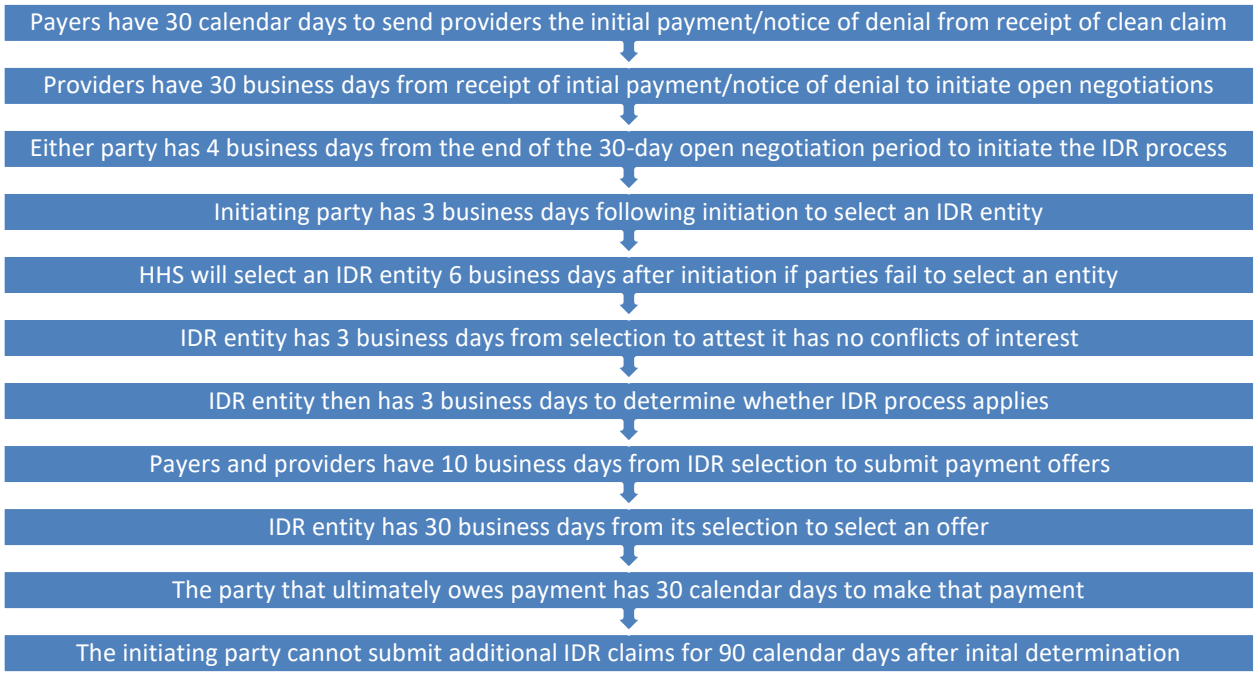
Once the final payment determination amount has been calculated, the SDR entity must inform the uninsured/self-pay individual and the provider using the Federal IDR portal, electronically or by paper mail (depending on patient and provider preferences), of the determination along with justification for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

Generally, determinations made by an SDR entity are binding absent fraudulent claims or evidence of misrepresentation of facts. However, the provider may provide financial assistance or agree to an offer for a lower payment amount than the SDR entity's determination. Additionally, the uninsured/self-pay patient may agree to pay the billed charges in full, or the uninsured/self-pay individual and the provider may agree to a different payment amount.

Federal IDR Process

Below is a timeline and detailed explanation of the Federal IDR process outlined in Part II. The Departments established the qualifying payment amount (QPA), the median of a plan's in-network rates, as the primary factor Federal arbiters must consider when determining a payment rate for out-of-network services. IHA sent a *letter* to the Illinois Congressional Delegation on Oct. 7, urging the members of the Delegation to request the Departments implement the NSA in a manner consistent with the NSA as written. Over the course of two years, Congress rejected numerous legislative proposals that relied on a benchmark for arbitration purposes, with a recent bipartisan *letter* from the House Ways and Means

Committee chairman Richard Neal (D-MA) and ranking member Kevin Brady (R-TX) informing the Departments that Part II does not align with Congressional intent.



