GLOBAL MEDICAL RESPONSE COMMENTS ON THE NO SURPRISES ACT PART II RULEMAKING

August 4, 2021

In this paper, GMR offers its recommendations for Part II of the No Surprises Act (NSA) rulemaking. We believe these recommendations will protect patients from surprise medical bills, consistent with the intent of the law, and ensure a fair and transparent Independent Dispute Resolution (IDR) process.

GMR recommends the Departments address the following three key areas in Part II of its rulemaking:

- **No Special Weight to Qualifying Payment Amount (QPA).** Congress elected not to assign any special weight to the QPA, and the Departments cannot override that election through rulemaking. Furthermore, the QPA methodology established in Part I of the rulemaking will in many instances result in a QPA that is completely divorced from actual market conditions. It is imperative that IDR Entities have the discretion to consider all of the information required to be taken into consideration under the statute, and determine whether the QPA calculated by the insurer is a reasonable benchmark for a fair market rate.

- **Close the Medical Necessity Loophole.** Currently, many out-of-network emergency air ambulance transports are initially denied based on a supposed lack of "medical necessity," although the majority of those determinations are overturned after appeal. Under the policies adopted in the Part I rulemaking, such denials will not be eligible for IDR, leaving it up to the patient to challenge a coverage denial (and the surprise bill that will result) through the claims appeal process. Payors should not be allowed to "opt-out" of the IDR process for any emergency air ambulance claims merely by denying them for medical necessity, whether or not that is later borne out by the facts, leaving the patient with the full financial responsibility for the billed charges. In Part II, the Departments can protect patients from these inappropriate denials of emergency air ambulance claims by clarifying that emergency air ambulance services are "emergency services" appropriate for treating an "emergency medical condition," which would explicitly require payors to cover emergency air ambulance services under a "prudent layperson" standard prior to an initial denial, and regardless of whether the services are considered hospital outpatient services (already expressly subject to the prudent layperson standard) or non-hospital ambulance services.

- **Encourage Settlement in Open Negotiation through Transparency.** To encourage settlement during the open negotiation period (avoiding IDR), discourage parties from withholding relevant information during the open negotiation period. The Part II regulations should provide that where a party introduces new information during IDR that had not previously been disclosed to the other party, the other party will be entitled to an extension of time, on the grounds of extenuating circumstances, to respond to the new information.

We address each of these recommendations more fully below.

1. Do Not Grant any Special Weight to the Qualifying Payment Amount (QPA)

In Part I of the No Surprises Act rulemaking, the Departments established the methodology that group health plans and health insurance issues (collectively, "payors") must use to determine the QPA.

In the preamble discussion to the Interim Final Rule with Comment Period (IFC), the Departments state the preference that payors should be able to rely upon their contracted rates in calculating a QPA, and that alternative methodologies (like reference to a claims database) should be used "only in limited circumstances where the plan or issue cannot rely on its contracted rates as a reflection of the market dynamics in a geographic region."[1] The Departments implemented this preference by only requiring three (3) in-network agreements to calculate a QPA, and also permitting the reference geographic region to include just three contracts across up to eight states. This will lead to inconsistent and irrational results. For example, a payor with a national insurance network that only has rural provider in-network agreements in Oregon would be able to use its Oregon-only contracts to set the QPA for flights for all its covered lives in Washington, California, Alaska, and Hawaii, and then would rely on a database for all other states outside the Census Region. State-based regions are reasonable and predictable, which encourage settlement through negotiations and will help prevent claims from going to IDR.

For 2022, an in-network agreement is required only to be in effect on January 31, 2019—there is no requirement that any transports were ever actually covered by the in-network agreement or that the agreement remain in effect in 2022. Payor standard in-network agreements for air ambulance services often include rates for emergency rotor-wing services and both emergency and non-emergency fixed-wing services. Many air ambulance providers offer only one of those services in a specific state and focus their rate negotiations exclusively on the services actually provided, which can lead to rates that are never used being included in in-network agreements. Also, there are air ambulance providers who are no longer in existence but who had in-network agreements on January 31, 2019. At least some of those providers have ceased to operate because they were not financially viable. It does not make sense to use in-network rates for a company that no longer exists to determine the QPA.

Given the policy decisions made in the Part I IFC—especially for emergency air ambulance services—the QPA calculation as currently designed will naturally result in amounts that are completely divorced from the market realities within a given locality. In some areas, we may see artificially high QPAs, and in others we may see artificially low QPAs. Neither represent a real market rate, and neither will have the desired effect of limiting advancing to IDR.

[1] 86 Fed. Reg. 36,872, 36,888 (July 13, 2021).

