IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION

TEXAS MEDICAL ASSOCIATION, *et al.*, Plaintiffs, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, Defendants.	No. 6:21-cv-00425-JDK

NOTICE OF FILING OF SUPPLEMENTAL ADMINISTRATIVE RECORD

The Defendants respectfully submit the attached supplement to the administrative record in support of the portions of *Requirements Related to Surprise Billing: Part II*, 86 Fed. Reg. 55,980, 56,046 (Oct. 7, 2021), that are at issue in this case.

Dated: January 24, 2022

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify on this 24th day of January, 2022, a true and correct copy of this document was served electronically by the Court's CM/ECF system to all counsel of record.

/s/ Joel McElvain
JOEL McELVAIN

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS

TEXAS MEDICAL ASSOCIATION and DR. ADAM CORLEY, *Plaintiffs,* v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.* *Defendants*.	Civil Action No. 1:21-cv-00425

SUPPLEMENTAL CERTIFICATION OF THE ADMINISTRATIVE RULEMAKING RECORD

I, Sheli Harris, Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs, Centers for Medicare & Medicaid Services ("CMS"), United States Department of Health and Human Services ("HHS"), certify that, to the best of my knowledge, the attached constitutes a true and complete copy of two documents that CMS considered in promulgating the portions of the interim final rule that Plaintiffs challenged in this action, which address the considerations for a certified independent dispute resolution ("IDR") entity to take into account in making a payment determination for a qualified IDR item or service, as well as related regulatory definitions including the definition of "material difference," 45 CFR §§ 149.510(a)(2)(v), (viii), (c)(4). *See Requirements Related to Surprise Billing; Part II*, 86 Fed. Reg. 55,980 (Oct. 7, 2021) (Interim Final Rule). These documents were inadvertently excluded from the previously produced administrative record for the challenged portions of the interim final rule. These documents, along with the documents previously designated as the administrative record, *see* ECF No. 66, constitute the complete administrative record for this matter.

Executed this 24th day of January 2022, in Baltimore, Maryland.

Sheli Harris

Sheli Harris, Deputy Director
Regulations Development Group
Office of Strategic Operations and Regulatory Affairs
Centers for Medicare & Medicaid Services
United States Department of Health and Human Services

SUPPLEMENTAL INDEX TO THE ADMINISTRATIVE RECORD FOR
Texas Medical Association v. HHS, 1:21-cv-00425

AMERICAN BENEFITS COUNCIL

June 11, 2021

Submitted via email

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RE: Implementation of the Surprise Billing Provisions in the Consolidated Appropriations Act, 2021

I write on behalf of the American Benefits Council ("the Council") to provide comments in anticipation of forthcoming regulations implementing the surprise billing provisions included in the Consolidated Appropriations Act, 2021 (CAA), to be issued by the U.S. departments of Health and Human Services (HHS), Labor and Treasury (collectively, "the Departments"). These provisions were enacted to achieve two vital policy goals. First, to protect consumers from "surprise bills" – unexpected (and

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typically large) bills for the difference between the provider's billed charge and the amount the plan will pay, for out-of-network emergency services and services provided by out-of-network providers in in-network settings. Second, to lower health care costs for all consumers. The extent to which the CAA ultimately achieves these goals hinges on the Departments' implementing regulations. The comments contained in this letter are aimed at ensuring that the forthcoming regulations achieve the CAA's goals as intended. The Council plans to separately follow up, in short order, with comments on the transparency provisions relevant to employer-sponsored group health plans contained in the CAA.

The Council is dedicated to protecting employer-sponsored benefit plans. The Council represents more major employers – over 220 of the world's largest corporations – than any other association that exclusively advocates on the full range of employee benefit issues. Members also include organizations supporting employers of all sizes. Collectively, Council members directly sponsor or support health and retirement plans covering virtually all Americans participating in employer-sponsored programs.

For many years, employers have been deeply concerned about the burden that surprise bills place on employees and their families. The root cause has shown itself to be a lack of meaningful patient choice in selecting providers in these contexts, which has allowed certain specialized providers to charge inflated rates by staying out-of-network, generating surprise bills, without providers needing to be concerned that they will lose patient volume.

In addition to burdening specific employees and their families, surprise bills have had a negative impact on health care coverage for all consumers. This is because the incentive for certain providers to stay out-of-network and charge inflated rates constitutes a market failure that has limited the benefits of networks in controlling costs for patients and plans. The ability to stay out-of-network and impose surprise bills has given certain providers more leverage to inflate the rates they will agree to for participating in-network, which increases costs for plans and participants.[1] In addition, surprise bills have had an adverse impact specifically on self-insured employers' health care expenditures and, as a result, on participants in these plans. This is because many employers have established processes to pay or to help employees negotiate these surprise bills. These costs are ultimately passed through in whole or in part to employees and their families.

To address these significant issues, for the past several years the Council urged Congress to address surprise billing, both in order to protect consumers who would otherwise face these bills and to address the more general market failure and reduce health care costs for *all* consumers.

[1] *See* https://www.ajmc.com/view/policies-to-address-surprise-billing-can-affect-health-insurance-premiums

As such, the Council fully supports the prohibition against imposing surprise bills on consumers as reflected in the CAA. In addition, we also strongly support the effort to lower health care costs for all consumers. This was clearly the intention of the CAA, as reflected in the related Congressional Budget Office (CBO) report, which estimated that the surprise billing provisions would reduce premiums by between .5 percent and 1 percent, with a resulting $17 billion in federal savings.[2] Due to the importance of lowering health care costs, we strongly urge the Departments to implement the surprise billing provisions in a way that not only protects specific consumers from surprise bills but that also achieves the goal of reducing health care costs.

To that end, the Council urges the Departments to implement the surprise billing provisions in a way that protects the ability of employers to provide robust and affordable provider networks to participants and that avoids incentives for providers to stay out-of-network. Many employers and plans have put a great deal of effort into developing provider networks in order to provide access to quality providers and to keep coverage affordable. As described in detail below, in particular, the regulations implementing the independent dispute resolution (IDR) process and defining the "qualifying payment amount" (QPA), which is the basis for participant cost-sharing and central to the IDR process, will determine whether these new provisions lower health care costs and protect employer-sponsored plans and their provider networks or, instead, whether they have the unintended effect of undermining provider networks and increasing health care costs.

In addition, the way in which the surprise billing provisions are implemented will impact the extent to which new administrative costs are imposed on plans and consumers. In the vein of lowering health care costs system-wide for consumers, we also urge the Departments to prioritize minimizing administrative processes and costs in implementing the surprise billing provisions, particularly in implementing the IDR provisions, as explained in detail later in this letter. It is important that providers be encouraged to resolve payment issues outside of the IDR process, that the costs of the IDR process be minimized and that the IDR process be transparent.

With these essential policy goals in mind, in the remainder of this letter the Council provides specific recommendations for the Departments to consider, as summarized as follows:

- **Provider Payments:** With regard to initial payments by plans to providers, we request guidance:
    - confirming that plans have the discretion to determine the initial payment amount;

[2] *See* https://www.cbo.gov/system/files/2021-01/PL_116-260_div%20O-FF.pdf

- delineating how the ERISA claims procedure rules, and similar procedures, interact with the new processes set out under the CAA, including confirmation that the CAA relates only to payment amounts, not coverage decisions; and

- providing that the 30-day payment timeframe for plans does not begin until the plan has received a "clean" claim from the provider.

- **Qualifying Payment Amount:** We note the importance of the QPA, due to its centrality in the statute both for purposes of participant cost-sharing and the IDR process and emphasize that regulations that produce a QPA that is credible and not inflated are essential to achieving the policy goals of the CAA. More specifically, we request guidance:

  - Confirming that the basis for the QPA is contracted rates, rather than paid claim amounts, and that a contracted rate means the rate agreed to between the plan or issuer and a provider or group of providers;

  - Defining the same or similar items and services plans should look to in determining the QPA, by using common payer identifiers and codes;

  - Providing that for self-insured plans, the geographic regions used to determine the QPA are metropolitan statistical areas (MSAs) or Medicare Geographic Price Cost Index (GPCI) areas, rather than qualified health plan (QHP) rating areas, in order to produce QPAs that are credible and not inflated;

  - Providing that if a plan has at least three contracted rates to look to for an item or service, that is sufficient information to determine the QPA; if there are fewer than three contracted rates, the State should be used as the relevant geographic area; and if there are still fewer than three contracted rates, the QPA should be based on Medicare rates and never on a third party database that captures billed charges;

  - Providing that for self-insured plans, the plan should be able to choose whether the QPA is measured over all the similar self-insured plans/plan options administered by its third party administrator (TPA) or, in the alternative, over the similar self-insured plans/plan options maintained by the plan sponsor; and that in either case, the plans over which the QPA is determined should be only those plans that are of a similar network type and/or benefit option;

  - Providing that quality-related performance payments for in-network providers can be excluded from the QPA and providing a methodology for

plans that are not based on fee-for-service to calculate the QPA, such as an actuarially sound internal methodology;

- Allowing plans and issuers to use any 12-month period for purposes of the years used to determine the QPA;
- Requesting clarity on the calculation of cost-sharing amounts for out-of-network air ambulances, including guidance which takes into account the fact that there are limited in-network air ambulance providers and prices are generally inflated; and
- Confirming that facility fees only should be part of the QPA analysis where the fees are built into the contracted rates, which should be very rare.

- **Notice and Consent Provisions:** We request guidance requiring providers to provide to plans notice in the event a participant waives surprise billing protections; imposing specific requirements regarding the provider notice to ensure patients are sufficiently protected; and confirming that even if a participant consents to a balance bill, they are not entering a contract to agree to any certain payment amount to the provider.

- **Applicability:** For the sake of clarity, we ask the Departments to confirm whether or not various types of plans are subject to the surprise billing protections.

- **Independent Dispute Resolution:** We emphasize that in order to ensure that health care costs do not increase and that provider networks are not undermined, IDR must be established as a process of last resort and the costs of the process must be minimized. We also request guidance:
  - Confirming that the QPA is the primary factor to be considered by an IDR entity – based on the statute, Congressional intent and the policy goals of the CAA – and that the QPA only be deviated from in compelling, extenuating circumstances;
  - Providing that to be certified by the Departments, an IDR entity must have expertise in economics and health care pricing, rather than general IDR experience, and certify that is has no conflict of interest with respect to any party to the IDR;
  - Establishing a selection process of IDR entities prioritizing low-cost qualified entities that generally have a record of choosing a payment amount close to the QPA and establishing parameters for claims to be batched in IDR so as not to lead to abuse of the system;

- Prohibiting parties from forum shopping; precluding IDR entities from using decisions in other IDR processes as precedent; and preventing IDR entities from using third party databases due to the inclusion of billed charge information;
- Clarifying the interaction with state law, for self-insured plans;
- Minimizing IDR fees; and
- Implementing the provisions regarding transparency in the IDR process, fully and timely.

- **Good Faith Compliance.** We fully support consumer protections from surprise bills beginning in 2022 but due to the incredible complexity of the new system and the changes required by plans and issuers, we request that the Departments apply a good faith compliance standard at least through 2023.

For context, we also note that many of our employer plan sponsor members expect to rely heavily on their TPAs to implement and administer the surprise billing provisions, and we ask that the Departments keep this in mind, as the regulations are developed.

Moreover, we understand that the Departments have a great deal of work ahead in implementing these important provisions, and we appreciate those efforts. While employers and group health plans need certainty in order to implement these provisions, due to their importance and potential to impact health care costs we ask that the Departments not sacrifice a robust policy making process for the sake of speed. Although we understand that the Departments are working to issue rules within certain aggressive deadlines as set forth in the statute for some of the regulations required by the CAA, and that some of the surprise billing regulations will be in the form of an interim final rule, we encourage the Departments to provide proposed regulations under the CAA when possible.

We appreciate the time that the Departments have taken to host listening sessions for stakeholders and to discuss these issues. We emphasize that we are always available for additional discussions or to provide additional information to the Departments, to the extent that would be helpful. We also note that in the interest of time, we are providing these comments now but due to the complexity of the issues at hand, we are continuing to consider implementation of the surprise billing provisions in the CAA and may provide additional input in the future as well. Further, to support our efforts, and other stakeholder efforts, in seeking to identify implementation issues, it would be helpful to be able to review the letters the Departments have received from others on this topic, and we ask that you make such letters publicly available, as appropriate.

PROVIDER PAYMENTS

Initial Payment

The CAA imposes a series of requirements to minimize the occurrence of surprise bills. These requirements generally apply to (1) emergency services provided by a nonparticipating provider or facility; and (2) non-emergency services at a participating health care facility by a nonparticipating provider. With regard to these services, one requirement under the CAA is that plans and issuers must send an initial payment or "denial of payment" to a provider or facility within 30 days after the bill for services is sent to the plan or issuer. Unlike several other terms in the CAA, the statute does not define "initial payment," or otherwise dictate the amount or calculation of the initial payment.