Open Negotiation

When the payer provides an initial payment or a notice of denial of payment for an item or service furnished by an out-of-network provider, the provider may accept the initial payment or notice of denial or initiate the open negotiation period. The open negotiation period lasts 30 business days, and the entire 30 business days must elapse before either party may initiate the federal IDR process.

Either party may initiate open negotiations. The initiating party must provide written notice to the other party of its intent to negotiate. The notice must include:

- The date the item or service was furnished;
- The service code;
- The initial payment amount or notice of denial of payment, as applicable;
- An offer for the out-of-network rate; and
- Contact information of the party sending the notice.

The notice must be sent within 30 business days of the initial payment or notice of denial of payment and must be provided in writing (it may be sent electronically). The 30-business day open negotiation period begins on the day the notice is sent. The Departments encourage payers and providers to take reasonable measures to ensure the non-initiating party receives the notice, including confirming accurate contact information and using read receipts. If the notice is not properly provided to the other party, the Departments may determine that the 30-

business day open negotiation period never began, making any subsequent payment determination from a certified IDR entity unenforceable.

To facilitate communication between parties and compliance with notice requirements, the Departments will require use of a standard notice to satisfy the open negotiation notice requirement.

Initiation of the Federal IDR Process

If the open negotiation period does not result in an agreed-upon rate, either party may then initiate the Federal IDR process. The Departments created a *Federal IDR portal* to facilitate and support IDR entity certification, the initiation of the Federal IDR process, the selection of certified IDR entities, the submission of supporting documentation to certified IDR entities, and the submission of certified IDR entity reporting metrics.

Either party may initiate the Federal IDR process during the four business days beginning on the 31st business day after the start of the open negotiation period. To initiate the IDR process, the initiating party must submit a notice to the other party and to the Departments through the Federal IDR portal. The Notice of IDR Initiation must include the following:

- The qualified IDR items or services (and whether they are batched items and services);
- The date(s) and location(s) of the items or services;
- The type of qualified IDR items or services (i.e., emergency services, post-stabilization services, professional services, hospital-based services) and corresponding service and place-of-service codes;
- The amount of cost sharing allowed and the initial payment made by the payer, if applicable;
- The names and contact information of the parties involved (email addresses, phone numbers, and mailing addresses);
- The state where the qualified IDR items or services were furnished;
- The commencement date of the open negotiation period;
- The initiating party's preferred certified IDR entity;
- An attestation that the items or services are qualified IDR items and services within the scope of the Federal IDR process.

The notice should also include general information describing the scope of the Federal IDR process and key deadlines, including how to select a certified IDR entity, and the process for selecting an offer. The Departments developed a *form* that parties must use to provide this general information.

Selecting a Certified IDR Entity

In the notice of IDR initiation, the initiating party indicates its preferred certified IDR entity. The non-initiating party has three business days to agree or object to the identified entity. If it objects, both parties can use the rest of the three business days to jointly select a certified IDR entity. On the fourth business day, the entities must notify the Departments whether they

have selected a certified IDR entity via the Federal IDR portal. The Departments will make a list of certified IDR entities and their contact information available in the Federal IDR portal.

The selected IDR entity must ensure that assigned personnel comply with certification requirements and do not have any conflicts of interest. Additionally, any personnel assigned to the case must not have been a party to the determination being disputed or an employee or agent of such a party within the one-year immediately preceding assignment.

If the parties agree on a certified IDR entity, they must notify the Departments of their joint selection by providing the following information:

- The name of the certified IDR entity;
- The certified IDR entity number (provided in the Federal IDR portal); and
- An attestation by both parties that, based on reasonably accessible information, the selected certified IDR entity does not have a conflict of interest at the time of selection. If the non-initiating party does not respond affirmatively or negatively to the suggested IDR entity, then the initiating party may complete this attestation. (The Departments define a conflict of interest as a material relationship, status, or condition of the entity that impacts the ability of a certified IDR entity to make an unbiased and impartial payment determination.)

