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M E M O R A N D U M

TO: **The Council**

FROM: **Scott Sinder**
Ashelen Vicuña

RE: **"No Surprises Act" – Interim Final Regulations (Round 2)**

The Departments of the Treasury, Labor, and Health and Human Services (the "Departments"), along with the Office of Personnel Management issued Part II of their interim final regulations (the "Part II Rule") implementing the "No Surprises Act" (the "Act").[1]

The Departments released Part I of the interim final regulations in July 2021, which implemented the three core balanced billing prohibitions, the options for determining the out-of-network ("OON") payment, and the methodology for calculating the "Qualifying Payment Amount" ("QPA") should the alternative options not apply.[2] The Part II Rule builds on Part I and focuses on the most contentious piece of the "surprise billing" legislation – the parameters of the independent dispute resolution ("IDR") arbitration process that the payor or the provider can initiate when they are unable to agree on the OON payment amount.

As explained in more detail below, the Part II Rule generally tracks the statutory requirements of the No Surprises Act related to:

- Requirements, procedures, and timelines governing the initiation of the federal IDR process, including the required initial 30-day negotiation period between providers and payers, the certification and selection of IDR entities, and the submission of offers;
- How the IDR entity (i.e. the arbitrator) must make the final OON payment determination, including the type of information the IDR entity must consider, how that information must inform their decision, and what information must not be considered;
- Expansion of the external review process to include claims related to compliance with surprise billing rules and the extension of such requirements to grandfathered plans;

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[1] *See* Interim Final Rule, Requirements Related to Surprise Billing; Part II, 86 Fed. Reg. 55980 (October 7, 2021) (hereinafter "Part II Rule"). *Available at* https://www.govinfo.gov/content/pkg/FR-2021-10-07/pdf/2021-21441.pdf
[2] *See* Interim Final Rule, Requirements Related to Surprise Billing; Part I, 86 Fed. Reg. 36872 (July 13, 2021) (hereinafter "Part I Rule"). *Available at* https://www.govinfo.gov/content/pkg/FR-2021-07-13/pdf/2021-14379.pdf.

- Requirements for good faith cost estimates and a payment dispute resolution process for uninsured individuals.[3]

Although the Part II Rule, like the Part I Rule, largely tracts and reiterates the statutory framework, it also creates a regulatory presumption that the QPA should be the OON payment amount that is being viewed as very favorable for payers. Specifically, the Part II Rule requires the IDR entity to –

- select the offer closest to the QPA unless there is credible information to suggest that the QPA is materially different from the appropriate rate;
- more fully explain its decision if it chooses the rate that is not closest to the QPA rate; and
- establish a set fee which will apply to all proceedings it oversees for the year that, for 2022, cannot exceed $500 for single determinations and $670 for batched determinations.

These factors collectively should create some stickiness to the QPAs that may – ultimately – help to minimize the number of claims that are disputed through this process.

The Departments estimate the overall cost of the process to be approximately $500 million per year.[4] These estimates include costs attributable to preparing materials and paying the IDR entity fee, among others. Notably, the Departments predict that the usage and cost of certified IDR entities will likely decrease on account of their use of the QPA as the "rebuttable presumption in payment determination."[5]

The Part II Rule became final on an "interim" basis on October 7, 2021 and, like Part I, will apply to plan years that start on or after January 1, 2022. Comments on the Rule are due by December 6, 2021. The analysis below focuses on the components of the Rule that impact health plans.

Analysis

THE FEDERAL IDR PROCESS

The No Surprises Act establishes an independent dispute resolution process that a provider or facility or plan or issuer (the "parties") may initiate in the event that the parties cannot reach mutual agreement over the OON rate following a 30-day open negotiation period. The Part II Rule specifies the scope, procedures, and timelines governing the federal IDR process as follows:

1. Before IDR – Open Negotiation Period (30 Days)

Absent an All-Payer Model Agreement or applicable state law, the parties may engage in open negotiations to determine the OON payment rate, including any cost sharing. This open negotiation period may be initiated by either party by sending the opposing party written notice

[3] *See generally* 29 CFR §§ 2590.715-2719 – 2590.717-2 (as added by the Rule).
[4] Rule preamble discussion at 56049
[5] Rule preamble discussion at 56056.

within 30 business days of the provider's receipt of the initial payment or notice of payment denial. The 30-day negotiation period begins the day the notice is sent to the opposing party. If the parties do not reach agreement on the OON rate during the negotiation period, either party may initiate the federal IDR process only after the 30-day period lapses.

