# CLIENT ALERT

## Interim Final No Surprises Act Regulations Provide New Detail on Regulatory Scheme, Continue to Leave Critical Aspects Up in the Air

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On September 30, 2021, the Departments of Health and Human Services ("HHS"), Labor, and Treasury, as well as the Office of Personnel Management (collectively, "the Departments"), issued a second interim final rulemaking implementing provisions of the No Surprises Act passed by Congress earlier this year.

The interim final regulations, slated to take effect January 1, 2022, announce new standards and procedures for the Act's independent dispute resolution ("IDR") process between certain payors and out-of-network providers, impose new disclosure requirements on providers who render services to patients who are uninsured or choose to self-pay for care, and announce "special dispute resolution" ("SDR") procedures for disputes between providers and uninsured or self-pay patients. Notably, however, the interim final rules leave certain key terms undefined, and the Departments have solicited comments on critical provisions in the rulemaking—including the regulations' new payment standards, batching and bundling rules, and IDR entity certification requirements—indicating that these provisions could be modified further.

**Payment Standard for Disputes Between Payors & Out-of-Network Providers**

The No Surprises Act establishes a baseball-style IDR process where, should a payor and out-of-network provider fail to agree on a reimbursement rate within 30 business days of the payor's initial payment for an item or service, parties can ask an arbitrator (called the "IDR entity" in the regulations) to select between competing payment offers. This process, however, may only apply in states where there is no state law method for determining the total amounts payable for: (i) out-of-network emergency care, (ii) items and services rendered by out-of-network providers at in-network facilities, and (iii) out-of-network air ambulance services. The rule does not address the level of specificity required by state law payment methods that would exempt out-of-network claims from application of the standards for payment imposed by the No Surprises Act. The interim final rulemaking also establishes new standards for selecting between payment offers in IDR proceedings.

Specifically, the interim final rules require the entity overseeing the IDR dispute to presume that the so-called Qualifying Payment Amount ("QPA"), *i.e.*, the payor's median contracted rate for the relevant service codes in the same geographic area, is the appropriate rate for out-of-network services. IDR entities are instructed to select the offer closest to the QPA and can only deviate from this amount if there is credible evidence that "clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate."

Should an IDR entity choose to deviate from the QPA, its determination must be made based on additional factors set forth in the statute, including the provider's training and experience; the quality of services provided; the teaching status, case mix, and scope of services provided at the facility; patient acuity; market shares for each party; and the complexity of the procedure. Additionally, in cases involving air ambulance providers, the IDR entity must also consider the ambulance vehicle type, the

location where the patient was picked up, and the population density at that location. These factors may only be considered by the IDR entity, however, to the extent the parties submit evidence on these issues.

Additionally, IDR entities are prohibited from considering certain factors, including the provider's billed charges, and reimbursement rates payable by public payors for items and services provided.

**Batched Items and Services in the IDR Process**

The new IDR regulations also permit items and services to be "batched" together, *i.e.*, submitted and considered jointly as part of one IDR payment determination, if the following conditions are met:

i. the items and services must be billed by the same provider, group of providers, facility, or same provider of air ambulance services (same National Provider Identifier ("NPI") or Taxpayer Identification Number ("TIN"));
ii. payment would be made by the same group health plan or issuer;
iii. the items and services are the same or similar items or services (billed under the same service code or a comparable code under a different procedural code system (Current Procedural Terminology ("CPT"), Healthcare Common procedure coding system ("HCPCS") and Diagnosis Related Group ("DRG")); and
iv. the items and services were furnished within the same 30-business-day period or the 90-calendar-day "cooling off" period following a resolution determination.

The interim final rulemaking also provides flexibility for alternatives to the 30-business-day period if, for instance, the batched claims are for so-called "low-volume items and services," but the Departments do not state what would qualify as a low-volume item or service. Further, the rules allow multiple items or services from an episode of care to be "bundled" together for consideration as part of one payment determination by a certified IDR entity.

If items and services in a single batch of IDR claims have different QPAs (*e.g.*, because one claim is for an enrollee with individual market coverage while another is for an enrollee with a group health plan), then the parties must provide relevant information for each QPA, and the certified IDR entity must separately consider each QPA for each claim. For batched claims, the certified IDR entity may select different offers, from either or both parties, when the QPAs for the claims in the batch are different.