If the parties fail to agree on a certified IDR entity, the Departments will randomly select a certified IDR entity that charges a fee within the allowed range. If no such entity is available, the Departments will randomly select a certified IDR entity that has received approval to charge a fee outside the allowed range. The Departments will notify the parties of their assigned IDR entity no later than six business days after the initiation of the Federal IDR process.

After being selected, the certified IDR entity must review its selection and attest that it does not have any potential conflicts of interest. If the entity cannot attest to no conflicts of interest, it must notify the Departments through the Federal IDR portal within three business days. In such cases, the Departments will notify the parties and the parties will have an additional three business days to select another certified IDR entity. If the parties cannot agree on a certified IDR entity, the Departments will randomly select another entity.

The selected certified IDR entity must also review information submitted by the parties to determine whether the Federal IDR process applies. This includes ensuring that the item or service is subject to NSA protections for which notice and consent requirements are not a factor, and that the Federal IDR process is not superseded by an applicable All-Payer Model Agreement or specific state law. If the Federal IDR process does not apply, the certified IDR entity will notify the Departments and parties within three business days.

Authority to Continue Negotiation

Payers and providers may continue negotiating payment throughout the Federal IDR process. If the parties come to an agreement after initiating the Federal IDR process but prior to a determination, the Federal IDR process will cease with the agreed-upon amount serving as the

out-of-network rate. In such cases, the initiating party must notify the Departments and certified IDR entity of the agreement via the Federal IDR portal within three business days of reaching an agreement. The payer has 30 business days to pay the provider the balance of the agreed-upon rate after accounting for any cost-sharing or initial payments. Additionally, each party must pay half of the certified IDR entity's fee, unless the parties agree on an alternative method for allocating the applicable fee. Notification to the Departments must include the total payment rate, including both cost sharing and the total plan or coverage payment, and signatures from an authorized signatory for each party.

Batched Items and Services

When there are multiple claims for qualified IDR items and services, the initiating entity may batch the items and services for one payment determination by a certified IDR entity. Batched items and services are subject to an administrative fee that is separate from the fee charged for single item or service determinations. Batched claims must meet the following conditions:

- The same provider, group of providers, facility, or provider of air ambulance services must bill for the items and services. This means the entities billing for items or services have the same national provider identifier (NPI) or taxpayer identification number (TIN);
- Billing providers must seek payment for items and services from a single group health plan or health insurance issuer;
- The qualified IDR items and services must be the same or similar items or services. The definition of "same or similar" mirrors the definition in Part I, meaning the items or services are billed under the same service code, or a comparable code under a different procedural code system, using either Current Procedural Terminology (CPT), Healthcare Common Procedure Coding System (HCPCS), or Diagnosis-Related Group (DRG) codes; and
- All qualified IDR items and services must have been furnished within the same 30-business day period, or within the 90-calendar day cooling off period (described below).

The Departments may modify the 30-business day period criteria under certain circumstances, such as when the items or services in question are low-volume items and services. In cases where items and services are bundled for payment, the qualified items or services are considered as part of one payment determination and subject to the fee for a single determination.

There may be instances where batched items and services have different QPAs. In such cases, 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. This may occur, for example, when patients in both individual market plans and large group market plans receive the same or similar items or services.

Payment Determination

The payer and provider must each submit to the certified IDR entity a payment amount offer for the item(s) or service(s) under review within 10 business days of selecting a certified IDR

entity. Offers must be expressed as both a dollar amount and the corresponding percentage of the QPA represented by that dollar amount. (Payers are required to communicate the QPA for each item and service to the providers; this should occur when the patient cost sharing amount is determined. For more information, see IHA's *summary* of Part I.) For example, if the QPA is $50 and the provider offer is $100, then the provider must submit both the dollar figure ($100), and the dollar figure as a percentage of the QPA (200% of the QPA).