2. Initiating the Federal IDR Process

Initiation of IDR Process
Either party may initiate the IDR process within 4 business days of the lapse of the open negotiation period by providing written notice to the opposing party and notifying HHS by submitting notice through the federal IDR portal. The notice of IDR initiation must contain sufficient information about the item/service, the parties, the negotiation process, the party's preferred certified IDR entity, and other information as specified in the Rule.[6]

Selection of Certified IDR Entity
To be eligible for selection, an IDR entity must meet specified certification criteria (see Certification section below) and be certified by the Departments.[7] The parties may jointly select a certified IDR entity within 3 business days of the IDR initiation, otherwise they must notify HHS who will select a certified IDR entity within 6 business days of the IDR initiation. Each party must pay a non-refundable administrative fee at the time of the IDR entity's selection, to be established annually. The fee for 2022 is $50.

The certified IDR entity must meet the following requirements and attest to such upon selection:

- Have no conflicts of interest;
- Ensure that any personnel assigned to the dispute has no conflicts of interest; and
- Ensure that any assignment of personnel to the dispute is not based on the likelihood that the assigned person will support a particular party to the dispute. [8]

Certification of IDR Entities
In order to be certified by the Departments, an IDR Entity must satisfy the following standards:

- Possess sufficient arbitration, health care claims administration, billing, medical and legal expertise to make payment determinations
- Employ sufficient number of personnel to make the determination
- Maintain current accreditation from recognized organizations or otherwise demonstrate completion of the requisite training
- Have a process to ensure no conflicts of interest exist between personnel and the parties
- Have a process to maintain confidentiality of individual health information obtained during IDR process
- Meet appropriate indicators of fiscal integrity and stability[9]

[6] *See* 29 CFR § 2590-716-8(b)(2)(iii) (as added by the Rule).
[7] *See Id.* at (e).
[8] *See Id.* at (a)(iv), (c)(1)(ii).
[9] *See Id.* at (e)(1)-(6).

Each IDR entity must also submit the fee amount it intends to charge for payment determinations, which must fall within the fee limits set forth annually in guidance by HHS. For calendar year 2022, IDR entities must charge between $200 and $500 for single determinations and $268 and $670 for batched determinations.[10] In developing the allowable fee ranges, HHS considers fees for similar state-managed IDR processes, the costs for IDR entities to meet IDR process requirements, and the anticipated volume of determinations, among other factors.[11] IDR entities may receive approval from HHS to charge a fee beyond the upper or lower fee limits by submitting a written proposal demonstrating that the alternative fee is appropriate.

Batched Services

Qualified IDR items and services may be considered jointly as part of one payment determination under the following conditions:

- The items/services are billed by same provider, group of providers, facility, or ambulance service (a/k/a billed with same NPI or TIN);
- Payment would be made by same group health plan or health insurance issuer;
- The items/services are the same or similar items and services (billed under same service code, or comparable code); and
- The items/services were furnished within same 30-day business period or 90-day suspension period.[12]

Joint submission is also permitted where the items/services are part of a bundled payment arrangement. Bundled submissions are subject to the batched determination rules above. Notably, prong two of these requirements specifies that the payment must be made by the same plan or issuer. It is worth noting that the Act does not offer an option for multiple self-insured plans to batch their payments if administered by the same TPA and there is therefore no such option in the Part II Rule. The restriction to plan or issuer in the batching context is, however, markedly different from the Act's approach to the QPA methodology, which explicitly allows various self-insured plans administered by the same TPA to make up the relevant "insurance market."[13]

3. Determining the Out of Network Payment Amount

Submission of Offers

Within 10 business days of selecting the certified IDR entity, each party must submit an offer of an OON rate and submit the calculated QPA for the same/similar item or service. The offer must be expressed as both a dollar amount and the corresponding percentage of the qualified payment amount (QPA) represented by that dollar amount. The methodology for calculating the QPA is laid out in the Part I Rule and, in general terms, represents the median of the contracted rates

[10] *See* CMS Technical Guidance No. 2021-01, *Calendar Year 2022 Fee Guidance for the Federal Independent Dispute Resolution Process under the No Surprises Act*, September 30, 2021, available at https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Technical-Guidance-CY2022-Fee-Guidance-Federal-Independent-Dispute-Resolution-Process-NSA.pdf.
[11] Rule preamble discussion at 56005.
[12] *Id.* at (c)(3).
[13] *See* 29 CFR § 2590-716-6(a)(8).