The absence of a specific statutory definition of "initial payment" indicates Congress intended for plans and issuers to determine the amount of the initial payment amount owed to the provider. Moreover, such a rule is consistent with sound policy. Permitting plans to determine the initial payment will allow for payments that are reflective of market conditions and will help to manage consumers' premium costs, which could be impacted if plans were required to pay a specific initial payment. Plan-determined initial payments will also avoid disincentives for in-network participation by providers, which is crucial for plans to maintain robust networks to ensure access to care for employees and their families. Moreover, plans already have systems and processes in place to determine these amounts and imposition of an alternative payment calculation or minimum payment amount by the Departments would complicate plan benefit administration and undermine plans' flexibility in responding to market conditions and addressing provider network issues.

Accordingly, we urge the Departments to issue guidance confirming that plans and issuers may determine the initial payment amount. We also ask that the Departments acknowledge the flexibility that plans and issuers have in determining these amounts in that they may determine the initial payment amount consistent with the respective plan's terms for determining payments for other out-of-network services, if the plan determines that is best, or may instead determine the initial payment amounts on a different basis, including by paying, in some cases, the QPA discussed later in this letter.

Interaction with ERISA Claims Procedures

As noted above, for services subject to the CAA, plans and issuers are required to send an initial payment or "denial of payment" to the provider or facility within 30 days after the bill for services is sent to the plan or issuer. The statute also requires the Affordable Care Act ("ACA") external review process "to apply with respect to any adverse determination" by a plan or issuer for surprise billing protections, "including with respect to whether an item or service that is the subject to such a determination is

an item or service" to which the surprise billing protections apply. Questions have arisen regarding how these provisions interact with ERISA's existing claims procedure rules.

The existing ERISA claims procedure rules allow participants and beneficiaries to appeal an "adverse benefit determination," which generally encompasses any denial of, or a failure to provide or make payment (in whole or in part) for, a benefit. In addition, pursuant to changes made by the ACA, an independent external review of denials is available for denials involving medical judgment, whether a benefit is properly classified as experimental or investigational, or for rescissions of coverage.

Given the CAA's inclusion of a comprehensive dispute resolution process and the fact that ERISA's claims procedures rules continue to apply to plans and issuers, it will be important that future guidance clearly delineate under what circumstances ERISA's claims procedures and external review may be invoked by a participant or beneficiary, with respect to a claim otherwise covered by the CAA, and to confirm that nothing in the CAA changes the fact that participants have the right to bring claims for benefits, and to appeal denials of those claims, under ERISA and that providers do not.

We suggest that a reasonable approach would be to have participants and beneficiaries utilize the plan's existing ERISA claims procedure to exhaust appeal rights for a coverage decision and denial of benefits, including external review, and if the denial of benefits is overturned, then the surprise billing protections would apply (*i.e.*, the initial payment would be made within 30 days of the denial being overturned, and the provider or plan would then have a 30-day negotiation period). If the denial of benefits is upheld, then the surprise billing provisions would *not* apply to this claim. And this same process could be used by a participant to bring an appeal, in the event a claim is not denied but is determined by the plan not to be subject to the surprise billing protections.

Thus, the surprise billing regulations should clarify that the ERISA claims procedures are for participants to exhaust appeal rights for "coverage decisions" and "denial of benefits" (*i.e.*, whether an item or service is covered under the plan and whether an item or service is subject to the surprise billing protections), and the surprise billing process is for nonparticipating providers to dispute payment amounts (*i.e.*, how much the out-of-network provider should be paid) for services covered (*i.e.*, not excluded) by the plan and provided to eligible participants and beneficiaries. In addition, the regulations should clarify that while nonparticipating providers are permitted to utilize the surprise billing IDR process, they cannot utilize ERISA claims procedure processes to dispute payment amounts.

"Clean" Claims

As noted above, the CAA provides that plans and issuers are to send an initial payment or "denial of payment" to the provider or facility within 30 days after the bill for services is sent to the plan or issuer. The statute does not explicitly address how this timing requirement applies if claims that are sent to the plan or issuer are missing certain essential information for claims processing and may need to be sent back to the provider for additional information.

This situation in which initial claims are not "clean" (*i.e.*, do not contain all the information necessary to process the claim) is not uncommon, and it is standard practice for these types of claims to be sent back to the provider for clarification or to provide the missing information, before the claim is processed. We can see no reason why the CAA would intend for plans to attempt to process claims that are not "clean", as that would introduce inaccuracies and uncertainty into the very first step of the intricate and extensive process contemplated by the CAA. As such, we request that the Departments clarify that the 30-day requirement for the initial payment only apply to "clean" claims, so that such 30-day period not begin to run unless and until the plan or issuer has all of the necessary information for determining whether an initial payment is required, and the amount of such payment. We also ask that the Departments provide a definition for a clean claim, that applies uniformly, at least for self-insured plans.

QUALIFYING PAYMENT AMOUNT

Under the CAA, the QPA is a central concept. How it is defined and interpreted in regulations will be critical to the implementation and operation of the CAA and in achieving the legislation's overall goals of protecting consumers and lowering health care costs. This is in large part because the QPA plays many roles for purposes of the legislation. First, it is the amount that is determinative of the patient's cost-sharing. Second, as described later in this letter, Congress included a statutory directive that the QPA be the presumptive payment amount for purposes of the IDR process. Third, we suspect many plans and issuers will choose to pay the QPA as the plan's or policy's out-of-network reimbursement rate with respect to claims otherwise covered by the CAA.

Under the CAA, for 2022 the QPA means, with respect to a plan sponsor or health insurance issuer, for an item or service, the median of the contracted rates recognized by the plan or issuer (determined with respect to all plans of the sponsor or all coverage offered by an issuer within the same insurance market as the plan or coverage) under such plan or coverage on January 31, 2019, for the same or similar item or service that is provided by a provider in the same or similar specialty and provided in the geographic region in which the item or service is furnished, increased by inflation (*i.e.*, CPI-U) over 2019, 2020 and 2021. For items and services furnished during 2023 or later, the QPA is based on the rates in the previous year, increased by inflation. And the insurance

markets that apply for this purpose are the individual market, large group market, small group market, and self-insured group health plans.

Although the statutory definition includes a fair amount of detail, as discussed below, there are several significant decisions left to the Departments in terms of how to define and implement this term. In setting out the QPA methodology, we urge the Departments to think holistically about how the definition can support the legislation's broader goals of both protecting consumers and lowering health care costs.

In this regard, we note that regulations that result in a QPA that is credible and not inflated will achieve a number of key goals. First, a reasonable QPA that is not inflated will reduce participant cost-sharing, perhaps substantially, which will benefit many consumers. The number of participants who are subject to cost-sharing under employer-sponsored coverage is significant. In 2020, 84% of employees covered by large employer plans had deductibles, and 65% of covered employees had coinsurance requirements for hospital admissions and 68% had coinsurance requirements for outpatient surgery, oftentimes in addition to the deductible.[3] This means that many of the approximately 180 million Americans with employer-sponsored coverage would benefit from a reasonable QPA that is not inflated, and by the same token, many millions of Americans would be worse off, were the QPA to be inflated.

In addition, because the QPA is central to the IDR process, as described later in this letter, a reasonable QPA that is not inflated would lead to more reasonable payment outcomes under the IDR process, which would both avoid increases in plan premiums for consumers and disincentivize the use of the IDR process, leading to decreased administrative costs, which also inure to the benefit of plan participants. Moreover, a QPA that is reasonable and not inflated will help employers continue to provide, and improve, robust provider networks to employees and their families, by avoiding incentives for providers to remain, or go, out-of-network.

Relatedly, while we emphasize the importance of avoiding an inflated QPA, we also understand that in order for the QPA to be central in the IDR process, and to achieve the policy goal of avoiding extra costs through that system, the QPA must be credible and sufficient. As such, in our comments below, we make recommendations for a QPA methodology that will result in a fair and reasonable QPA, as the best way to ensure the CAA functions as intended. We urge the Departments to issue guidance that properly takes into account the multi-faceted role that the QPA plays with respect to the CAA.

Contracted Rates

As noted above, the statutory definition of QPA references the contracted rates recognized by the plan or issuer. Specifically, the statute provides that the QPA is based on the "median of the contracted rates recognized by the plan." This is to be

[3] *See* https://www.kff.org/report-section/ehbs-2020-section-7-employee-cost-sharing/.

distinguished from amounts actually paid by a plan or issuer for a particular claim, which in certain cases can exceed contracted rates when paying out-of-network providers. Accordingly, we urge the Departments to confirm in regulation that the QPA is based on the "contracted rates recognized by the plan," and not *paid* claim amounts. Only if a plan does not have contracted rates (*e.g.*, it does not have a provider network or it is a reference-based pricing plan design) should the QPA be based on an alternative reference point, such as median paid claim rates. Such a rule is directly contemplated by the statute and will help maintain existing incentives for providers to join provider networks, which will, in turn, avoid upward pressures on health care costs and related premiums.

As a more technical matter, for the sake of clarity, we ask for confirmation in the QPA regulations that a contracted rate means the rate agreed to between the plan (or the TPA on behalf of the plan) or issuer and a provider or group of providers (whichever entity is the party to the contract). That is, if a plan enters into a contract with a provider group that contains fifty providers, that should be considered one contracted rate. To interpret the rule otherwise would risk inflating or deflating the QPA and seems inconsistent with the statutory intent. In addition, for the sake of clarity, it would be helpful for the regulations to specify how the median contracted rate is calculated if there is an even number of contracted rates. Our assumption and recommendation is that in that case the median is the average of the middle two rates, consistent with the commonly accepted definition of the median and consistent with the current regulations under Public Health Service Act (PHS Act) Section 2719A.[4]

Same or Similar Item or Service

As noted above, the QPA is based on contracted rates "for the same or similar item or service that is provided by a provider in the same or similar specialty." Also, as noted above, the QPA plays a multi-faceted role with respect to the surprise billing protections. Thus, it is imperative that the Departments issue clear guidance defining the "same or a similar item or service." This will ensure that all parties (*i.e.*, payers, providers, consumers, and IDR entities) have a shared and consistent understanding of how this important phrase is to be interpreted and applied. It will also help protect against the occurrence of gamesmanship or manipulation intended to undermine or otherwise pervert the QPA determination or the IDR process.

We recognize that how "similar item or service" is defined could have the effect of reducing the QPA (*i.e.*, by resulting in a lower median contracted rate, *e.g.*, if the claim is grouped with a lower cost similar service) or increasing the QPA (*i.e.*, by resulting a higher median contracted rate, *e.g.*, if the claim is grouped with a relatively higher cost similar service). To avoid complexity and provide certainty, we suggest that in defining what constitutes a "similar item or service," the Departments do so using common

[4] *See* 75 Fed. Reg. 37188, 37195 (June 28, 2010).

payer identifiers such as Current Procedural Terminology (CPT) codes and Diagnosis Related Group (DRG) codes for purposes of calculating the QPA.

Geographic Region

For purposes of determining the QPA, the CAA provides that the contracted rates taken into account in determining the median of the contracted rates are those rates for the same or similar item or service in "the geographic region in which the item or service is furnished." The statute goes on to direct the Departments to issue regulations to define the geographic regions, "taking into account access to items and services in rural and underserved areas, including health professional shortage areas."

As discussed above, it is critical that the Departments establish a methodology that results in a QPA that is not inflated, but nonetheless reasonable in amount. How geographic regions are defined is a significant, perhaps the most significant, factor in doing so, because as we understand, which geographic region definition is chosen will have a significant impact on the amount of the QPA. As such, we urge the Departments to define "geographic region" in such a way that achieves the policy goals of lower consumer costs and lower health care costs in general and that also produces a QPA that provides a reasonable basis for participant cost-sharing, that does not incentivize providers to seek IDR or undermine provider networks and that could be used by an IDR entity as the default payment amount.

In developing our specific comments here, we first considered some guiding principles. In particular, we considered the advantages to defining the geographic regions broadly, such as reducing the impact of outliers (which in this context are likely to be very high-cost providers) and reducing the chance that there will be insufficient information in a region to produce a median contracted rate. However, we also appreciate that there are real differences in the cost of providing medical care in different geographic regions. Defining geographic regions more narrowly has the advantage of more closely reflecting the costs in a specific geographic area and avoids a QPA that seems too general and insufficiently accurate, for purposes of providers and IDR entities. We also considered the importance of establishing geographic regions that are transparent, easy to identify and not manipulable.

Based on discussions with our employer plan sponsor members and taking these factors into consideration, we have identified methods for determining geographic regions that appear to meet these goals. One method could be to use metropolitan statistical areas (MSAs) (and then aggregating non-MSA areas per state), which is a well-known, long-standing metric established by the Office of Management and Budget (OMB) and used for various governmental purposes, including census statistics. Another acceptable method would be the geographic areas used for purposes of the Geographic Practice Cost Index (GPCI), which are the geographic cost indices used since the early 1990s to adjust Medicare physician rates and which are routinely

updated. Both of these metrics appear to be sufficiently broad to address concerns about outliers, sufficiently specific to capture real geographic differences in the cost of providing health care and are also clearly identifiable and not easily subject to manipulation. As such, we recommend that the Departments use one of these metrics to define geographic regions for purposes of determining the QPA for self-insured group health plans.

We are aware that the CAA looks to the National Association of Insurance Commissioners (NAIC) for a recommendation on this issue and that the NAIC generally recommended the use of qualified health plan (QHP) rating areas. However, feedback from our members indicates the QHP rating areas, which are much more numerous than MSAs or GPCI areas, are not sufficiently broad to avoid inflated QPAs in certain areas, at least for self-insured group health plans. As such, we would encourage the Departments to consider other geographic region definitions, at least for self-insured group health plans.