For air ambulance, given that the QPA will serve as the amount against which patient cost-sharing is calculated,[2] we appreciate the incentive to protect patients by keeping the QPA low, but these multi-state groups may instead increase the patient out-of-pocket with an artificially high QPA in some cases.[3] The second purpose of the QPA is to serve as one of several evidentiary data points the IDR entity must consider in determining an appropriate payment rate. In this respect, the IDR entity's incentive is to achieve a fair result—the patient's financial responsibility will not change based upon the final IDR-determined rate. Fairness dictates that an IDR entity have the ability to consider all of the facts before it, without special weight or consideration being given to any one factor.

We understand that insurers and payor organizations (including payor-backed organizations like the Coalition Against Surprise Medical Billing) are urging the Departments to require, through regulation, IDR entities to give presumptive weight to the payor-calculated QPA in making payment determinations. But as discussed above, because of the policies adopted in the Part I IFC, the QPA will often not be a good proxy for an air ambulance fair market rate, which is yet another example of how the air ambulance market differs from other markets. Where the QPA is artificially low or artificially high, fairness dictates that the IDR entity be free to assign less probative value to the QPA, and ultimately be free to select the offer that is most reasonable given all the facts, whether or not it closely aligns with the QPA. Placing extra weight on the QPA is tantamount to placing a thumb on the scale in favor of payors.

In addition to the dictates of fairness, the Departments must abide by the dictates of the law. Here, the law clearly forecloses the approach favored by payor organizations like the payor-supported Coalition Against Surprise Medical Billing. Congress has directly addressed the questions of what an IDR entity must consider, what it may consider, and what it cannot consider.[4]

The IDR entity *must* consider:

- The QPA;
- All information submitted by the parties relevant to the payment determination (including information supporting offers submitted);
- All information submitted by the parties as requested by the IDR entity;
- Quality and outcomes measures of the air ambulance provider;
- The acuity of the individual receiving such services, or the complexity of furnishing services to the individual;

[2] Patient responsibility is calculated for air ambulance services as based on the lower of the QPA billed charges.

[3] For example, the patient responsibility in rural West Virginia could be calculated based on a reference QPA from contracts in South Florida.

[4] E.g., PHSA § 2799A-2(b)(5)(C).

- The training, experience, and quality of medical personnel furnishing the air ambulance service;

- Ambulance vehicle type, including clinical capability level of such vehicle;

- Population density of the pick-up location (such as urban, rural, or frontier); and

- Demonstrations of good faith efforts (or lack of good faith efforts) made by the parties to enter into network agreements and contracted rates during the previous 4 plan years.

The IDR entity *may* also request additional information relating to the parties' offers, and must consider any information submitted by the parties in response to such request. The IDR entity is expressly *prohibited* from considering certain factors, like a provider's usual and customary charges, or rates paid by federal health care programs.

Notably absent from this section of the NSA is any invitation from Congress to the Departments to weight the considerations enumerated in the law. Nor is there any ambiguity or gap for the Departments to fill.[5] To know what Congress intended the IDR entity to consider, one need only look at the plain language of the law.[6] In reviewing this language, there is absolutely no evidence that Congress intended the QPA to carry any greater weight than any other of the enumerated factors.[7] Indeed, had Congress wanted the QPA to be given presumptive weight or be the primary driver of the IDR entity's decision, it certainly could have done so.

Given that the statute says the IDR entity must consider the QPA, the Departments have done what they can to ensure that a QPA can be calculated and that, together with a long list of other information, it may demonstrate to the IDR entity that the QPA is not an appropriate market rate.

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[5] Under the *Chevron* framework, the court, "applying the ordinary tools of statutory construction, … must [first] determine 'whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.'" *Ciox Health, LLC v. Azar*, 435 F. Supp. 3d 30, 63 (D.D.C. 2020) (invalidating an agency regulation that expanded upon a Congressional directive, stating that the text of the statute "evinces no intent by Congress for HHS to take steps to augment or further define" the directive) (citations omitted).

[6] As noted above, under *Chevron*, the court is to employ the "traditional tools of statutory construction," in its step-one analysis. *Chevron*, 467 U.S. at 843, 104 S.Ct. 2778. While there are differing approaches to what constitutes the "traditional tools of statutory construction," the principle step in statutory interpretation is typically to begin with a textual analysis. See *Massachusetts v. EPA*, 549 U.S. 497, 528-29 (2007). Cf. Zuni Pub. Sch. Dist. No. 89 v. Dep't of Educ.,550 U.S. 81, 93 (2007) ("[N]ormally neither the legislative history nor the reasonableness of the Secretary's method would be determinative if the plain language of the statute unambiguously indicated that Congress sought to foreclose the Secretary's interpretation.").

