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July 13, 2021

MEMORANDUM

TO: **The Council**

FROM: **Scott Sinder**
Ashley Stewart

RE: **"No Surprises Act" – Interim Final Regulations (Round 1)**

The Departments of the Treasury, Labor, and Health and Human Services, and the Office of Personnel Management issued their first set of regulations – which technically will become final on an "interim" basis on September 13, 2021 but which do not apply to plans until 2022 – implementing the "No Surprises Act" which was enacted into law last December.[1] The surprise billing provisions are designed to protect consumers from surprise medical or "balance" bills from out-of-network ("OON") providers in certain situations.

The first round of "interim final" regulations (the "Rule") is generally a straight forward application of the statutory requirements related to:

- The three core balanced billing prohibitions for both payors and providers (OON emergency services; services provided by OON providers at in-network facilities; and OON air ambulance services);
- The manner in which the payment is calculated if an applicable state law regime applies;
- How the payor's "Qualifying Payment Amount" (which is the basis on which the payor's initial payment offer to the OON provider in the absence of an applicable state regime) is calculated;
- Consumer complaint notices and procedures for both payor and provider rule violations; and
- Plan consumer provider choice requirements.[2]

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[1] *See* Interim Final Rule, Requirements Related to Surprise Billing; Part I, 86 Fed. Reg. 36872 (July 13, 2021) (hereinafter "Rule"). *Availabale at* https://www.govinfo.gov/content/pkg/FR-2021-07-13/pdf/2021-14379.pdf.
[2] *See generally* 29 CFR §§ 2590.716-1 – 2590.722 (as added by the Rule).

As outlined in more detail below, there are a few key areas in the Rule that do provide clarification beyond the four-corners of the statutory text and that may warrant comment:

- Whether self-insured ERISA plans should be permitted to opt-in to a State's surprise billing regulatory regime even if the state law does not affirmatively provide for that?

- The regulators recognize that the QPA calculations for self-insured plans likely will be made by TPAs and there are a number of provisions that seek to make that process as administratively simple for self-insured plans as possible. That said, the regulators specifically are seeking comments on whether these proposals are viable and on the ability of plan sponsor fiduciaries to monitor their TPA's QPA calculations?

This first round of regulations does not address the most contentious piece of the "surprise billing" legislation – the independent dispute resolution arbitration process that can be used when the payor and the provider are unable to agree on the payment amount. We anticipate receiving those rules in the next few months.

The regulators estimate that insurers and TPAs will spend $4 billion in technology transition costs and that they will spend an additional $725 million per year on on-going operational costs. Because the IDR process is omitted from this round of rules, no costs related to that process are included in the cost estimates.

The Rule clarifies that, for payors, the new requirements will apply to plan years that start on or after January 1, 2022.[3] The Rule also clarifies that the Act's requirements do not apply to excepted benefits, short-term limited-duration insurance and Health Reimbursement Accounts or other account-based group health plans.[4] Comments on the Rule are due by September 7, 2021. The analysis below focuses on the components of the Rule that impact health plans.

Analysis

1. **Basic Rule**

The No Surprises Act caps cost-sharing obligations for patients who receive OON care to their applicable in-network levels (and requires plans to make up the difference) in the following circumstances:

- For emergency services performed by an OON provider and/or at an OON facility and for post-stabilization care after an emergency if the patient cannot be moved;

- When non-emergency services are performed by OON providers at in-network facilities (inclduing hospitals, ambulatory surgical centers, labs, radiology facilities and imaging centers); and

- For air ambulance services provided by OON providers.

[3] *See* 29 CFR §§ 2590.715-2719A, 716-4(d), 716-5(d), 716-6(f), 717-1(c) (as added by the Rule).
[4] *See* 29 CFR § 2590.716-2(b) (as added by the Rule).

The Rule effectuates these requirements by essentially restating them, incorporating a host of pre-existing definitions[5] and by requiring that these services be covered –

- Without the need for any prior authorization, even if the services are provided on an OON basis;

- Without regard to whether the provider is a participating provider or a participating emergency facility with respect to the services;

- Without limiting what constitutes an "emergency medical condition" solely on the basis of diagnosis codes; and

- For covered services other than air ambulance services, without imposing any administrative requirement or limitation on coverage that is more restrictive than and without imposing any cost-sharing requirements that differ from the requirements or limitations that would apply to the provision of such services on an in-network basis.[6]

The Rule does allow the application of benefit coordination rules (to the extent that they do not otherwise conflict with the emergency services billing requirements), affiliation or waiting period requirements, and applicable cost-sharing requirements.[7]

Most notably, the Rule incorporates a pre-existing definition of "emergency services" and the regulators make clear that plans may not deviate from the definition or limit the applicability of the plan to "emergency services" if any "emergency services" are covered by the plan.[8]

2. Determining The Amount The Plan/Insurer Must Pay To The OON Facility/Provider

To determine the amount the patient's plan owes the provider(s) when the OON rules apply, the No Surprises Act imposes three different rules and the Rule clarifies the scope of their application. First, if the care is provided in a State that participates in the All-Payer Model Agreement, then the Act dictates that the amount the State approves under that system applies to determine the OON rate if the Agreement applies to:

- the coverage involved;
- the nonparticipating provider, nonparticipating emergency facility or nonparticipating provider of air ambulance services involved; and
- the item or service involved.[9]

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[5] *See* 29 CFR § 2590.716-3 ("Definitions") (as added by the Rule).
[6] *See* 29 CFR § 2590.716-4 (as added by the Rule).
[7] *Id.* at (b)(5).
[8] *Id.* at (c); *see also* Rule preamble discussion at 36878-79.
[9] Rule preamble discussion at 36885-86.