Sufficient Information to Determine QPA and Use of Third Party Databases

In situations in which there is insufficient information available to calculate the QPA - specifically where there is insufficient information to calculate the median of the contracted rates for an item or service in a region or when there are newly covered items and services – the CAA provides for the use of a database that is determined, through rulemaking by the Departments, not to have any conflicts of interest and to have sufficient information reflecting allowed amounts paid to a health care provider or facility for services furnished in a geographic region, such as a State all-payer claims database.

First, on this topic, we urge the Departments to provide clear guidance on what is considered a sufficient number of contracted rates for an item or service in a geographic region. Consistent with a recommendation made by the Brookings Institution, our recommendation is that the regulations provide that as long as there are at least three contracted rates for an item or service in a geographic region, that should be considered sufficient information to calculate the QPA.[5] And as described above, a contracted rate is the rate agreed to between the plan (or the plan's TPA) or issuer and a provider or group of providers (*i.e.*, if the contract is with a group of fifty providers, that is considered one contracted rate).

We also suggest that in the event a plan or issuer does not have at least three contracted rates for an item or service in a geographic region, that the plan or issuer be allowed to broaden the geographic region to the State-level (if it isn't already at the State-level under the basic geographic region definition) in an attempt to capture

[5] This is consistent with a recommendation by the Brookings Institution: https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2021/03/16/recommendations-for-implementing-the-no-surprises-act/.

sufficient contracted rates. If at that point there is still insufficient information, we understand the Departments might consider instructing plans and issuers to look to a third-party database. Our general concern with the use of information from third-party databases in this context is that they often include charges billed by providers, which could artificially inflate the QPA. This is why, on a high level, we urge that the rules minimize the use of such databases.

However, we understand that the Departments are looking for recommendations of third-party databases which meet the parameters set out in the statute. Our recommendation is that the Departments specify databases that reflect, or are based on, Medicare reimbursement rates, to avoid incorporation of billed charges and inflation of the QPA. (We understand that in the context of IDR, the IDR entity is not to look to Medicare rates but nothing in the statute precludes the use of Medicare rates in establishing the QPA in the event of insufficient information.) In contrast, we do not support the use of the FAIR Health databases based on our understanding that, even for the data sets that ostensibly are intended to capture in-network rates, some of the data is based on billed charges.

In those instances where a database must be used (which should be rare) we also ask that the Departments provide multiple databases that can be used, so that plans and issuers have a choice and are not obligated to use any particular database. This is important because as we understand some databases are more expensive than others and this would allow plans and issuers to research and use the database that will minimize the inclusion of billed charges in the QPA calculation. To the extent the Departments provide that a database may be used that includes billed charges information, we ask that the Departments require that the information be purified so that the billed charge information is not part of the determination. In addition, we anticipate that the third-party databases that exist will evolve over time and so setting out specific databases in sub-regulatory guidance, rather than final regulations, would provide the Departments more flexibility to update the guidance over time as needed.

Plans Across Which Contracted Rates Are Measured

The QPA is based on the median of the contracted rates recognized by the plan, determined with respect to "*all such plans of such sponsor*" within the market of self-insured group health plans. We understand that the Departments are considering how to interpret this aspect of the QPA determination, in particular with respect to self-insured plans, and that the Departments are considering whether self-insured plans should only consider their own plans (or specific benefit options) or whether the median contracted rate for self-insured plans should be determined with respect to all plans administered by a plan's TPA.

For issuers, it seems clear that they will look across all the plans they insure in a market, but it is unclear how this should work for self-insured plans. As the

Departments consider this question, we encourage the Departments to balance the need for administrative ease, as well as the fact that many self-funded plans will presumably be relying on their Administrative Services Organizations ("ASOs") or TPAs to implement and administer the surprise billing protections. Moreover, many of these plans may utilize the ASO's or TPA's national provider network without variance. On the other hand, many employers may utilize customized provider networks, direct contracting strategies, value-based arrangements, or otherwise utilize an array of networks and ASOs across their employee populations. It may also be the case that contracted rates for the same network provided by a TPA vary employer by employer. Additionally, employers offer (and TPAs may be administering) different types of plans (*e.g.*, reference-based pricing) and a plan may have lower reimbursement rates depending on the type of plan or plan option within a plan.

At base, what matters most is that self-funded group health plans not be disadvantaged by the Departments' rulemaking and that the QPA determination reflect actual market conditions. That Congress intended for a different result to apply to self-funded plans is clear from the statutory language. And given the wide variety in plan designs in the self-funded plan context, we urge the establishment of rules that will provide sufficient flexibility for plans to realize the economic realities of their unique plan designs to arrive at a proper and accurate QPA determination, without undue administrative burden. Taking all of these factors into account, our recommendation is that the Departments provide self-insured plan sponsors the choice as to whether they measure the QPA based on the plans administered by the TPA or, in the alternative, over the plans sponsored by the employer. We assume employers may choose the former if they believe the contracted rates for their plans are similar to the contracted rates for the other plans administered by the TPA and that having the TPA make the determination will be more efficient and practical. We assume employers may choose the latter if they believe their contracted rates differ from those of the other plans administered by the TPA, or to account for more complicated plan designs and situations in which an employer uses multiple TPAs.

In both instances – that is looking across an employer's plans or a TPA's plan – clarity is also needed as to which specific plans or plan options are to be used to determine the median contracted rate for an item or service for a particular participant. For example, should the QPA for an individual in a plan with a narrow network be based only on contracted rates for that item or service in narrow network plans, or all plans of the TPA or plan sponsor, as applicable? In order for the QPA to be sufficiently specific, our recommendation is that the Departments provide that the QPA for a participant or beneficiary be based on the contracted rates only for plans (either of the TPA or the employer, as applicable) that are similar to the benefit option and/or network type of the plan in which the participant or beneficiary is enrolled.

We appreciate that these terms and concepts are fairly amorphous and difficult to define in a standard way and so we suggest the Departments provide general

parameters but defer to plan sponsors as to how to apply those parameters to specific plans, plan options and networks.

Value-based Arrangements

As employers increase efforts to improve the quality and decrease the cost of care provided, it is not uncommon for plans and issuers to agree to certain bonus payments based on the provider's ability to meet certain quality metrics with respect to its provision of care. While these quality bonus payments are an important tool for plans in encouraging high-quality care, these payments generally should not be considered part of the reimbursement rate for calculating the QPA. This is because the providers that have received these payments have generally engaged in additional activities and efforts to warrant their reward of the payments (such as coordinated care arrangements, increased provider reporting, etc.) that the typical out-of-network provider will not have similarly performed. Thus, to include these quality bonus payments as part of the QPA determination would generally be inappropriate. It would also undermine the ability of employers to maintain high-quality provider networks.

Congress recognized the merit of these types of payment arrangements by directing the Departments to consider these types of arrangements as part of the QPA rulemaking. As such, we strongly urge the Departments to make clear that quality-related performance payments for in-network providers may be excluded from the QPA calculation. (As a technical matter, while we expect that plans will make great efforts to exclude these amounts for the reasons noted above, we understand that in some cases these payments cannot be separately parsed and so we ask that the guidance here provide plans the option to exclude these amounts from the QPA, rather than imposing a requirement, to avoid operational issues).

More generally, the QPA methodology in the statute assumes plans have contracted rates on a per item/service basis. However, many plans have worked with providers to implement designs that are value-based and other-than-fee-for-service arrangements. We ask that the Departments provide guidance on how these types of plans are to calculate the QPA and we suggest that the rules provided impose as little burden as possible and are sufficiently flexible to account for the range of plan designs that exist. For example, it would seem reasonable for such a plan to be able to calculate a per/item service amount, based on internal methodology so long as the method is actuarially sound.

Plan Years

The statute refers to specific years for purposes of calculating the QPA. However, the statute does not specify whether "years" is intended to refer to calendar years or plan/policy years. In general, typically it is best to apply year-based rules to employer-sponsored health plans on a plan year basis, because this avoids additional complexity

and administrative issues for non-calendar year plans. However, as noted earlier in the letter, we are asking that self-insured plan sponsors be permitted to choose whether the QPA is to be determined based on the contracted rates for all the plans similar to the plan the participant is enrolled in as measured either across plans sponsored by the employer or, in the alternative, across plans administered by the TPA. As such, because multiple plans may come into play in determining the QPA, the different plans used to determine the QPA could have different plan years. So, we ask that plan sponsors be allowed to apply the QPA analysis based on any 12-month period, as determined by the plan, given the plan's specific facts and circumstances.

Air Ambulance Surprise Billing

The CAA includes similar protections from surprise billing for air ambulance services provided by a nonparticipating provider. More specifically, the statute provides that the cost-sharing for participants and beneficiaries must be the same that would apply if the service was provided by a participating provider and any coinsurance or deductible must be "based on rates that would apply for such services if they were furnished by such a participating provider." Our expectation is that this provision will primarily apply in emergency situations, as those are the situations in which plans typically cover air ambulance services.

Questions have arisen regarding exactly how this amount will be calculated, including whether it relates to contracted rates for the current year or a prior year and whether there are additional specifics to consider. In addition, although basing cost-sharing on the contracted rates makes sense in theory, there is some concern about how this approach will work as applied in this context because there are so few participating air ambulance providers, including in any given geographic area. A broad region may need to be captured to produce a reasonable resulting amount, which would include at least measuring on a state-wide basis.

Additionally, we understand there to be in many instances a significant price difference between hospital-owned air ambulances and those that are owned by unaffiliated private entities (such as those owned or financed by private equity firms). Moreover, it is very clear that the CAA was not intended to reward or incentivize air ambulance providers who refuse to participate in the network. It is important that the Departments consider these factors to make sure that the plan's in-network rate is not inflated and, therefore, the amount used to determine cost-sharing and considered as part of the IDR process does not capture inflated prices. We are continuing to consider issues related to the application of the CAA to air ambulances and we may provide more specific comments in the future.

Facility Fees

We understand there may be some confusion about the extent to which facility fees should be considered as part of the QPA analysis. As a general comment, facility fees only should be part of the QPA analysis where the fees are built into the contracted rates. As we understand, that will be the case very rarely, as these fees are often written off or discounted for in-network providers, which are the only rates relevant to the QPA. And as we understand, this is only likely to be relevant in emergency situations when patients are taken to out-of-network facilities, as facility fees should not come into play if the facility is in-network.

NOTICE AND CONSENT PROVISIONS

The CAA allows certain nonparticipating providers providing non-emergency, non-ancillary services at an in-network facility to balance bill the patient if the provider satisfies the notice and consent criteria set out in the CAA ("non-emergency notice and consent provisions"). The provider must provide a signed copy of the consent to the participant or beneficiary through mail or email. Notably, a nonparticipating provider that satisfies the notice and consent requirement and, therefore, is exempt from the prohibition on balance billing, is not permitted to pursue IDR.

Separately, the CAA allows an out-of-network emergency services patient who is stabilized to consent to additional items and services and potential balance billing if the following conditions are met: (1) the provider determines the individual is able to travel using nonmedical transportation or nonemergency medical transportation; (2) the provider satisfies the non-emergency notice and consent provisions; (3) the individual is in a condition to receive the information, as determined by the Departments pursuant to rulemaking, and to provide informed consent; and (4) such other conditions, as specified by the Departments, such as conditions relating to coordinating care transitions to participating providers ("post-stabilization notice and consent provisions"). In the absence of the patient providing the requisite consent, the provider generally will not be permitted to balance bill the patient for the additional items and services provided post-stabilization.

Consent to Plans

The CAA does not provide any mechanism for the provider (or the participant or beneficiary) to provide a signed copy of the consent to the plan or issuer. However, as noted above, the statute provides that nonparticipating providers who satisfy the notice and consent criteria may not submit a notification to an IDR entity and, therefore, it is important for plans and issuers to have documentation of the consent. It is also important for the plan to understand when an employee may be faced with a balance bill, as often times employers take action to mitigate or pay balance bills on behalf of employees and, as such, employers and plans need to know when a balance bill may

arise. Accordingly, the Departments should require that out-of-network providers provide plans and insurers, as applicable, a signed copy of the patient's consent or some other notification that the patient has signed the consent, for example by using specified electronic codes.

Provider Notice Standards

The CAA requires certain information be provided as part of the notice, specifically: (1) that the provider or facility is a nonparticipating provider or facility; (2) a good faith estimated amount for the item or service and that the provision of the estimate or consent to be treated does not constitute a contract with respect to the estimate; (3) if the service will be provided at a participating facility and by a nonparticipating provider, a list of participating providers at the facility who can provide the service and, at the option of the participant or beneficiary, a referral to a participating provider at the facility who can provide the service; and (4) information about whether a prior authorization or other care management limitation is required in advance of receiving the service.

Given the importance of this information for participants and beneficiaries and the potential consequence of facing a substantial balance bill, it is essential that the notice from the nonparticipating provider be written in a clear and understandable manner and that the standards for the notice take into account the context – which is a participant or beneficiary making health care decisions while unwell, overwhelmed, scared and in some cases immediately following stabilization from an emergency. We request that the Departments provide clear guidance for providers on this issue.