[7] Indeed, had Congress wanted HHS to exercise discretion in prescribing how the IDR entity weights the statutory factors, it would have included such discretion in the statute. In many other parts of the No Surprises Act, Congress explicitly invites the Secretary to fill gaps in the statute. *See e.g.* PHSA 2799A-2(b)(7)(C) ("For 2022 and each subsequent year, an IDR entity, as a condition of certification as an IDR entity, shall submit to the Secretary such information as the Secretary determines necessary for the Secretary to carry out the provisions of this paragraph."). The absence of similar language with respect to the factors the IDR entity must consider is telling. *See Ciox Health*, 435 F. Supp. 3d at 64 (noting that, unlike in other places throughout the HITECH Act, Congress did not invite the Secretary to augment or further define the statutory directive, and the absence of such invitation was telling).

The fact that the QPA appears first in a long list of considerations does not suggest, however, that Congress wanted it to be superior over all other factors. Were the Departments to use an item's place on a list, without more, as evidence of its importance to Congress, the Departments would be inventing a brand new canon of statutory construction—not to mention one that would have ramifications far beyond the No Surprises Act implementation.

Lastly, determination of a QPA based on a database fares no better. First, there is no existing database that contains more than 5% of the air ambulance transports in a State and, second, no existing database distinguishes between emergency and non-emergency transports.

2. Close the Medical Necessity Loophole

Under the NSA, payors must, within 30 days of receiving a clean claim for payment for covered emergency air ambulance services, if the services are covered, send an initial payment or a *notice of denial of payment* to the out-of-network provider. Upon receipt of such initial payment or notice of denial of payment, the out-of-network provider may initiate open negotiation and, if that fails, IDR.

In Part I of the NSA rulemaking, the Departments defined a "*notice of denial of payment*" to *exclude* a notice of benefit denial due to an adverse benefit determination (ABD).[8] According to the Departments, there is a "significant distinction" between an ABD, which patients can challenge through existing claims appeal processes, and payment denials that can be disputed by providers through IDR. However, we cannot conceive of any situation where a payor would issue a notice of denial of a clean claim for a covered service. We assume that the Departments are giving meaning to this statutory term, and urge the Departments to use the Part II rulemaking to provide stakeholders with a meaningful definition of this phrase.

This broad prohibition permits discretionary payor denials for an arbitrary, purported lack of medical necessity. Accordingly, if a payor initially determines services **are NOT covered** (for lack of medical necessity or another benefit denial reason), then (i) the payor and patient can proceed with an ABD resolution process under the terms of the patient's insurance coverage and (ii) the patient can receive the full bill for the air ambulance transport (which may be a surprise to the patient but is not a prohibited balance bill because the payor initially determined the services are NOT covered). Further, assuming the ABD resolution process takes longer than 30 days to resolve (which it undoubtedly will), even if the initial payor ABD is overturned months later, there is no process to bring the claim back into the NSA after 30 days from the payor's receipt of a clean claim.

On the other hand, if the payor initially determines the services **are covered** but no payment is due **for any reason other than an ABD,** then the payor would send a notice of denial of payment to the provider, the negotiation process established by the No Surprises Act will commence, and the patient will NOT receive the full bill, a surprise bill or a balance bill for the services, whether or not they are ultimately covered under the patient's insurance.

[8] Notably, the Departments did not provide any examples of what this might mean in Part I of the rulemaking. We cannot identify any notice of payment denials that would be unrelated to coverage. We encourage the Departments to address this apparent diversion between the IFC and the statutory text.

Potentially unique to emergency air ambulance services, this has the unintended consequence of allowing payors to opt-out of the IDR process entirely by making a discretionary, coverage-based denial, such as deeming a lack of medical necessity for an emergency air ambulance flight, whether or not ultimately supported by the facts. Currently, a material number of out-of-network emergency air ambulance flights are initially denied for a lack of medical necessity—often as a delay and negotiation tactic—as shown by the fact that most of those denials are later overturned on appeal.

However, the consequences of this determination are severe for the patient, who would otherwise be protected from such surprise insurance denials under the NSA. A coverage-based denial (or ABD) leaves the patient with full financial responsibility. Even if they are successful in appealing the denial through the claims appeal process, without further clarification from the Departments that the patient's claim subsequently becomes eligible for the IDR process, the patient is not protected by the provisions of the NSA. Unless the payor pays 100% of the claim following the internal/external review process, the patient would be responsible for the remainder of the claim.

If past is prelude, and payors continue to initially deny a significant number of emergency air ambulance claims as medically unnecessary, many patients who should otherwise be protected from surprise insurance denials may still be responsible for full billed charges. This outcome would be clearly inconsistent with the intent of the NSA.

One way to avoid this outcome would be for the Departments to revisit the position taken in Part I of the rulemaking that excludes all ABDs from the definition of "notice of denial of payment." For instance, the Departments could treat all ABDs, as a "denial of payment," which results in a payment of $0, each triggering negotiations or IDR between payors and providers. Patients retain their own rights to appeal under the statute, if they so desire, under existing internal and external review procedures.