paid by the plan or issuer for the same/similar items or services in the same insurance market and geographic region, increased for inflation.[14]

The parties must also submit any information requested by the IDR entity relating to the offer and specific information regarding the size and practice specialty (for provider/facilities) or the plan/issuer's coverage area, relevant geographic region, and whether the coverage is fully/partially and/or self-insured (for payers). The parties may submit additional information relating to the offer, except information prohibited from being considered as described below. Along with their offer, each party must pay the predetermined certified IDR entity fee. The prevailing party will be reimbursed for their entity fee within 30 business days of the IDR entity's determination.

Considerations in Determining Payment Amount

In determining the payment amount, the IDR entity must consider the QPA for the applicable year for the same or similar service and the information requested by the IDR entity (as noted above), if credible. Notably, "the certified IDR entity **must** select the offer closest to the qualifying payment amount unless the certified IDR entity determines that credible information submitted by either party… clearly demonstrates that the qualified payment amount is materially different from the appropriate out-of-network rate, or if the offers are equally distant from the qualifying payment amount but in opposing directions. In these cases, the certified IDR entity must select the offer as the out-of-network rate that the certified IDR entity determines best represents the value of the qualified IDR item or services, which could be either offer" (emphasis added). [15]

The certified IDR entity must also consider the following additional information submitted by a party if the information is credible and clearly demonstrates that the QPA is materially different from the appropriate OON rate:

- The level of training, experience, and quality measures of provider/facility that furnished service
- The market share of provider/facility or plan/insurer (or TPA when self-insurer relies on that network) in geographic region where service furnished
- The acuity of patient or complexity of furnishing service
- The teaching status, case mix, scope of services of the furnishing facility
- Demonstration of good faith efforts (or lack thereof) to enter into network agreements and, if applicable, contracted rates between them during previous 4 plan years[16]

Note that the additional information that must be considered if submitted with respect to air ambulance services is similar to those noted above (with the exception of market share), and also includes the following:

- Ambulance vehicle type, including the vehicle's clinical capability
- Population density of the pick-up point [17]

[14] *See* 29 CFR § 2590.716-6 (as added by the Rule).
[15] 29 CFR § 2590-716-8 (c)(4)(ii)(A) (as added by the Rule).
[16] *Id* at (c)(iii).
[17] 29 CFR § 2590-717-2(b) (as added by the Rule).

The certified IDR entity must also consider any additional credible information relating to the offer that is submitted by a party, however the IDR entity may NOT consider usual and customary charges, the amount that would have been billed absent the balance billing prohibition, or public payer reimbursement rates.

IDR Entity Decision

The IDR entity must explain its determination in a written decision to the parties and HHS within 30 business days after being selected. If the IDR entity does not choose the offer closest to the QPA, then the decision must include an explanation of the credible information relied upon. The IDR entity's decision is binding and is not subject to judicial review except in instances of corruption, fraud or other specified forms of arbitrator misconduct.[18]

The plan or issuer must make any additional payment (if applicable) to the provider/facility within 30 calendar days of the IDR entity's payment determination. If the plan or issuer paid in excess of the offer selected, the provider/facility must reimburse the payer within same time 30-day time period.

EXTERNAL REVIEW

The Part II Rule implements the Act's expansion of the scope of claims subject to the existing external review process available to insured individuals following an adverse benefit determination.[19] Under the Rule, determinations related to compliance with the surprise billing and cost sharing protections under the No Surprises Act are eligible for external review. Notably, the Rule also extends this expanded requirement to grandfathered plans (who are not otherwise subject to external review).

PROTECTIONS FOR THE UNINSURED

The Part II Rule also includes protections for uninsured/self-pay individuals. Specifically, upon a patient's request or upon scheduling a service, the provider or facility must furnish a good faith estimate of expected charges to the uninsured individual.[20] If the uninsured individual is billed $400 or more in excess of the good faith estimate, the Rule establishes a patient-provider dispute resolution process that the individual may initiate.[21]

[18] *See* 9 USC § 10(a)(1)-(4) for specific instances in which judicial review is permitted.
[19] 29 CFR § 2590-715-2719 (as added by the Rule).
[20] *See* 45 CFR § 149.610 (as added by the Rule).
[21] *See* 45 CFR § 149.620 (as added by the Rule).