The notice should be required to be provided on its own and not in conjunction with various other forms and disclosures. It should be provided in sufficiently large font so that participants have adequate notice and the language should be clear for participants or beneficiaries regardless of education level. Due to the importance of the notice we suggest that the Departments provide a model notice or model specifications to ensure that all patients understand the notice and its implications.

We also ask that in providing model notices the Departments separately provide one notice for the non-emergency notice and consent provisions and one for the post-stabilization notice and consent provisions due to the fact that the circumstances facing the participant or beneficiary in those two cases is likely to vary greatly, with the standards needing to be especially high for participants and beneficiaries in a post-stabilization setting, having just experienced an emergency and continuing to experience medical issues while being asked to consent to a balance bill. To that end, it would also be ideal for the Departments to provide that, in order to sufficiently seek and obtain notice and consent in the post-stabilization context, that the provider or his or her designate must counsel the patient as to the contents of the notice and sign the consent form as well, indicating that they provided the requisite counseling.

Other Ancillary Services

As noted above, nonparticipating providers at participating facilities who provide "ancillary services" may not seek notice and consent to impose balance billing. The statute provides that for this purpose ancillary services include items and services related to emergency medicine, anesthesiology, pathology, radiology and neonatology and diagnostic services (including radiology and laboratory services, except if the Secretary exempts certain advanced diagnostic laboratory tests). The CAA authorizes the Departments to specify through rulemaking additional items and services provided by other specialty practitioners that should also be prohibited from satisfying the notice and consent criteria.

Although we do not have any specific recommendations for provider categories to add to the list at this time, we request that the Departments maintain the flexibility to provide additional categories of ancillary specialty providers in the future. We expect the Departments may gain valuable insight into other specialty areas that are problematic from a surprise billing standpoint after the CAA has been effective for a period of time and this experience will help inform where there may be other ancillary services by specialty providers that should be prohibited from satisfying the notice and consent criteria.

Continually working to make sure that the list of ancillary providers is appropriately inclusive will not only ensure patients are sufficiently protected from surprise bills but will also help to control costs for health plans, as explained earlier in this letter, which also benefits consumers. Accordingly, we encourage the Departments to make clear as part of its rulemaking that it will continue to evaluate patient experience and, as needed, may issue future guidance expanding the covered suite of ancillary services.

Post-Emergency Stabilization

As noted above, the CAA allows an emergency services patient who is stabilized to consent to additional items and services and potential balance billing if certain conditions are met.

Concerns have been raised that the consent could be used to enforce a contractual requirement to pay by the provider against the patient because we are aware of similar actions in related circumstances. The Departments should make clear that the notice/consent is not intended to create a commercial contract for a specific amount of payment and that participants are not bound to any estimates contained in the relevant documents, especially where used in settings where consumers feel they may not have meaningful choice.

SURPRISE BILLS – OTHER

Applicability

For the sake of clarity, it would be helpful if the Departments could confirm whether or not the surprise billing provisions apply to various types of health plans, in order to address common questions and provide certainty. Types of plans where questions have been raised include transitional or "grandmothered" plans, expatriate plans and grandfathered plans. (We understand that the statute provides that the provisions apply to grandfathered plans but we note that, nonetheless, the question is often asked and it would be helpful to have confirmation that the requirements on providers related to the surprise billing protections apply without regard to whether the coverage at issue is grandfathered).

It would also be helpful if the Departments could confirm that the surprise billing requirements do not apply to emergency services received out of the country. And for the sake of clarity, it would also be helpful for the Departments to reiterate that plans and issuers have no obligation to engage in the process set out in the CAA, including regarding payments or the IDR process, for items and services that are not covered under the plan or coverage.

IDR PROCESS

General Comments on IDR Process

The CAA provides for an open negotiation period beginning 30 days after the provider or facility receives the initial payment. In the event the open negotiations do not result in a determination of an amount of payment for such item or service, the provider or plan may initiate the IDR process to determine the out-of-network amount.

Below we provide specific recommendations regarding the IDR process but, to begin, more generally, we urge the Departments to develop an IDR process which is fair, consistent, predictable and transparent. And while we acknowledge that the IDR process is included in the CAA and that it is intended to ensure that out-of-network providers in the covered situations receive sufficient remuneration, we also wish to emphasize that the public policy goals of the CAA, namely to protect consumers and reduce health care costs, will only be achieved if the IDR process is an option of last resort rather than a loophole allowing providers to preserve the status quo, remain out-of-network and add significant costs to the system.

More specifically, we urge the Departments to design the IDR process keeping in mind that it should not conflict with the current network model. As noted earlier in this letter, plans and issuers have worked hard to develop strong provider networks. These networks are essential to the provision of affordable and patient-protective health

coverage. Provider networks improve access to coverage for patients; help bring down the cost of care, which in turn reduces premium amounts; and allow for higher-quality, coordinated care across network providers. An IDR process which often results in payments above the median contracted rate, or which can be manipulated to do so in certain circumstances, certain locations or with certain IDR entities, will result in widespread use of the IDR system by providers and run counter to strong provider networks by incentivizing providers to remain out-of-network. As such, IDR should not be the default mechanism for determining out-of-network reimbursement.

Moreover, the overuse of the IDR process by nonparticipating providers would serve to increase health care costs, both due to the administrative costs of IDR itself and inflated payments that may result from the IDR process. The end result being increased premiums for American families. Our comments are aimed at minimizing IDR in order to prevent increased health care costs and to protect strong provider networks – by urging the Departments to develop a system that is predictable, transparent and generally results in a payment consistent with the median contracted rate.

QPA Presumption

The CAA specifies that in determining whether the provider or the payer's offer is to be applied, the IDR entity *must* consider the QPA for the applicable year for items or services that are comparable to the qualified IDR item or service and that are furnished in the same geographic region as the qualified IDR item or service.

Beyond the QPA, the statute provides a host of "additional considerations" to be considered, consisting of: (1) the level of training, experience and quality and outcomes measurements of the provider or facility that furnished such item or service; (2) the market share held by the nonparticipating provider or facility or that of the plan or issuer in the geographic region in which the item or service was provided; (3) the acuity of the individual receiving such item or service or the complexity of furnishing such item or service to such individual; (4) the teaching status, case mix and scope of services of the nonparticipating facility that furnished such item or service; and (5) demonstrations of good faith efforts (or lack of good faith efforts) made by the nonparticipating provider or nonparticipating facility or the plan or issuer to enter into network agreements and, if applicable, contracted rates between the provider or facility (as applicable) and the plan or issuer, as applicable, during the previous four plan years.[6]

[6] The Act also specifies that certain factors shall *not* be considered, including: (1) usual and customary charges; (2) the amount that would have been billed by such provider or facility with respect to such items and services; and (3) the payment or reimbursement rate for such items and services furnished by such provider or facility payable by a public payor.

For the reasons set forth below, we urge the Departments to issue guidance reinforcing the statutory directive that the QPA be the presumptive payment amount for purposes of the IDR's consideration of the parties' offers.

That the QPA should be presumed the payment amount by the IDR is evident by one very simple fact – that the QPA is the only factor listed in the statute that is an actual objective *amount*. The other considerations are factors or criteria, but they do not constitute an actual monetary amount. Thus, based solely on the statutory language and construction, there can be no doubt that the IDR's determination *must* begin with the QPA. In addition to being the most objective and concrete of those factors, the QPA is listed in the statute on its own as the key factor and the QPA is the only factor that the statute provides specific instructions through notice and comment regulation on how to calculate. Not only does the statute include a detailed definition of the QPA over several pages, but the importance of the QPA is also emphasized in that the items that the Departments are to publicly disclose regarding the IDR process require the disclosure of payment amounts, and proposed payment amounts, expressed as a percentage of the QPA and under the statute, there is a robust audit process to be run by the Departments regarding the QPA. Accordingly, we request that the Departments recognize the statutory directive that the QPA be the primary criterion for the IDR entity in choosing between the parties' offers.

Not only is this outcome consistent with the statutory language but also the statutory intent and legislative history. As noted earlier, the CBO estimated that the surprise billing provisions in the CAA would lead to reductions in premiums by up to a percentage point. If the QPA is not the primary focus of the IDR process, and payment amounts resulting from the IDR process often exceed the QPA, that finding would not hold true as out-of-network providers would retain incentives to stay out of network and their leverage would remain in negotiating rates.

In addition, confirming the primacy of the QPA in the IDR process is essential to ensuring that the CAA achieves its policy goals. By making IDR outcomes more predictable, establishing the QPA as the presumptive payment amount will encourage the parties to resolve disputes without IDR and, thus, limit administrative costs for both parties and ultimately limit increased costs for enrollees. Additionally, by establishing regulations that require the IDR entity to consider the QPA as the primary/presumptive factor, it will help protect against incentives for providers to go/remain out-of-network (versus in-network) and will also help protect against unnecessary cost and premium increases for the consumer.

As such, as recommended in the Brookings report, an IDR entity should be directed to choose the reimbursement offer closest to the QPA and demonstrate reasonable cause for deviation in limited extenuating circumstances. The IDR entity should begin with the presumption that the QPA is neither too high nor too low. Absent credible evidence that overturns this presumption, the IDR entity should choose the offer closest to the

QPA amount. The IDR entity should discard this presumption only if (1) one of the parties presents clear evidence that the services or circumstances at issue in a specific case materially differ from those reflected in the historical data used to calculate the QPA, (2) the data is credible and from a well-functioning market and (3) that evidence pertains to one of the other factors the IDR entity is statutorily required to consider. The bar should be high here because, significantly, the QPA, as calculated, will take into account a significant amount of the relevant information for the IDR entity to consider (*i.e.*, training and experience of the provider, market share of the provider). Thus, we strongly recommend that the Departments reinforce the QPA as the primary criterion for choosing between the two reimbursement offers.

IDR Certification

The CAA directs the Departments to establish a process to certify IDR entities and, as part of that process (among other things), the Departments must confirm that an IDR entity has "sufficient medical, legal and other expertise" to make determinations. The Departments may also specify additional requirements. These certified IDR entities are the entities that the parties may choose from themselves, or, if no such agreement is reached, these are the entities that the Departments may choose from.

Consistent with the statute, and to ensure the IDR entity can make informed decisions on the appropriate payment amount under the plan for the item or service furnished by the nonparticipating provider, it is critical that the certified IDR entity have the requisite expertise to fully evaluate and understand health care market dynamics and economics. Accordingly, we urge the Departments to clarify that as part of the certification process, the applicant IDR entity should be required to demonstrate sufficient knowledge and expertise of economics and health care pricing. It should not be sufficient to have arbitration experience in other areas and the arbitrators who are certified should primarily focus on health care related IDR. This would help ensure the making of informed determinations, minimize the extent of variance across IDR determinations and protect against decisions that both undercompensate providers or unnecessarily inflate health care costs.

Selection of IDR Entity

In the event the parties do not make a joint selection of a certified IDR entity within three business days, the CAA requires the Departments to select a certified IDR entity that does not have any conflict of interests. The selection of the certified IDR entity is dependent on clearing any conflicts of interest.

We request that the Departments define and apply this conflict of interest rule to avoid abuse of the IDR process. We also request that the Departments clarify the process that the Departments will use for selecting the certified IDR entity if the parties do not make a joint selection. The process defined in regulation should provide for a

selection rule that focuses on the following factors: (1) whether the IDR entity charges a relatively lower administrative fee; (2) whether the IDR entity has a record of rendering decisions that are, on average, close to the QPA; and (3) whether the IDR entity has a record of choosing the party offer that is closest to the QPA. We believe such a selection rule is consistent with Congressional intent and reinforces the statutory directive that the QPA be the primary consideration of the IDR entity, as noted above.

We appreciate for the first year of application of the surprise billing provisions, prior data on behavior of the IDR entity in applying the surprise billing regulations under the CAA will not be available. In that case, if possible, the Departments could consider looking at information about the IDR entity's decision-making in a related state IDR process, including whether the ultimate decisions were generally consistent with median in-network rates, to the extent such information is available.

Batching

Under the IDR process, the Departments are required to specify the criteria under which multiple qualified IDR dispute items and services are permitted to be considered jointly as part of a single determination by an entity for purposes of "encouraging the efficiency (including minimizing costs) of the IDR process." The statute includes the following criteria for determining whether batching of claims is permitted: (1) items and services are furnished by the same provider or facility; (2) payment is required by the same plan or issuer; (3) the items or services are related to the treatment of a "similar condition;" and (4) the items and services were furnished during the 30-day period or an alternative period as determined by the Secretary, for use in limited situations, such as by the consent of the parties or in the case of low-volume items and services, to encourage procedural efficiency and minimize health plan and provider administrative costs.

We request that the Departments develop clear rules regarding when batching of claims is permitted. Moreover, we urge the Departments to use their regulatory authority to limit the scope of claims eligible for "batching" to prevent abuse of the IDR process.