Another way would be to use the Part II rulemaking to expressly apply the definition of "emergency medical condition" and "emergency services" as applied to all other providers under the NSA in requiring payors to cover the services as essential health benefits and applying a "prudent layperson" standard to *all* emergency air ambulance claims, *prior to* the initial denial. This policy would better protect patients from surprise medical bills, and would better align policy with the reality of how emergency air ambulance services are furnished. It is also consistent with the Departments' efforts to prevent plans or issuers from relying on diagnosis codes or methods other than the application of the prudent layperson standard for denying coverage for emergency services.[9] This would be reasonable, as:

- in the case of emergency air ambulance services, it is a physician or first responder—not the air ambulance provider—that makes the call as to what kind of transport is appropriate given the condition of the patient.[10]

[9] *See* 86 Fed. Reg. 36,872, 36,889–90.

[10] Medical necessity is a particularly challenging topic for air ambulance. Emergency Air Ambulance services do not self-dispatch. Requests for emergency air ambulance transport is based on established protocol at the determination of a trained medical professionals or first responder. In fact, Medicare applies a deemed medical

- air ambulance services are already considered "emergency services" requiring coverage and use of the prudent layperson standard **when provided by hospitals** subject to EMTALA. As the Departments recognized in the Part I rulemaking, "participants, beneficiaries, and enrollees frequently do not have the ability to choose their air ambulance provider,"[11] yet the standard by which their claim is reviewed—and the likelihood that the patient will be protected by the NSA at all—will nevertheless depend almost entirely upon whether the hospital has its own air ambulance or relies on an independent air ambulance provider. The regulations should reflect the fact that an emergency air transport by an independent air ambulance provider is no less of an emergency service than the same emergency air transport by a hospital air ambulance. Further, the Departments have acknowledged that a patient's emergency situation can continue from a transferring hospital to a receiving hospital. Imagine the patient's surprise to learn that the ED services at both the transferring hospital and receiving hospital are covered by the NSA, but the physician ordered air ambulance transport between the two hospitals is not covered under the NSA because it was initially denied by their insurance company as not medically necessary.

Finally, the Departments could also distinguish just medical necessity denials (under the statutory prudent layperson definition for "emergency medical condition" as applied to "emergency services," which expressly does not require medical judgment or payor contract analysis) from other ABD denials. By treating a medical necessity denial as a "$0" notice of denial of payment, it would be up to the the parties or a neutral IDR entity to determine if the emergency air ambulance flight did not meet the "prudent layperson" standard for an emergency, and accordingly was not medically necessary (and a $0 payment was appropriate). Notably, in such a situation, the patient would still be protected from a balance bill.

If the Departments do not address the medical necessity gap, the Departments should confirm that, if an adverse beneficiary determination (ABD) is issued, the provider can and will bill the patient for the full billed charges for the services as, when the payor pays nothing for services it determines are not covered, there is no balance bill—just a bill (even if the payor's ABD may be a surprise to the patient, who must then take it up with the payor through internal and external review). At the end of the internal or external review process, any remaining balance not covered by insurance would remain the patient's responsibility, when they receive a balance bill.

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necessity standard for rural air ambulance transports. However, after these emergency services are rendered, plans often make a post hoc determination that the services were not medically necessary by applying an internally developed standard of review. This standard is divorced from the reality of emergency medicine. The application of this heightened standard to independent air ambulance providers leads to a significant number of claims being denied on medical necessity grounds.

[11] 81 Fed. Reg. 36872, 36891 ("The Departments also understand that hospital-based air ambulance providers sometimes have lower contracted rates than independent, non-hospital-based air ambulance providers. The Departments, however, are of the view that because participants, beneficiaries, and enrollees frequently do not have the ability to choose their air ambulance provider, they should not be required to pay higher cost-sharing amounts (such as coinsurance or a deductible) solely because the air ambulance provider assigned to them has negotiated higher contracted rates in order to cover its higher costs, or because it has a different revenue model, than other types of air ambulance providers… The Departments have concluded that this interpretation is consistent with the statute's intent to protect individuals from surprise medical bills.").

3. IDR Process: Encourage Settlement in Open Negotiation through Transparency by Providing Parties with an Opportunity to Respond to the Other Party's New Information Provided with Submissions in IDR

To encourage transparency and efficiency in the open negotiations before entering the IDR process (thereby limiting the need for IDR), the Departments should encourage both parties to make robust disclosures of all relevant information during that open negotiation process. While GMR appreciates that there is a 10-day statutory deadline for both parties to submit their claims and supporting information to the IDR entity, the Departments have the express statutory authority to adjust those timeframes for "extenuating circumstances."

GMR recommends that the Departments include an "extenuating circumstances" provision that allows the IDR entity to give a party at least 5 days to respond to new information submitted by the opposing party during the IDR process, if that information was not disclosed during the open negotiation period.