Critically, the Rule notes that self-insured plans may opt into voluntary All-Provider Model Agreement regimes like the regime in place in Vermont and the Rule implies that self-insured plans in States that have compulsory regimes like Maryland are fully subject to those regimes.[10]

Second, if the care is provided in a State that has a law in place that would apply on its own terms to determine the amount the plan would owe to the provider, the State law applies.[11] The Rule notes that some States allow self-insured plans to opt-in to these regimes and the Department of Labor endorses that participation.[12] In States that have statutory payment regimes that are silent with respect to whether self-inured plans can opt-in, the regulators have asked whether they should dictate by rule that such an opt-in is expressly permitted?[13] They have made clear that any such opt-in, if allowed, will be required to be on an all or nothing basis.[14]

For care provided in States with no applicable rule and for air ambulance services disputes, the Act prescribes the following process:

1. The provider or facility submits an invoice to the care recipient's insurer or health plan for payment for the items or services received;
2. Within 30 calendar days after receiving that invoice, the insurer/health plan must send an initial payment to the provider or issue a notice of denial of payment;
3. During the 30 days after the initial payment or the notice of denial of payment is received, the provider, facility, insurer or health plan may initiate open negotiations in an effort to agree on a payment;
4. Within 4 days after the expiration of the 30-day negotiation period, any of the parties may initiate the new formal Independent Dispute Resolution Process (IDR) by submitting a notice to the other party and to HHS;
5. Within 3 days after the IDR initiation notice has been provided, the parties must jointly select a certified IDR entity (if the parties cannot agree, then HHS will select the IDR entity);
6. Within 10 days after the date the certified IDR entity is selected, the parties shall each submit an offer for a payment amount for the item or service furnished by the provider or facility and supporting information;
7. Within 30 days after the date the certified IDR entity is selected, the IDR entity is required to issue its payment determination by selecting one of the offers for payment submitted by the parties (so-called "baseball style arbitration");
8. The IDR determined payment must be made within 30 days of the rendering of that determination.

The amount that the insurer/health plan is required to pay initially if it does not issue a denial of payment is the "qualifying payment amount" for that item or service within that same geographic region. The Rule includes extensive guidance for calculating the "qualifying payment amounts"

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[10] *See* 29 CFR § 2590.716-3 (Definition of "Out-of-Network" rate in a State that has an All-Payer Model Agreement) (as added by the Rule).
[11] *See* 29 CFR § 2590.716-3 (Definition of "Specified State law") (as added by the Rule).
[12] *See* Rule preamble discussion, Example 4 at 36887.
[13] *See* Rule preamble discussion at 36885.
[14] *See Id.*

which generally are the median payment amounts for the same/similar items or services paid by the insurer or the plan within the same "insurance market" within the same "geographic area."[15] The guidance includes the requirements that apply when the payor has insufficient data to calculate the median rates in accordance with the Rule because, for example, the specified "geographic market" is too limited or the OON claim relates to a newly covered item or service.[16] And the Rule also outlines the inflation adjustments that are to be applied to the calculations which vary to some extent by the service being provided.[17]

Self-insured plans are defined as a separate "insurance market" (along with the individual, small-group and large-group markets). The Rule requires that all of the plans of the same plan sponsor be aggregated together in calculating the qualifying payment amounts on behalf of the plan.[18] In addition, the Rule allows, "at the option of the plan sponsor, all self-insured group health plans administered by the same entity (including a third-party administrator contracted by the plan" to be aggregated together for the purpose of making these calculations.[19] As noted above, the regulators recognize that TPAs generally will be making the QPA calculations on behalf of self-insured plans and they asked for comment on whether the plans would be able to properly oversee these TPA activities.[20] They also are seeking comment on whether there are any contractual issues that would interfere with or prevent any entity, such as a third-party administrator, from using contracted rates from different self-insured plans it administers to calculate the QPA for a particular self-insured group health plan" in accordance with the self-insured plan aggregation opt-in allowance.[21]

The Rule also dictates the manner in which QPA calculations must be shared with the OON provider(s) along with specified disclosures related to the payment resolution process and the OON provider(s) right to request additional information related to the manner in which the QPA was calculated.[22]

Finally, the Rule outlines the consumer complaint process and establishes a process through which the Department of Labor can request additional information from the plan to which the consumer complaint relates and the rules related to the statutory right to designate the in-network primary care provider of the plan participant's choice.[23]

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[15] *See* 29 CFR § 2590.716-6 (as added by the Rule).
[16] *See, e.g., Id.* at (a)(7)(C) and (c)(3).
[17] *Id.* at (c)(1).
[18] *Id.* at (a)(8)(iv).
[19] *Id.*
[20] *See* Rule preamble discussion at 36890.
[21] *Id.*
[22] Rule at 36957.
[23] *See* 29 CFR §§ 2590.716-7 and .722 (as added by the Rule).