It is important that the Departments develop clear rules on batching of claims to prevent manipulation of the IDR process by nonparticipating providers. We recognize that batching may reduce administrative costs for any single IDR process, but IDR more generally must not become the default for rate setting for nonparticipating provider reimbursement rates. Moreover, the use of batching and the IDR process should not be manipulated to the detriment of the health care system. Accordingly, regulations should define "provider" for purposes of batching as an individual practitioner (as defined by an individual provider's National Provider Identifier ("NPI")). Additionally, the Departments should issue regulations that define the items and services related to the treatment of a "similar condition" in such a way as to avoid provider manipulation

(such as by use of the same CPT or DRG code). These rules will help discourage overuse of the IDR process, ensure that the IDR process is focused on meaningful payment disputes and ensure that the IDR process does not become the default setting for out-of-network reimbursement rates, at the detriment to current network arrangements and the health care system as a whole.

Interaction with State IDR

We understand the Departments are considering how the federal IDR process should interact with state IDR process rules. As we understand, ERISA-covered plans must comply with the new federal requirements in the CAA insured ERISA-covered plans may also need to comply with other state requirements in addition. In some states, self-insured plans have been allowed to opt-in to the state-based IDR process. As we understand, nothing in the CAA would preclude a self-insured plan from continuing to opt into a state-based IDR process, as long as these plans also comply with the requirements of the CAA. Although we are not aware of any self-insured plans choosing to opt-in to state IDR programs, for the sake of clarity, it would be helpful for the Departments to confirm that our understanding of this aspect of the state/federal interaction is correct.

IDR Data Sources

We understand the Departments are interested in what data sources an IDR entity should be able to utilize, or should be prevented from utilizing, in making its determination of the payment amount. As noted above, the CAA dictates what information the IDR entity should and should not consider. Additionally, the statute provides that the IDR entity may also consider "information as requested by the certified IDR entity relating to such offer" and "information relating to such offer submitted by either party" to the certified IDR entity.

As noted above, the statute clearly directs that the QPA be the primary consideration for the IDR entity in choosing between the parties' offers. Absent credible evidence that overturns the presumption that the QPA is the correct payment amount, the IDR entity should choose the offer closest to the QPA amount. While the statute instructs the IDR entity to consider other factors in its deliberations, the QPA is by far the most objective and concrete of the enumerated factors and the only factor that the statute provides specific instructions through notice and comment regulation on how to calculate.

Accordingly, to the extent the Departments are considering rulemaking regarding the "information" and databases that may be considered by the IDR entity, we are opposed to any rulemaking that would encourage the IDR entity to access information or databases that would cause the IDR to choose an offer that deviates materially from the QPA. To that end, we are specifically against allowing or otherwise directing the

IDR to rely on a third party database, particularly one that utilizes billed charges, including FAIR Health databases.

Forum Shopping and Precedent

A concern has been raised that nonparticipating providers may "forum shop" for a certified IDR entity that the provider believes will provide the highest payment amount based on a high payment under a previous IDR determination. We request that the Departments consider this when establishing the IDR process to prevent providers from "shopping" for an IDR entity that has a record of providing for the highest payment rates (for example, by service or CPT code).

Similarly, the concern has been raised that IDR entities may look to decisions in other IDRs as precedent. Using other IDR decisions as precedent may not accurately reflect the current facts and could raise other issues, including to the extent State-specific decisions are used in the Federally-developed IDR process, as applied to self-insured plans which are not subject to the State laws. As such, we ask the Departments to confirm that IDR entities are not to look to the decisions of other IDR entities, or to past decisions of the same IDR entity, in determining the final payment amount in any given IDR process.

IDR Fees

The CAA provides that the party whose offer is not chosen must be responsible for paying all fees charged by the certified IDR entity. In enacting this provision, we understand that Congress' understanding was that a certified IDR entity's fees would be minimal, such as a few hundred dollars. However, it is our understanding that an IDR's fees are closer to a few *thousand* dollars (or more). We request the Departments consider this in rulemaking and place limits on a certified IDR entity's fees to the extent possible, including by directing the Departments to consider IDR fees in the certification of IDR entities and in the selection of an IDR entity in the event the parties do not make a joint selection of a certified IDR entity.

Transparency of the IDR Process

The CAA requires the Departments to disclose information quarterly about the IDR process, including the number of claims submitted for IDR, the number of times the final amount exceeds the QPA, the final payment amount as expressed as a percentage of the QPA and the identity of the parties.

It is essential that the Departments implement this aspect of the CAA fully and timely and that it make the disclosures in a way that are easily accessible and searchable by the public. As noted earlier, there are a number of areas where we are concerned about potential abuse or overuse of the IDR process and the potential for the IDR process to undermine provider networks and lead to increased plan and consumer

costs. As such, we intend to monitor this process closely as it is implemented and robust disclosures by the Departments will be essential in helping stakeholders work with the Departments to ensure that the CAA is implemented as intended.

GOOD FAITH COMPLIANCE

As is clear from this letter, we anticipate that the regulations implementing the application of the surprise billing provisions in the CAA to plans and insurers, including the QPA definition and the IDR process, will, by necessity, be incredibly complicated. As the Departments are aware, requirements of this nature require significant time and effort to fully implement. Depending on the extent and nature of the rulemaking, plans and issuers may need to engage in significant changes to their claims and IT systems to properly comply with the new rules.

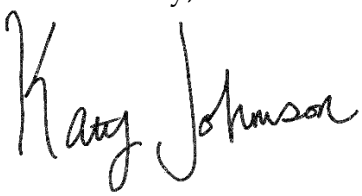
Although we are fully supportive of the 2022 effective date for the consumer protections prohibiting surprise billing, we are also cognizant of the immense burden on plans and insurers in implementing these provisions and of the potentially significant consequences for failure to do so. Employers, plans and insurers are working incredibly hard to implement these provisions and they will continue to do so, especially once final guidance is provided. But given the complexities involved, and given the near-term effective date, we urge the Departments to provide a good faith compliance standard at least through 2023, consistent with those provided by the Departments in similar contexts. We will continue to monitor this issue as implementation gets underway and will follow up to the extent additional relief is needed.

* * * * *

Thank you for the opportunity to submit these comments. We greatly appreciate your attention to these comments among the many other essential matters before you.

If you have any questions or would like to discuss these comments further, please contact us at (202) 289-6700.

Sincerely,



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September 1, 2021

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Associate Director
Healthcare and Insurance
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Douglas W. O'Donnell
Deputy Commissioner for Services and Enforcement
Internal Revenue Service

Mark J. Mazur
Acting Assistant Secretary of the Treasury (Tax Policy)

Ali Khawar
Assistant Secretary
Employee Benefits Security Administration
Department of Labor

Xavier Becerra
Secretary
Department of Health and Human Services

Re: Requirements Related to Surprise Billing; Part I

Dear Ms. Bodenheimer and Mr. O'Donnell, Mr. Mazur, Mr. Khawar and Mr. Becerra:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) thanks you for the opportunity to comment on the first set of regulations implementing the No Surprises Act. Hospitals and health systems strongly support protecting patients from gaps in their health care coverage that may result in unanticipated medical bills, and we look forward to working with you on implementation of these critical protections.

The primary objective of the No Surprises Act is to reduce instances where patients face unexpected medical bills because they received care from an out-of-network provider either as a result of an emergency or because they could not have been expected to reasonably know the network status of the provider. In order to achieve this, the law established protections against balance billing in certain scenarios. However, throughout the process leading to the passage of the No Surprises Act there was broad stakeholder agreement that network participation, where possible, was the best solution

to prevent out-of-network billing from the outset. Congress worked carefully to craft a solution that would not inadvertently disrupt network participation. Such disruption could occur if plans and issuers are able to pay less for services under the provisions of the No Surprises Act than by contracting at commercially reasonable rates with providers and facilities. Congress, therefore, avoided solutions like setting a benchmark payment rate which could financially reward plans for not contracting with certain types of providers.

While there are some safeguards in existing laws and regulations related to network adequacy to prevent plans and issuers from relying completely on the No Surprises Act, these protections are far from comprehensive. Indeed, no network adequacy requirements apply to plans regulated under the Employee Retirement Income Security Act (ERISA), and the requirements on fully insured health plans often do not address a number of critical provider types, including anesthesiologists, radiologists, and laboratories. Indeed, these gaps in network adequacy standards directly contributed to where we are today by enabling plans and issuers to exclude many ancillary providers from their networks and instead push the responsibility of coverage directly onto patients.

However, our concerns regarding inadequate networks are not limited to just the financial implications for patients. Inadequate provider networks also undermine patients' access to care and create coordination of care challenges for their providers. Specifically, inadequate networks make it harder for patients to find providers who will accept their coverage. Once they do, the primary provider may find that there are insufficient providers in the network for referrals. This can leave the patient saddled with the responsibility of finding a downstream provider whose services they can afford, and this provider may have no history or mechanism for routine collaboration on patient care with the primary provider.

These risks will continue to exist even once the No Surprises Act provisions go into effect. The law does not address every instance of out-of-network care, nor does it address instances where plans or issuers label a provider as "in-network" but then fail to cover medically-necessary services delivered by that provider, a form of network inadequacy not fully accounted for in existing rules. In this very regulation, the departments called out such troubling behavior on the part of some plans and issuers as it relates to denying emergency services.

Hospitals and health systems strongly support network-based coverage where the rules for coverage and enrollee out-of-pocket costs are clearly established, and where regulators ensure adequate access points to care. **We continue to believe that the best way to protect patients from surprise medical bills is to ensure that every form of comprehensive coverage – including plans regulated under ERISA – are subject to strict network adequacy rules.** We therefore strongly encourage the departments to ensure that the No Surprises Act is implemented in a way that improves the adequacy of networks. **Specifically, we urge you to:**

- **Not tilt the independent dispute resolution process (IDR) in favor of plans and issuers by overly weighting the qualifying payment amount as a factor for consideration;**
- **Strengthen existing network adequacy rules through regulation where possible; and**
- **Work with Congress to establish network adequacy requirements where they do not currently exist (i.e., ERISA).**

Additional detailed comments follow.

IMPLEMENTATION CONSIDERATIONS

The No Surprises Act is a large and comprehensive piece of legislation with a number of different interdependent policies. We urge your departments to ensure sufficient time for all stakeholders to implement the various components and ensure adequate and comprehensive guidance. For example, hospitals and health systems will need substantial lead time to educate staff on the new requirements, adjust workflows to account for different patient communications, and develop processes for new information sharing with plans and issuers. While hospitals and health systems are committed to making every effort to be ready for Jan. 1, 2022 implementation, we note that there are considerable challenges that exist in meeting this deadline. Notably, a substantial portion of the regulations have yet to be released, and many of the policies will require new information flows across different entities for which no standard transactions currently exist. Reliance on manual information sharing and proprietary communication flows (such as unique plan portals) will not be workable for the scale of new information that will need to be shared. **We ask for your partnership in addressing any barriers to implementation and additional enforcement discretion as we begin implementation.**

For example, we are grateful for the departments' Aug. 20 Frequently Asked Questions that identified several areas where the departments intend to provide enforcement discretion, including for the advanced explanation of benefits, continuity of care, and provider directory provisions. **We ask that the departments exercise such discretion for other portions of the law and regulations, as well as to allow for a clearer understanding of the rules and allow time for all stakeholders to operationalize the provisions.** For example, we strongly recommend convening a committee of technical experts from providers, facilities, plans and issuers to advise on implementation of certain provisions, including how to identify when an episode of care is subject to state or federal laws, as well as implementation of the notice and consent policies.

In addition, we urge the departments to allow stakeholders additional time to comment on certain portions of this regulation. The departments address some of the No Surprises Act provisions in part in this interim final rule while additional rules related to those same policies are still forthcoming. For example, this regulation addresses the methodology for calculating the qualifying payment amount (QPA); however, the full

scope of the use of the QPA – specifically, how it will factor into the IDR process – is not addressed. We cannot fully assess the QPA methodology without knowing how it will be used. In another example, the regulations require that hospitals and health systems include the good faith estimate – as calculated based on other provisions in the No Surprises Act – on the notice and consent forms. However, guidance implementing the good faith estimates, including how to calculate them, has not been released. Therefore, we are also unable to fully comment on the ability of hospitals and health systems to comply with this portion of the notice and consent process. We address both of these issues in more detail in the following comments.

SCOPE OF REGULATIONS

Applicable Forms of Health Coverage

The regulations apply the balance billing protections to patients enrolled in most forms of comprehensive, commercial health care coverage. They do not apply to public coverage programs (e.g., Medicare, Medicaid) or limited coverage benefit plans (e.g., short-term limited duration products). In general, we support the scope of the regulations with respect to health care coverage with the following recommendations and comments.

Application to No-network Forms of Coverage

We disagree with the departments' decision to apply these protections in instances where the health plan or issuer does not provide in-network benefits for the particular service. Specifically, these protections should not apply when the plan or issuer does not contract with any providers to deliver benefits in-network but instead relies on an out-of-network, reference-based pricing scheme. Under this type of coverage, the plan sets a pre-determined amount it will reimburse a provider for a service but does not enter into any provider contracts. Instead, enrollees are left to find providers that will deliver the service for under the pre-determined amount and have no guarantees that any provider will accept the amount. The enrollee is on the hook for any cost above the set price.