For batched items and services with different QPAs, the parties must provide the various QPAs and may provide different offers for batched items and service, so long as the same offer applies for all items and services with the same QPA.

Providers must also indicate the size of their practices/facilities and information on practice specialty type (if applicable) when submitting payment offers. Provider practices must select from the following categories: fewer than 20 employees, 20 to 50 employees, 51 to 100 employees, 101 to 500 employees, or more than 500 employees. Facilities must select from 50 or fewer employees, 51 to 100 employees, 101 to 500 employees or more than 500 employees. Similarly, payers must provide the coverage area of the plan or issuer, the relevant geographic region for purposes of calculating the QPA, and, for group health plans, whether they are fully-insured or partially or fully self-insured. Additionally, Federal Employees Health Benefits (FEHB) Program carriers must identify if a particular item or service relates to FEHB plans.

The certified IDR entity may request additional supporting documentation from both payers and providers. Further, payers and providers may submit any other information they feel supports their offer except information specifically disallowed under the NSA. Disallowed information includes usual and customary charges (or rates expressed as a proportion of usual and customary charges), billed amounts, and public payer rates (i.e., Medicare, Medicaid, the Children's Health Insurance Program, TRICARE, 1115 Demonstration Projects, or rates expressed as a proportion or public payer rates). All documentation should be submitted through the Federal IDR portal.

Certified IDR entities must select one of the submitted offers within 30 business days from being assigned a determination. For each qualified IDR item or service, the amount by which this out-of-network rate exceeds the cost-sharing amount is the total plan or coverage payment. Any initial payment made must count toward the total plan or coverage payment.

When selecting an offer, the Departments direct the certified IDR entity to assume that the QPA is an appropriate payment amount. Certified IDR entities must also consider additional information submitted by payers and providers if the information is credible and related to the submitted offers. The Departments define "credible" as, if upon critical analysis, the information is worthy of belief and is trustworthy.

Credible factors the certified IDR entity must consider (if submitted) include:

- The level of training, experience, and quality and outcome measurements of the provider that furnished the item or service. The onus is on the provider to demonstrate that the QPA failed to take into account, for example, that the experience or level of

training of a provider was necessary for providing the item or service to the patient, or that the experience or training made an impact on the provided care. Additionally, if a plan or issuer's contracted rates included risk-sharing, bonus, penalty, or other incentive-based or retrospective payments that were excluded from the QPA calculation (as required by Part I), a party may provide evidence as to why the provider's quality or outcome measures support an out-of-network rate that is different from the QPA.

- The market share held by the provider or plan/issuer in the geographic region in which the item or service was provided clearly demonstrates that the QPA is materially different from the appropriate out-of-network.
- Information that patient acuity or the complexity of furnishing the item or service clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate. The Departments note that the plan or issuer is required to calculate the QPA using median contracted rates for service codes, as well as modifiers, if applicable. Therefore, the QPA should already reflect patient acuity and service complexity, and the Departments anticipate that there would only be rare instances in which the QPA would not adequately account for these factors. However, the Departments indicated that payers may inappropriately alter service codes or modifiers, making it possible that the QPA does not adequately account for patient acuity or service complexity.
- Teaching status, case mix, and scope of services of the out-of-network provider that result in a QPA that is materially different from the appropriate out-of-network rate. The Departments note that the QPA should reflect the market-driven rate, and that a party must provide credible information that the characteristic of the teaching status, case mix, or scope of services of the out-of-network provider was in some way critical to the delivery of the item or service and not adequately accounted for in the QPA.
- Information about any demonstrations of good faith efforts (or lack thereof) made by the out-of-network provider or payer to enter into network agreements and, if applicable, contracted rates between the provider and payer during the previous four plan years which clearly demonstrate that the QPA is materially different from the appropriate out-of-network rate. For example, a certified IDR entity must consider what the contracted rate might have been had the good faith negotiations resulted in the out-of-network provider being in-network if a party is able to provide related credible information of good faith efforts or the lack thereof.

Beyond these specific factors, the certified IDR entity must also generally consider additional information submitted by a party, provided the information is credible and relates to the submitted offers.

