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The Devil may be in the Details of the Part II No Surprises Act IFR

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This post reviews Part II of the federal No Surprises Act regulations. In previous publications, we have commented upon the No Surprises Act, and Part I of the regulations.

The "Requirements Related to Surprise Billing; Part II" (the "Part II Rule"), published on October 7, 2021, is the second interim final rule (IFR) implementing the No Surprises Act, following a prior No Surprises Act IFR (the "Part I Rule") published on July 13, 2021. Both of these regulations are generally set to take effect on January 1, 2022.

In this post, we outline how the Part II Rule addresses: (A) the independent dispute resolution (IDR) and open negotiation processes for health plans and other payers ("Plans"), (B) patient-provider dispute resolution processes for uninsured individuals, and (C) the expansion of the federal external review provisions of the Affordable Care Act to cover disputes regarding the application of the No Surprises Act.

By way of background, the No Surprises Act and its implementing regulations provide new federal protections against surprise medical billing. Surprise medical billing generally occurs when an individual receives an unexpected medical bill from a health care provider or facility after receiving services, where the individual did not understand that the provider or facility was not an "in-network" participating provider or facility under the individual's Plan. In this scenario, the health care provider or facility is an "out-of-network" (OON) or "non-participating" provider or facility. OON providers or facilities will typically not be subject to the discounted rates and favorable health benefit rules (such as lower cost sharing responsibilities) applicable to the use of in-network participating providers or facilities. As a result, receiving services from an OON provider or facility can result in the imposition of significant and unexpected financial liability on the individual and their family.

Additionally, and as we touched upon in our January 7, 2021 post on the *No Surprises Act*, these new measures supplement state laws governing surprise medical billing, and so in cases where a state No Surprises law applies, the state law generally determines an individual's OON payment rate.[1]

A. Independent Dispute Resolution and Open Negotiation

The Part II Rule establishes a federal IDR process to settle certain disputes over OON payment rates for certain emergency services, and certain non-emergency items and services furnished by OON providers at in-network health care facilities.[2]

Under the federal IDR process, once a provider or facility receives an initial payment or notice of denial of payment by the Plan[3], the provider, facility or Plan may initiate an open negotiation period within 30 business days beginning on the date such payment or denial was received. The open negotiation period may continue for up to 30 business days. If a payment amount cannot be agreed upon during the 30-business-day window, either party may initiate the federal IDR process by submitting a written Notice of IDR initiation to the other party and to relevant federal agencies (the "Departments").[4] The parties must then jointly select an independent dispute resolution entity that has been "certified" under the No Surprises Act to perform such role ("IDRE"). If the parties cannot mutually agree on an IDRE, the Departments will assign one.

Once an IDRE is selected or appointed, the issuer and the OON provider or facility must each submit an offer for a payment amount for the disputed service. The IDRE is required to select the offer closest to the Qualifying Payment Amount (QPA) (which generally is the median contracted in-network rate paid by the payer for the same or similar services in that geographic area),[5] unless the parties submit additional information to the IDRE that proves the QPA is materially different from the appropriate OON rate.

The Part II Rule sets forth factors that the IDRE may consider in its assessment of additional information, including: (a) the level of training, experience, qualities and outcome measurements of a provider or facility;[6] (b) the market share held by the OON provider or facility, or the Plan; (c) patient acuity or the complexity of furnishing a particular item or service; (d) teaching status, case mix and scope of services of the OON facility; (e) demonstrations of good faith efforts made by the OON provider, facility and/or Plan to enter network participation agreements between the provider or facility and the Plan and (f) all other credible and relevant information submitted by either party.

The Part II Rule lists specific examples of factual circumstances and appropriate IDRE outcomes, and makes clear that a mere statement of higher case complexity, experience level or other status-based factors will not in themselves justify overruling the QPA, unless the provider demonstrates how the factors make the QPA an inappropriate OON rate.

The IDRE's decision is binding on all parties. The decision is treated as an arbitrator's award under the Federal Arbitration Act, and subject to the same limitations on judicial review.[7] The party that initiated the IDR process cannot submit a subsequent claim for the same or similar item or service for a "cooling-off period" of 90 days.

Since the median rate that the provider is paid by Plans, when it is in-network may exceed the median rate the Plan otherwise pays to other providers, the use of the latter median in-network rate paid by the payer as the presumptive appropriate OON rate may, in certain circumstances, give payers little incentive to negotiate.

With respect to the No Surprises Act's emphasis on the QPA for resolving these disputes, we note that, significantly, managed care negotiations sometimes turn on the risks to the provider and the payer of the provider being OON and non-participating. The "thumb on the scale" QPA presumption may have less of an impact on providers that are "must-haves" for a plan based on clinical importance, or high patient-satisfaction scores. But for other providers and facilities, the impact is likely to be greater. In simple terms, in the past, if a provider or facility did not reach an in-network payment agreement with a given health plan, the tradeoff was less volume for the provider or facility (e.g., no elective services) but greater revenue when treating the OON patient (because of the ability of the provider or facility to obtain charge-based or otherwise premium OON payments). These calculations can no longer apply. It is likely for this reason that "demonstrations of good faith efforts… to enter into network agreements" are among the factors that are included in the No Surprises Act, and in the Part II Rule, as potentially overcoming the presumption of the QPA as the appropriate OON rate.