We have already enumerated a number of concerns with inadequate provider networks, and reference-based pricing plans are the extreme form of network inadequacy. This entire form of coverage is predicated on conveying no in-network benefits with the plan or issuer intentionally shifting more financial responsibility, as well as coordination of care, onto their enrollees. Application of the No Surprises Act to these plans could facilitate their growth in the market by enabling plans and issuers to reimburse providers substantially less than what is considered commercially reasonable for emergency and post-stabilization services. Meanwhile, as we read the law and regulations, patients' protections for non-emergent scheduled services would not apply as there would be no in-network facilitates where out-of-network providers would deliver services.

In order to not create an incentive for more plans and issuers to adopt reference-based pricing models, we urge the Departments to not apply these provisions to those forms of coverage.

Limited Scope Coverage

We support limiting the application of these policies to more comprehensive forms of health care coverage. However, we urge the departments to clarify that health care sharing ministries are another limited scope health care "product" that does not qualify as coverage and is therefore not subject to these protections. We remain deeply concerned about the growth in enrollment in these products, which offer consumers no protections and frequently result in unanticipated coverage denials. Hospitals and health systems report to the AHA of a number of instances where patients have believed themselves to have coverage through one of these products only to have their "plan" deny reimbursement for their care, including for emergency, oncology and other critical services.

While outside of the scope of this regulation, we note that the inability to apply the No Surprises Act protections to individuals and families enrolled in limited scope health care coverage is another reason for the Department of Health and Human Services (HHS) to move quickly to discourage enrollment in these types of products. **Specifically, we urge HHS to again restrict the sale of short-term limited duration health plans to no more than three months and to take steps to discourage enrollment in health care sharing ministry products when being sought as primary health care coverage.**

Clarification on Interaction with Out-of-network Coverage. We agree with the departments' decision to consider instances where a plan and provider have a single case agreement as having a contractual relationship for coverage and that the provider is therefore considered "in-network" for purposes of these provisions. We are unclear, however, how the provisions interact with more general out-of-network coverage policies. Some health plan benefit designs offer some form of out-of-network coverage, such as covering 60% of the cost of an out-of-network service rather than 80% for an in-network service. We read the law as superseding those plan benefits in the applicable instances. However, such out-of-network benefits may continue to exist for instances in which the patient consents to be balance billed or the service is not subject to protection under these provisions. We request confirmation.

Applicable Providers

The regulations generally align with the law in terms of which providers are subject to these provisions. We note, however, that the law (and therefore, regulations) contains a major discrepancy: while applying to physicians and other clinicians practicing in hospital outpatient departments, they do not apply to freestanding physician and clinician offices. Often, these practices operate similarly, and yet, this law does not apply equally to both. For example, we read the law as not applying to ancillary services when ordered by a physician practicing in an independent office that does not qualify as

a "facility" under the law. However, in a hospital-based physician's office, the ancillary provider would be prohibited from billing the patient. While the AHA is not recommending extending these policies to additional providers at this time, we raise this discrepancy as something oversight bodies should consider when evaluating the impact of these policies on the adequacy of provider networks, market dynamics and the financial stability of the health care system.

In addition, the departments sought comment on whether to extend these provisions to urgent care centers in states where these centers are not licensed to perform emergency services. We support excluding urgent care centers in this scenario. First, the objective of the law was to protect patients when they either cannot control whether they receive out-of-network care due to an emergency or when they cannot reasonably be expected to know they may receive care from an out-of-network provider. While we fully support enhanced patient protections within the context of health insurance coverage, we also recognize that an expansion of the law beyond these instances could have far broader consequences for how health care coverage works. For example, expanding these protections to instances where patients have the time and information to knowingly choose an in-network provider would essentially make provider networks moot. We continue to support the fundamental design of network-based insurance products with consumer education regarding how to select and use coverage.

Applicability Date

The regulations apply to plan years beginning on or after Jan. 1, 2022. We interpret this to mean that some portion of patients will not be covered by these protections on Jan. 1, 2022, but rather some date thereafter; however, there is no way for a facility or provider to know from the outset whether such protections apply. This is another example of information the plan must share with providers in order to operationalize these policies. We request clarification on how the departments expect this information to be communicated from plans to providers.

BAN ON CERTAIN BALANCE BILLING

Scope of Services Subject to Ban

The AHA strongly supports the ban on balance billing for emergency services and certain scheduled professional services where a patient may not be aware of or able to choose their provider. The regulations state that the ban on balance billing applies to all items and services provided during the applicable visit, including any equipment, devices, telemedicine services, imaging services, laboratory services, and perioperative and postoperative services. We generally agree with this scope of services, subject to the following comments.

Definition of Emergency Services

The law and regulations define emergency services consistent with the Emergency Medical Treatment and Labor Act (EMTALA) with two significant modifications. Specifically, consistent with EMTALA, emergency services include an appropriate medical screening examination and any such further examination and treatment as is

required to stabilize the individual, including services provided after a patient has been moved from the emergency department and admitted to the hospital. For purposes of this regulation, the departments broaden the definition in two key ways: 1) the definition includes such services when provided by a freestanding emergency department, and 2) the definition includes services provided after stabilization unless certain conditions are met.

While we recognize that the law includes post-stabilization services in the definition of "emergency services," we have several questions on how this provision will be operationalized. For example, the regulations address the period of post-stabilization services as extending until the patient is transferred to an in-network facility or when the patient consents to be balance billed. However, the regulations are silent as to what likely will be the most common scenario: discharge. Specifically, we expect that few patients will meet either the conditions for transfer or consent to be balance billed for post-stabilization services. Therefore, in most cases, we expect that the out-of-network facility and providers will care for the patient through discharge. **We urge the departments to clarify that health plans and issuers are responsible for covering (or issuing a notice of denial) for all of the services through the point of transfer, consent or discharge**.

In addition, we ask that the departments unequivocally state that health plans and issuers must work in a timely manner to arrange transfers, and until the transfer is complete, the plan or issuer is obligated to reimburse the provider for the services provided. Plans and issuers should not be permitted to delay finding or authorizing an in-network placement to the point where it is no longer relevant. It is often in the best interest of the patient to be reconnected to their network providers; however, such delays are not uncommon. Hospitals and health systems frequently report that plans and issuers will wait days before responding to requests to transfer during which the patient's condition could deteriorate and the out-of-network hospital must resume care for the patient. Additional comments on post-stabilization in the context of obtaining patient consent to balance bill are included in a subsequent section.

Finally, we sincerely appreciate the departments' unequivocal assessment that certain health insurer practices of denying coverage for emergency medical services is inconsistent with the Affordable Care Act's prudent layperson standard, as well as the No Surprises Act. We fully support the departments' establishment of regulations to address this harmful practice. We continue to be deeply concerned that commercial health insurers, such as Anthem and UnitedHealthcare, have not fully rescinded policies intended to dissuade their enrollees from seeking emergency medical treatment. **We urge the departments to not allow for any loopholes and to monitor plans' and issuers' compliance with these regulations.** These policies are too risky for individuals' health and safety to exist in any permutation.

Inappropriate denials of emergency services are just one example of how some commercial plans' and issuers' actions put patient access to care at risk. Plans and issuers have adopted a number of other approaches to reducing what they spend on

health care services to patients' detriment. These include making changes in enrollees' coverage after the enrollee purchased their plan, such as by restricting which services can be received at "in-network" providers, as well as delaying care through lengthy and administratively complex prior authorization requirements. **This history reinforces our position that the departments must prioritize oversight of plans and issuers with respect to their responsibilities under the No Surprises Act.**

Application of the Balance Billing Protections to Out-of-network Non-emergency Services

We request clarification on the application of the balance billing protections to non-emergency services. We read these regulations to not apply to scheduled, non-emergency services when both the facility and the treating providers, including any ancillary providers, are out-of-network. In addition, we read the protections as not applying to any scenario in which the out-of-network provider is not providing services in one of the facilities identified in the regulations, e.g., a freestanding physician office that is not part of a hospital outpatient department as discussed above. **The AHA supports this interpretation of the law, but requests that the departments confirm this reading.**

Application of Balance Billing Protections in Instances of Denied Claims

The law and regulations permit health plans to deny payment on certain claims, and we seek clarification on the instances in which a provider may bill a patient when a claim is denied. For example, we interpret the regulations to permit providers to bill a patient in instances where a claim was denied because the service is not covered by the patients' health plan (including in instances where the patient has exhausted the scope of their benefits).

However, there are many other instances in which a plan or issuer may deny payment. Denials frequently occur when the plan or issuer unilaterally classifies a service as not medically necessary. We interpret the regulations to permit patient balance billing in these instances and for the plan and provider to adjudicate any disputes through existing plan appeals processes and not the IDR process created under the law. However, this raises the question of whether all denials are to be adjudicated through existing processes and not the IDR process. We request clarity on this issue as part of the regulations implementing the IDR process.

NOTICE AND CONSENT PROCESS FOR CERTAIN OUT-OF-NETWORK POST-STABILIZATION AND NON-EMERGENCY SERVICES

The interim final rule closely adheres to the statute in limiting the circumstances for which patients may waive their balance billing protections through notice and consent. For patients to forego these protections, they must willingly and knowingly consent. The rule clarifies the process that providers and facilities must adhere to in seeking such consent for out-of-network services provided in post-stabilization and non-emergency settings. For post-stabilization patients, the regulations are clear that the notice and consent process for the out-of-network facility or provider only should be used in very

limited circumstances. For non-emergency services, notice and consent is limited to certain out-of-network providers at in-network facilities where the patient willingly consents to care and is intended to preserve patients' rights to choose to see an out-of-network provider. The rule also outlines the content, timing and presentation of the notice, which also adhere closely to the statutory prescriptions**.** In separate guidance, the Centers for Medicare & Medicaid Services (CMS) published standard documents that providers and facilities must use for the notice and consent process and may use for public disclosure.

In a letter submitted earlier to CMS, the AHA provided comments regarding the standard notice and consent and public disclosure forms released by the agency for purposes of implementation of these provisions. This letter expands upon our earlier comments, to include comments on the policies underlying the documents. While both the interim final regulations and the guidance documents largely reflect the requirements in the law, they present some logistical and operational challenges for providers. **The AHA reiterates its recommendation that CMS convene a provider advisory group to better understand the implementation requirements of the notice and consent and public disclosure policies.** For facilities, in particular, the notice and consent process will require changes to information systems, management processes and, potentially, provider relations, depending on whether the facility accepts a providers' responsibilities related to the process. Such an advisory group should examine the ongoing operational challenges, as well as explore how the notice and consent information could be shared with patients and transmitted to payers in the least burdensome way.

Post-Stabilization

The rule establishes that the treating provider or physician will make the final determination as to when a post-stabilization patient can give consent for out-of-network care. The rule defines the factors that the treating provider must consider, such as the availability of non-medical transportation, whether the in-network alternative providers are within a reasonable travel distance, the patient's physical and mental state, as well as cultural challenges and contextual factors faced by the patient. **The AHA strongly supports the departments' approach in placing the responsibility to determine when a patient is able to provide consent with the treating provider, as we have previously requested**. We encourage the agency, however, to provide additional guidance for treating providers on how to better understand how cultural or contextual factors could impinge on informed decision-making, such as how to address a lack of trust arising from historical inequities for underserved communities.

In addition, for post stabilization patients at in-network facilities for which consent is being sought, the law requires the notice to include a list of in-network providers at the facility that are able to furnish the services. Providers will need to either rely on the plan's provider directory or contact the plan directly to obtain information on alternative in-network providers. This process will not guarantee accurate information and will be highly burdensome for providers. For example, health plan provider directories are notorious for containing errors. Providers should not be held responsible if they rely on

unknowingly erroneous directory information. In addition, there are nuances to how plan provider directories list facilities and providers. For example, the facility could be listed as in-network in the plan directory, but the plan chooses to exclude coverage for certain services performed at the facility, such as outpatient surgery, laboratory and diagnostic services, and specialty drug therapies. These health plan coverage nuances would make it nearly impossible for the in-network facility to know with any certainty whether the service would be covered at the "in-network" providers. We note that we have previously alerted CMS to how these health plan and issuer policies may skirt the No Surprises Act protections.

For these reasons, the AHA believes the responsibility to identify covered, in-network alternative providers should not be placed with the in-network facility. Instead, the regulations should require the notice and consent process to point patients to their health plan to identify an alternative.