**New Regulations for IDR Entities**

Once a payor or provider has initiated the IDR process, the parties will have 3 business days to jointly select a certified IDR entity to preside over the dispute. If the parties do not agree to a certified IDR entity, the Departments will randomly select one to preside over the dispute.

After a certified IDR entity is selected, it must review its selection for compliance with the interim final rulemaking's new conflict of interest regulations and determine whether the federal IDR process applies to the dispute. In addition to other conflict of interest regulations, IDR entity personnel assigned to a payment dispute cannot have been an employee or agent of one of the parties to the payment dispute within the 1 year immediately preceding the dispute resolution assignment.

To be certified to handle No Surprises Act payment disputes, IDR entities must, among other things, demonstrate that they have a conflicts screening process; that they can protect individually identifiable health information; that they have sufficient

personnel to decide IDR disputes within 30 business days; and that they have sufficient relevant expertise (whether directly or through contracts with other entities). IDR entities also must maintain a current accreditation from a "nationally recognized and relevant accreditation organization," such as the Utilization Review Accreditation Commission ("URAC"), or must otherwise demonstrate its personnel possess the requisite training to handle payment determinations (*e.g.*, by providing documentation showing its employees have completed arbitration training by the American Arbitration Association, JAMS, the American Health Lawyers Association, or a similar organization).

The Departments explicitly likened their new expertise requirements to those already imposed by states on independent review organizations, and they noted that they anticipated many of the organizations currently handling arbitration or dispute resolution would already meet at least some of the certification requirements.

**Protections for Uninsured and Self-Pay Individuals**

The interim final rules also implement protections in the No Surprises Act for the uninsured and individuals who plan to self-pay for medical care.

Starting January 1, 2022, providers and facilities will be required to provide these individuals with written "good faith estimates" of the expected charges for an item or service upon request and once an item or service is scheduled. The interim final rules provide guidance on the content of the notice and manner of providing it. Among other items, the notice must include the expected charges for all items or services provided in conjunction with the primary service in the same period of care, even if provided by separate "co-providers" or "co-facilities," although HHS will exercise enforcement discretion with regards to information required from such "co-providers" or "co-facilities" during 2022.

Additionally, the interim final rules implement a patient-provider SDR process that will be available to uninsured or self-pay individuals who requested a good faith estimate and then receive a bill that exceeds the expected charge by $400 or more. In such instances, the individual can initiate the binding dispute resolution process, and the case will be assigned to an SDR entity contracted with HHS.

Once assigned the case, the SDR entity will determine whether the difference between the billed charges and the expected charges are justified, meaning that the additional charge (i) reflects the cost of a medically necessary item or service and (ii) is based on unforeseen circumstances that could not have been reasonably anticipated. If not, the individual will only be responsible for paying the expected charge listed in the good faith estimate. If those criteria are met, however, the individual will be responsible for paying the lesser of the billed charge or the median payment amount for the same or similar service in the geographic area, unless the median amount is less than the expected charge in which case the expected charge in the good faith notice would be applied instead.

**Considerations Going Forward**

Although the Departments' interim final rulemaking adds significant details to the No Surprises Act's requirements, there are still critical aspects of the regulatory scheme that have yet to be fully fleshed out. For example, the Departments announced that they will be rolling out an as-yet unpublished online portal to administer the IDR process. As envisioned by the rulemaking, parties will use this portal to, among other things, provide opposing parties with notice of the initiation of IDR proceedings.

Even more fundamentally, the Departments seek additional comment on a number of topics that could significantly influence the IDR process. For example, the Departments requested additional comments on:

- The "appropriateness and scope" of the additional factors used to deviate from the QPAs in the IDR process and how IDR entities should consider the factors used to deviate from the QPA;
- The factors IDR entities are prohibited from considering in making payment determinations;
- The regulations' batching and bundling criteria, including whether allowing consideration of bundled claims could be used to evade batching requirements and incentivize overuse of the IDR process;
- The Departments' random selection approach when parties fail to agree on an IDR entity; and
- Whether any additional accreditation or training standards would meet the Departments' IDR entity certification requirements, including "whether additional flexibility is needed to help encourage innovation in the provision of IDR services."

With critical issues throughout the entire IDR process up for potential modification, the Departments' most recent interim final rulemaking may very well not be the last word on how the No Surprises Act will be administered. The rulemaking is scheduled to be published in the Federal Register tomorrow (October 7), meaning that comments on the rulemaking will be due December 6, 2021.

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