In addition, hospitals and medical associations have generally expressed serious concerns about the Part II regulations, including regarding use of the QPA as the presumptive choice for establishing payment rates under these circumstances, as well as the administrative burden presented. The Texas Medical Association ("TMA") has already sued to prevent the application of the presumptive QPA process, asserting that payers have an outsized amount of leverage in determining reimbursement rate pricing. Moreover the TMA lawsuit also claims that the regulations were issued without adequate notice for interested parties to submit comments.[8] More litigation is likely to follow.

Good Faith Estimates for Uninsured Individuals

The Part II Rule will require providers and facilities, upon scheduling an item or service to be furnished to an individual, or upon request of an individual, to provide uninsured (or self-pay) patients a written, good faith estimate of the expected charges for furnishing the item or service (including any item or service that is reasonably expected to be provided in conjunction with the scheduled or requested item or service and such item or service reasonably expected to be provided by another provider or facility, with the expected billing and diagnostic codes for any such item or service).[9] Although the good faith estimate provision will take effect on January 1, 2022, HHS has stated it will exercise enforcement discretion in situations where a good faith estimate does not include expected charges from co-providers and co-facilities through December 31, 2022.[10] By then, the Departments anticipate processes should be in place for the main provider or facility to obtain information regarding such price estimates from the co-provider or co-facility. Additionally, the Part II Rule provides that providers or facilities who act in good faith and with reasonable due diligence will not fail to comply with these requirements upon making an error in a good faith estimate, provided that they correct the information as soon as practicable.

We note the challenges associated with this new requirement to furnish good faith estimates to these individual patients, and have concerns that the January 1, 2022 effective date may not allow providers or facilities sufficient time to develop and implement systems for compliance. In addition, while some enforcement discretion has been signaled, as currently drafted, the Part II Rules arguably do not provide sufficient leeway to address these compliance challenges.

B. Patient-Provider Dispute Resolution

In the event an uninsured (or self-pay) individual receives a good faith estimate but is billed for an amount substantially in excess of the good-faith estimate, patients will have access to a patient-provider dispute resolution process to determine an appropriate payment amount. The Part II Rule defines “substantially in excess” as amounts that are at least $400 more than the total amount of expected charges listed on the good faith estimate. Parties must initiate the dispute resolution process within 120 calendar days of the patient receiving the bill. Once the dispute resolution process is initiated, HHS will appoint a selected dispute resolution entity, certified under the No Surprises Act (SDRE) to make a payment determination within 30 business days after information about the proceedings is received. The SDRE is expected to make a separate determination for each item or service charged based on the information provided for the billed charges and the expected charges. The Part II Rules state that the SDRE should use the expected charges in the good faith estimate as the presumed appropriate amount, and notes that the provider or facility may seek to justify the difference by demonstrating that the difference reflects unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided.

C. External Review

The Part II Rule generally expands the scope of claims eligible for external review as established under the Affordable Care Act to include adverse benefit determinations by health benefit plans and health insurance issuers related to compliance with the No Surprises Act. The Part II Rule provides examples of the types of adverse benefit determinations which are newly eligible for external review. In addition, the Part II Rule requires grandfathered health benefit plans that generally are exempt from requirements related to external review, nonetheless to provide for external review of adverse benefit determinations for claims subject to the surprise billing protections in the No Surprises Act. The Part II Rule specifies that patients in such grandfathered plans shall be permitted to access external review after exhausting applicable appeal rights under state law or under the terms of the patient’s health benefit plan coverage.

As noted, the Part II Rule is set to take effect generally beginning on January 1, 2022.

[1] See, *e.g.,* Centers for Medicare & Medicaid Services Fact Sheet, "Requirements Related to Surprise Billing; Part II Interim Final Rule with Comment Period (September 20, 2021) at https://www.cms.gov/newsroom/fact-sheets/requirements-related-surprise-billing-part-ii-interim-final-rule-comment-period . It appears that (i) all commercial Plans will be governed by the specified State law, (ii) federal employees (the FEHP) will not be subject to such State law and will utilize the federal IDR process, and (iii) self-insured ERISA Plans will use the specified State law unless such use is barred by ERISA (which at least as to the determination as to the OON payment amount, appears to be the case), in which event the Plan can "opt-in" to the specified State No Surprises law.

[2] See 86 Fed. Reg. 55980 at 55984 (October 7, 2021)

[3] The Part I Rule specifies that payers must provide certain disclosures and other information upon such initial payments or notices of denial of payments. See, *e.g.,* 86 Fed. Reg. at 36898 (July 13, 2021).

[4] The Departments include the Departments of Health and Human Services (HHS), Treasury, Labor, and the Office of Personnel Management ("the Departments")

[5] See 86 Fed. Reg. at 55984-55985 (October 7, 2021).

[6] In order for an IDRE to consider this additional information, the credible information must clearly demonstrate that the QPA failed to take into account that the experience or level of training of a provider was necessary for providing the qualified IDR item or service to the patient or that the experience or training made an impact on the care that was provided.

[7] Except as set forth in 9 U.S.C. 10(a)(1)-(4).

[8] https://www.healthcaredive.com/news/texas-medical-association-lawsuit-block-surprise-billing-ban/609198/

[9] See, *e.g.*, 86 Fed. Reg. at 56013 (October 7, 2021)

[10] See 86 Fed. Reg. at 56023 (October 7, 2021)

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