Finally, for post-stabilization services only, the out-of-network facility is required to include in their notice and consent form the good faith estimates for all out-of-network providers who may care for the patient during the post-stabilization period. We do not believe this is operationally feasible. Facilities, whether in-network or out-of-network, would not have definitive information on these providers' network status to confirm which providers may or may not be in-network for the patient's plan coverage and would not have the ability to run an eligibility check for each of these providers. Facilities also customarily do not have access to independent providers' fee schedules or revenue cycle functions. Obtaining this information would add a level of administrative complexity that could delay patient care or essentially render the consent process moot as the timeframe to complete the good faith estimate in the post-stabilization patient scenario would be incompatible with good patient care. We do not believe this therefore aligns with Congress' intent given that the law explicitly allows for a notice and consent process for post-stabilization services. **We recommend that the departments amend this provision and require that all out-of-network facilities and providers be responsible for their own notice and consent processes, consistent with the approach adopted for non-emergency services and our previous comments to the departments.**

Management Responsibilities of Notice and Consent Process

The management of the notice and consent process brings with it new responsibilities for providers and facilities. The AHA appreciates that the regulations specify that each out-of-network provider is responsible for their own notice and consent process for the services they provide unless they have an agreement with a facility to manage the process on their behalf.[1] We interpret this to mean that facilities can agree to manage the notice and consent process for some, but not all, of the out-of-network providers involved in a patient's care. This would presumably include obtaining all relevant information from those providers, including their estimated charges for purposes of

[1] With exception, as noted above, where the regulations require facilities to include out-of-network providers' good faith estimates in their notice and consent forms.

calculating the good faith estimates. **The AHA recommends that the regulatory policy and implementing guidance documents clarify that facilities are not required to manage the process for all providers and that they may do it for some. The standard notice form also could be modified to clearly state it may not encompass all potential out-of-network providers.** Providers not covered by the facility's notice and consent process would have to complete their own process if they wish to balance bill the patient for out-of-network services. **The regulations also should more clearly articulate that one provider's failure to appropriately obtain consent when sought separately from others should not impact another provider's (or facility's) ability to obtain consent.**

Information Regarding Health Plan Limitations on Coverage

The statute requires that the notice include information regarding any limitations the health plan may put on the patient's coverage, such as prior authorization. The rule strongly urges providers and facilities to include specific information in the actual notice document regarding the patient's health plan care limitation policies. Recognizing that getting this specific health plan policy information may prove challenging, the departments allow providers and facilities to adopt a general default statement that informs the patient that such limitations may apply. **The AHA agrees that the providers and facilities should only be required to use the default statement given that they cannot definitively speak to the health plan's or issuer's policies.** By taking this approach, the departments will both minimize the risk of inadvertent errors in the information shared with patients, as well as reduce the administrative burden of attempting to collect this information.

Good Faith Estimates

The statute requires that good faith estimates of the costs of services be included in the notice to fully inform patients of their potential out-of-pocket costs if they continue with care from the out-of-network providers or facilities. The regulations require that, for scheduled services, each out-of-network provider is responsible for completing their own notice and consent form, including with good faith estimates. For post-stabilization services, the facility is required to collate all of the good faith estimates from the various treating providers and incorporate it in their notice and consent form. The statute further instructs that such good faith estimates be conveyed using the expected billing and diagnostic codes for the items and services. The regulations and standard form reiterate the requirement that good faith estimates reflect the amount the out-of-network provider or facility expects to charge for furnishing such items or services, as well as include the service codes. However, neither the regulations nor the standard form stipulates which codes are to be used.

We have a number of concerns about these regulations. First, we point the departments to our comments above regarding the feasibility of facilities incorporating all potential out-of-network providers' good faith estimates into their notice and consent forms and ask that the departments amend the regulations to require each out-of-network provider to manage in its entirety their own notice and consent process. Second, we point to the lack of comprehensive guidance regarding the calculation of the good faith estimates.

Given that the underlying policy requires that providers and facilities follow the same rules that apply to the development of the good faith estimates established under another section of the No Surprises Act, we urge the departments to quickly release guidance on how providers are to calculate good faith estimates and to incorporate guidance on the specific codes to be used when providers and facilities complete the standard notice when seeking consent from the patient for out-of-network services.

Accessible Languages

The rule requires that providers and facilities provide notice and consent in the top 15 languages in a state or geographic region in which the applicable facility is located. **Because CMS intends to treat the adoption of the standard form as compliant with the law's notice and consent requirements, the AHA recommends that CMS provide translations of the standard form in the top 15 languages spoken nationally.** This would substantially lower the administrative burden on facilities and providers.

Application of Notice and Consent Process to Non-Emergency Ancillary Providers

The regulations prohibit balancing billing for some types of out-of-network ancillary services when delivered at an in-network facility. However, we believe that certain out-of-network providers identified as "ancillary" providers in the law and regulation should be able to use the notice and consent process for balance billing purposes in certain contexts.

First, we recommend that when the primary professional is out-of-network and uses the notice and consent process that they be permitted to also seek consent for any known out-of-network ancillary providers who will be part of the patient's care team. An example is when a patient schedules a surgery with an out-of-network surgeon and the surgeon knows the team of ancillary providers who will be part of the procedure. In this instance, patient protections could be maintained by only permitting the ancillary services to be subject to notice and consent when the ancillary provider is known at the time notice and consent is sought by the primary provider and when all other conditions for notice and consent are met (e.g., timeframe in advance of care). Any ancillary provider who is not known at the time of scheduling and who was not included in the notice and consent forms would not be permitted to balance bill.

Second, we ask that the departments clarify that certain types of providers listed as ancillary can sometimes deliver the primary service and, in those instances, may use the notice and consent process. For example, certain pain management physicians that perform injection procedures are anesthesiologists. When they provide this service, they are the primary provider, not an ancillary provider. We ask that the departments clarify that the context of the service matters for purposes of notice and consent, and specifically, that the ban on balance billing within the specialties outlined in the law only applies when those services are ancillary to a primary service.

Timing and Signature Requirements

The statute requires that the provider or facility notify an individual within 72 hours of a scheduled appointment regarding such items or services that may be out-of-network (or at the time of scheduling if the service is within 72 hours). The rule adds an additional timing standard for the conveyance of a notice for same-day services. Specifically, the regulations require providers and facilities to give notice to the patient no later than three hours prior to furnishing items or services for which the provider is seeking consent to balance bill. However, providers cannot use the same-day notice and consent process if a patient's condition would deteriorate during the three-hour window required to provide notice and obtain consent. The regulations do not address, however, what we expect will be a common scenario: the provider gives the notice and the patient immediately consents. **In these instances, we ask that providers be permitted to proceed with treatment as soon as possible and not have to wait the full three hours before delivering care.**

In addition to the timing requirements, the statute and regulations require two signatures – one when notice was provided and another for when consent was obtained. However, the standard documents issued by CMS provided only one signature line on the standard notice and consent form. Specifically, the standard document does not include a separate line for the patient's signature with the date to indicate that the patient received the notice. **Consistent with our comments on the standard documents, the AHA recommends CMS modify the standard document to include a distinct signature line for when the notice was given with a separate signature line confirming that consent has been provided.** This would remove any confusion about compliance with the notice requirements.

Transmitting the Standard Form to Payers

The regulations require that facilities and providers alert the patient's health plan or issuer when the notice and consent process has been used, as well as share the signed consent form. This is required so that the health plan or issuer can accurately calculate the patient's cost-sharing, for example, by applying any out-of-network benefits. With respect to post-stabilization patients, the provider or facility also must notify the plan or issuer as to whether all the conditions for notice and consent specific to post-stabilization patients have been met. However, neither the regulations nor the separately issued standard form provide any guidance on how the signed notice and consent documents should be transmitted to the plan. **Because there is currently no standard electronic transaction for this exchange of information, the AHA reiterates its recommendation that CMS adopt a standard process to ensure consistency and minimize the burden of alternate forms of transmission, such as faxing paper copies or use of health plans' and issuers' unique, proprietary portals. We encourage the departments to adopt an approach that would modify the standard claim to include a place for the provider or facility to attest that the requirements were met and provide the amount of the good faith estimate and forego sharing of the actual document.** Should the departments continue to require that the actual document be shared, the AHA recommends that the departments expedite the adoption of standard electronic transactions for the exchange of this

information between the provider, facility and plan, and that the agency modify the standard form to reflect these transaction standards.

Record Retention
Providers and facilities are required to retain signed notice and consent documents for seven years. The rule allows facilities to retain signed notice and consent documents for out-of-network providers upon agreement with those providers. **The AHA supports the departments' decision regarding the record retention requirements**.

DISCLOSURE REQUIREMENTS

Patient Notice
The law requires that providers and facilities must publicly post information about patient balance billing protections, as well as provide patients with a one-page notice outlining these protections as part of the public disclosure requirements. In separate guidance, CMS issued a standard form that providers and facilities may use. By adopting the standard form, providers and facilities will be considered compliant with the statute and regulations. The regulations and the instructions for the standard patient one-page notice stipulate that this notice be shared with the patient no later than at the time payment is requested or when claims are submitted to the patient's health plan. **The AHA recommends additional flexibility in the timing of when providers and facilities convey the disclosure notice to patients. Specifically, there are instances where patients will have ongoing treatment regimens that require multiple visits and/or courses of care. In these instances, we ask that providers not be required to provide the notice for every visit. Instead, providers could be required to provide the notice at the outset, followed by periodic reminders, such as each quarter.** This will allow for continued patient engagement on billing expectations without overburdening providers**.**

DETERMINATION OF PATIENT COST-SHARING

The AHA supports the approach taken in the No Surprises Act of establishing a methodology for determining patient cost-sharing that does not rely on a final reimbursement determination between the plan or issuer and the provider or facility, as well as counting this cost-sharing toward any in-network deductible or out-of-pocket maximums. Specifically, cost-sharing is based off the amount determined by an applicable All-payer Model Agreement; the amount determined under an applicable state law; the qualifying payment amount (QPA, as defined below); or the billed amount, if less than the QPA.

Methodology for Calculating the QPA
The No Surprises Act created the QPA for two purposes: to calculate patient cost-sharing and to serve as one of the factors for consideration by the arbiter in the IDR process, which will be established in future regulation. The statute defines the QPA as the plan's or issuer's median in-network rate for 2019 trended forward. In the case of a

self-insured group health plan, the administering entity may be treated as the issuer for purposes of these provisions.

The regulations address a number of factors that will determine how the QPA is calculated. These include:

- Defining terms such as: the type of contract (e.g., single case agreement, rental networks), the insurance market (e.g., individual market, small group market, large group market), the geographic region, “same or similar service,” “same or similar specialty,” and facility type;
- How to trend the QPA forward; and
- How to account for contracts using value-based payment methodologies or where services are reimbursed on a per-unit basis, such as anesthesia.

Issuers must have at least three contracted rates to complete the calculation. Where that is not possible, such as when an issuer does not have sufficient contract data for a given service or the plan is new, the regulations outline a process for using information from independent claims databases that meet certain standards to generate a calculation. The departments also address situations where entirely new service codes are created and for which neither the issuer nor an independent database would have adequate data to calculate the QPA. Finally, the departments address what information issuers must share with providers regarding calculation of the QPA.

The AHA is deeply concerned that stakeholders cannot fully assess the methodology for determining the QPA without understanding the extent of how it will be used. As we will discuss in more detail below, the departments made decisions regarding the QPA methodology to drive the QPA as low as possible (for example, by excluding case rate agreements). While we appreciate and strongly support an objective of lowing patient cost-sharing, this decision could impact more than just patient cost-sharing. In particular, an inappropriately low QPA could have a substantial impact on access to care if it is given prominence in the IDR process. To that end, **we urge the departments to release the regulations governing the IDR process as quickly as possible and solicit additional comments on the QPA methodology once stakeholders have a complete understanding of its use.**

In addition, we urge the departments to recognize that the objective of driving down patient cost-sharing may be at odds with achieving fair and reasonable reimbursement for providers. In order to accomplish both objectives, **we recommend the following: 1) clarify in the regulations that the QPA is not to be used by plans and issuers as the initial payment rate unless both the plan or issuer and the provider or facility agree to it through negotiation, and 2) refrain from overly weighting the QPA in the IDR process, as the median *in-network* payment has no relationship to what an *out-of-network* provider should get paid.** With these modifications, the departments can both lower patient cost-sharing while not disadvantaging providers in the IDR process, which could result in further reductions in the scope of provider

networks as health plans and issuers choose to rely on the No Surprises Act provisions rather than contract with providers.

- **Types of Rates Included in Calculation:** The departments define which rates are to be considered by plans and issuers when calculating the QPA. They direct plans to exclude certain rates, including rates contractually agreed to through a single case agreement, because such rates may not "reflect[s] market rates under typical contract negotiations." We disagree with this approach to defining contracted rates. Specifically in the instance of *out-of-network care*, a single case agreement is likely to be the contracted rate closest to a commercially reasonable payment amount. **We ask that the departments reconsider excluding single case agreement rates.**

- **Facility Type:** The regulations direct plans to calculate different QPAs for emergency services based on the type of facility "if the plan or issuer has contracted rates that vary based on facility type for a service code." The accompanying preamble text discusses only two different types of facilities: freestanding emergency departments and hospital emergency departments. This approach ignores the substantial differences between types of hospitals and again underscores why the QPA would be inappropriate as either the payment to the provider or as a substantial factor for consideration in the IDR process. **As such, we again urge the departments to clarify that the QPA is not intended to serve as the provider's or facility's reimbursement unless agreed to by the provider or facility and to not weight the QPA more heavily than other factors in the IDR process.** Absent these clarifications, we ask that the departments revisit this policy and require plans and issuers to only use rates for like facilities based on characteristics including trauma level, whether they are a cancer or children's hospital, and teaching status.

While we do not have any comments on the definition of same or similar service or same or similar provider for purposes of the calculation of the QPA, **we urge the departments to not apply the definitions for those terms adopted in these regulations for purposes of other provisions of the No Surprises Act. Specifically, we urge against adopting these definitions of same or similar service and same or similar provider for purposes of implementing the IDR process.**

As we noted in previous comments to the departments, the ability of providers and facilities to batch claims will be an important tool in minimizing the burden associated with the IDR process for all entities, as well as creating a disincentive for plans and issuers to pay an inappropriately low initial payment. We urge giving providers and facilities broad discretion to batch claims as they see appropriate. For example, providers and facilities should be permitted to choose to go to the IDR process based on a dispute for an individual claim for an individual provider or the totality of the out-of-network claims generated by all providers and facilities owned by the same

organization, or any scope of claims in between those bookends. The IDR process' very tight timelines, combined with the inherent volume of out-of-network claims providers will experience, necessitate providers' making substantial changes to their revenue cycle for out-of-network claims. Allowing providers to batch the broadest scope of claims into individual arbitrations is one of the most important levers for providers to be able to contain the anticipated costs of engaging in the IDR process.