Once the certified IDR entity makes a determination, it must provide the underlying rationale for its determination in a written decision submitted to the parties and the Departments through the Federal IDR portal in a form and manner specified in forthcoming guidance. If the certified IDR entity does not choose the offer closest to the QPA, it must include a detailed explanation of additional considerations, the credibility of those considerations, and the basis upon which it determined that the credible information demonstrated that the QPA is

materially different from the appropriate out-of-network rate. A determination made by a certified IDR entity is binding upon all parties involved, unless there is evidence of fraud or intentional misrepresentation of material facts.

Following a determination by the certified IDR entity, the initiating party may not submit a subsequent Notice of IDR Initiation involving the same non-initiating party with respect to a same or similar claim for 90 calendar days (i.e., there is a cooling off period). Should open negotiations for the same or similar item or service between the same provider and payer end during the 90-calendar day cooling off period, either party may initiate the Federal IDR process for said claims within 30 business days of the completion of the cooling off period. Then, the same process for determining the total payment amount ensues.

Once the certified IDR entity selects an offer, required payments must be made within 30 calendar days. If the selected offer is higher than the sum of any initial payment and cost-sharing amount, the payer is responsible for paying the provider. If the selected offer is less than the sum of any initial payment and cost-sharing amount, then the provider must reimburse the payer. The Departments noted that the determined rate does not change the patient's cost sharing. Additionally, the certified IDR entity must maintain records of relevant documentation associated with any Federal IDR process determination for six years.

Costs of the Federal IDR Process and Payment

Both the payer and provider must pay an administrative fee to the Departments for participating in the Federal IDR process, as well as a fee to the certified IDR entity. The Departments will post administrative and certified IDR entity fee amounts in the Federal IDR portal. Certified IDR entity fees must fall within a pre-determined range specified by the Departments through *guidance*, or be otherwise approved by the Departments.

Certified IDR entities will hold these funds in a trust or escrow account until a determination is made or until the Departments notify the certified IDR entity that it may remit the funds (e.g., when the parties negotiate a rate before the Federal IDR process concludes). The certified IDR entity may accrue interest on the funds, and is not required to remit any accrued interest to any other party.

After making a determination, the certified IDR entity must refund the fee paid by the prevailing party to cover the certified IDR entity's fee within 30 business days. The certified IDR entity will retain the fee submitted by the non-prevailing party, as the non-prevailing party is required to pay the entire certified IDR entity fee. In the case of batched determinations, the certified IDR entity may make different payment determinations for each qualified IDR item or service under dispute. The party with the 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, unless directed otherwise by both parties to distribute the total amount of that refund in different shares.

The administrative fee paid to the Departments is non-refundable, even in instances where the parties negotiate an out-of-network rate before the certified IDR entity makes a determination or where the certified IDR entity determines that the case does not qualify for the Federal IDR process. The Departments will establish the administrative fee amount in *guidance*, with the total administrative fees collected during a calendar year approximately equal to the estimated amount of expenditures by the Departments for that calendar year in carrying out the Federal IDR process.

Payer Oversight Modifications

Part II also makes several changes to existing rules that require an external review process as part of payer oversight. The rule expands the scope of adverse benefit determinations eligible for external review to include determinations on claims subject to surprise billing and cost-sharing protections under the NSA. Additionally, grandfathered health plans are newly subject to the external review process for NSA compliance.

Next Steps

IHA is working with national and state partners to address concerns with Part II requirements, including how the Departments established the QPA as the primary factor for consideration through the IDR process. IHA President & CEO A.J. Wilhelmi sent a *letter* to the Illinois Congressional delegation asking them to urge the Departments to make immediate changes. Additionally, IHA continues to engage federal and state partners to understand how these federal rules work with state Public Act 96-1523 (215 ILCS 5/356z.3a). IHA will submit comments to the Departments on this interim final rule with comment period, and we encourage member hospitals and health systems to submit comments as well by Dec. 6, 2021. Please send questions or comments to IHA.