Examples of why such flexibility may be needed to reduce burden on the system and create the right incentives for both plans, issuers, and providers and facilities include:

- The plan or issuer and the provider or facility have a dispute about a specific case, such as a complex trauma patient. This case may benefit from the ability to bring a single episode to the IDR process.
- The plan or issuer uses the same payment methodology for all out-of-network care, such as a percentage of the Medicare allowed amount. In this instance, providers and facilities should have the option to batch all claims paid under the same methodology as it is the fundamental methodology that is being challenged, not a specific dollar amount for a single service.
- The plan or issuer uses various reimbursement methodologies that result in inappropriate overall reimbursement for all out-of-network care. Examples may be when the plan or issuer pays a certain percentage of the Medicare allowed amount generally but then removes underlying components of the payment for certain cases and unilaterally changes the services on other claims (such as "downcoding" an emergency visit). In this instance, the provider or facility should be permitted to batch all claims from the plan or issuer under a dispute around the "totality of payment."

Allowing flexibility in batching in this way has significant benefits for all parties. First, it will significantly reduce the number of requests brought before the IDR process. It also may help disincentivize plans and issuers from adopting inappropriate out-of-network payment methodologies that would trigger IDR in the first place. Finally, by implicating a large number of claims in a single IDR decision, providers and facilities are not incentivized to batch in this way unless they have strong evidence to support their position.

The statute clearly intends for the departments to select experienced and knowledgeable arbiters. Such arbiters would have no problem assessing a case on its merits whether the case relates to an individual service or a collection of claims all paid under the same methodology.

<u>Calculating the QPA in Instances Where Sufficient Information is Not Available</u>
The regulations establish a process for calculating the QPA when the health plan or issuer does not have sufficient cases in 2019. First, the departments direct plans and issuers to use data from the first plan year in which they do have sufficient information. For example, if a plan does not have adequate information in the 2019 plan year but does in 2022, the data from 2022 would be used for 2023 moving forward. In an attempt

to avoid gaming of contracted rates by health plans, the departments require that in order to be deemed adequate for purposes of the QPA calculation, the rates must be for contracts representing a minimum of 25% of the plan's or issuer's business. In instances where sufficient information is still not available, the plan or issuer must rely on an independent database. We strongly disagree with this approach and believe that the ability of plans and issuers to use data from years after the law was passed will enable them to manipulate rates in response to the legislation. **We urge the departments to rescind the regulations that allow plans and issuers to use data other than from 2019 in any instance except when neither the plan or issuer nor an independent database has adequate information available, such as may be the case with new items and services. Instead, the plan or issuer should be required to rely on the independent database for rate information.**

Information to be Shared about the QPA

The departments require that plans and issuers share the QPA with providers for purposes of administering cost-sharing. Along with the amount of the QPA, the regulations direct plans and issuers to state that the QPA applies for purposes of the recognized amount, that it was determined in accordance with federal rules, and that providers or facilities, as appropriate, may initiate a 30-day open negotiation period on reimbursement. It appears that the departments require that this information be transmitted at the same time at which the plans remit the initial payment amount or issue a denial of payment. While we recognize that sending all information at the same time may alleviate some administrative burden, we are concerned that the departments have not sufficiently clarified that the QPA and the initial payment amount are not the same thing. **We strongly urge the departments to clarify in the regulations that the QPA and the initial payment amount are not equivalent unless the provider or facility has agreed to accept the value of the QPA as their final reimbursement.**

Second, we note that under these regulations, plans and issuers will not be required to provide any meaningful information to providers and facilities. Providers and facilities will have no way of knowing if the plan or issuer accurately calculated the QPA, such as by only including appropriately comparable rates. That being said, we recognize that providers or facilities likely would have little ability to assess the accuracy of any detailed information shared by plans or issuers. For example, if a facility requested and the plan and issuer shared information on the other providers for which the rates were based, the facility would have no way of verifying that the information reflected the full scope of the plan's or issuer's like contracts. Therefore, instead of requesting that plans and issuers provide additional information to providers, **we urge the departments to conduct frequent and thorough oversight of plan's and issuer's calculation of the QPA.** As is discussed later, we believe the departments cannot rely on existing audit mechanisms alone and instead must put in place more robust oversight. In addition, **the regulations must clearly state that plans and issuers are responsible for any consequences resulting from inaccurate calculations of the QPA, such as making patients whole for any excess cost-sharing based on an inaccurate QPA. In addition, the IDR process must have a mechanism for revisiting decisions that took into account a QPA that was later found to be inaccurately calculated.**

Request for Comment on a Potential Adjustment to the QPA to Account for "Large Consolidated Health Care System" Rates

The departments suggest that certain health system rates may inflate the QPA due to the "contracting practices" of such systems and ask for feedback on whether there should be some adjustment to the QPA to account for this. We strongly disagree with the departments' premise and question how such an adjustment could be operationalized. First, the departments offer no definition of "large consolidated health care system," no evidence that such systems necessarily have higher rates in a given community such that they could inflate the QPA, and no evidence that these systems' rates are out of sync with the value and access to care they provide to patients and the plans and issuers.

In order to fully assess the merit of such an idea, as well as to operationalize this kind of modifier, the departments would need to address a number of outstanding issues, such as:

- How would the departments define a "large consolidated health care system?" What characteristics would the system need to have? Would those characteristics need to be present in each community where the system has providers? Would they vary by geographic region depending on local dynamics?
- Would the departments consider Optum, as the largest employer of physicians nationally, a consolidated health care system given its expansive reach in ambulatory surgical centers, urgent care centers, specialty pharmacy services, health insurance, and a wide range of health care analytics and administrative health care support services? What about other vertically integrated health systems owned by insurers?
- If a facility is part of an integrated delivery system but is the only system-affiliated facility in that region, would its rates automatically be discounted for purposes of this regulation? For example, if a rural facility is part of a health system, would the rates at the rural facility be discounted despite the broadly acknowledged financial pressures and other challenges that rural hospitals typically face?
- How would the departments direct plans to treat facilities and providers within systems where rates vary based on location and there is no single "system" rate? Would the "systemness" of these providers and facilities matter?
- How would the departments define the value of a particular rate? For example, would the departments consider the rates of a system to be inflationary if they are higher than others because the provider is the only source of advanced care in a community or provided other benefits not available elsewhere in the community?

In addition, we question why the departments are not also seeking comment as to whether large, consolidated health insurers are inappropriately depressing rates in some markets. Approximately 25% of hospitals routinely operate with negative

margins.[2] Many of these hospitals are disproportionately dependent on public payers, such as Medicare and Medicaid. In many instances, the dominant commercial payer in the market will further compress these hospitals' revenue by refusing to adequately pay for services. These providers often are only able to stay open due to less reliable sources of funding such as non-patient care revenue (such as philanthropy and investments) and tax-payer supported funding. It is therefore not a surprise that 47 hospitals closed or entered bankruptcy last year. The pressure on rural hospitals is even greater; 138 hospitals have closed since 2010, including 19 in 2020 alone. For many rural hospitals, partnering with a system is key to staying open and maintaining access to care for their community. In light of the departments' comments regarding health systems, we are disappointed to see no recognition of the dominance of a very small number of health plans in most markets and the impact such dominance may have on payment rates.

PAYMENT TO PROVIDERS

Consistent with the law, the regulations require that plans or issuers either make an initial payment (or issue a notice of denial) to providers within 30 calendar days of receiving a clean claim for covered services. The initial payment may not be the final reimbursement amount. Final reimbursement will be determined by one of the following methods: the amount determined by an applicable All-payer Model Agreement; the amount determined under an applicable state law; the amount agreed to by both the plan and provider through negotiation (which may be the initial payment amount); or the amount determined through the IDR process. The departments note that they expect plans and issuers to act in good faith but will consider additional standards if they become aware of abuse or gaming by the plans and issuers, and the departments seek comment on whether they should establish a minimum payment amount.

Initial Payment

We support the requirement that plans and issuers must reimburse (or issue a notice of denial to) providers within 30 calendar days. While we recognize the logic of starting the clock at the point at which the claim is considered to be "clean," **we urge the departments to prioritize this issue for oversight and monitoring**. Health plans and issuers routinely create barriers to payment by changing the expectations around what constitutes a clean claim by, for example, implementing new and inconsistent documentation requirements after a claim has been submitted. Some payers also routinely fail to pay claims in a timely way, despite the existence of prompt pay laws. For example, in a state with a prompt pay law, one health system is currently reporting that 43% of their accounts receivable from one of their largest payers exceed 90 days. Another system in the same state is reporting that 34% of their accounts receivable for the same payer is also older than 90 days. To-date, no regulator has stepped in to enforce the prompt pay laws. In other words, insurers routinely delay payments in flagrant violation of the law and stopping these abusive tactics requires adequate oversight by regulators.

[2] This figure is based on 2019 to avoid the impact of COVID-19 on hospital operations and finances.

Minimum Payment Amount

Congress considered and clearly rejected setting a benchmark rate for reimbursement from plans to providers. **We urge the departments to adhere to the intent of Congress and not establish any minimum payment amount.** There is no approach to establishing a minimum payment amount that would result in fair and appropriate reimbursement in most instances, and the existence of such an amount would undoubtedly disadvantage providers and facilities who wished to challenge the minimum amount through the IDR process.

Health plans and issuers and hospitals have a longstanding history of resolving out-of-network emergency service claims, and this process should not be disrupted. We are particularly concerned that any attempt at setting a reimbursement standard in regulation will have significant consequences, including by creating a disincentive for insurers to maintain adequate provider networks. As noted earlier in our comments, growth in the use of no-network, reference-based pricing models in the commercial market suggests this is already a growing strategy, and one that would accelerate if the plan or issuer could simply default to a government-established, out-of-network rate or methodology.

The process of rate negotiation is a core function of managing a health plan. The process takes into account a number of factors that could not be accounted for in a government rate or methodology. For example, plans and issuers and providers and facilities often consider their entire lines of business, volume, quality, partnerships on special programs or initiatives, and other factors when setting rates. In addition, providers and facilities consider other elements besides reimbursement when negotiating contracts, such as the amount of administrative burden a plan or issuer creates for the provider or facility, such as through prior authorization and payment delays and denials. Setting a rate or methodology sufficiently simple for national use, even if geographically adjusted, would not be able to capture the many factors that specific health plans and specific providers consider and we believe could lead to additional use of the IDR process. In addition, a minimum standard could remove incentives for health plans to maintain comprehensive networks and follow fair business practices as a way of encouraging providers to enter into contracts. Health plans and issuers should not be absolved of the core function of establishing provider networks, and establishing a minimum reimbursement amount could create that incentive.

We reject any argument by plans and issuers that such a consequence is mitigated by network adequacy standards. First, the vast majority of plans that are impacted by the No Surprises Act and these regulations are regulated under ERISA, which does not mandate that plans meet any specific network adequacy requirements. Second, some of the large commercial insurers have begun flouting existing network adequacy standards by contracting with a provider such that the plan or issuer presents the provider or facility as in-network only to subsequently revoke coverage of many of the services delivered by the provider or at the facility. Several of the large commercial issuers routinely sell network-based health plans that present one set of participating,

in-network providers, and once the plan year has started, change their policies to deny coverage of certain services at that in-network provider. These issuers have implemented such policy changes on their enrollees for critical services such as certain outpatient surgeries, specialty pharmacy drug therapies, radiology, and imaging. Not only do these policies degrade access to care by reducing the provider network, they also lead to consumer confusion about their benefits, disruption in the relationship between patients and their providers, and higher out-of-pocket costs for enrollees who continue to seek care at their preferred *in-network* providers.

For these purposes, we urge the departments to not set a minimum payment benchmark and ensure that the IDR process, when established, does not inadvertently encourage plans and issuers to further restrict their provider networks.

Out-of-network Rate

As noted above, the No Surprises Act was clear that the out-of-network rate would be based on a state's All-Payer model, another applicable state law, negotiation between the plan or issuer and the provider or facility, or the IDR process. However, the regulations, including preamble text, include potentially confusing language with respect to the relationship between the out-of-network rate and the QPA. Specifically, the regulations require that the QPA, as well as the required information regarding the validity of the QPA, be transmitted at the same time as the initial payment amount (or notice of denial of payment). **In order to address any confusion we reiterate our recommendation for the departments to clarify in the regulations that the QPA is neither the initial payment amount nor the out-of-network rate, unless agreed to through negotiation between the provider or facility and the plan or issuer.**

Conveying the Application of Balance Billing Protections on Claim

The departments encourage providers and facilities to indicate on the claim whether the service is subject to the surprise billing protections. We note that providers and facilities may not be in the best position to assess whether or not a claim is subject to these protections. First, providers and facilities will not necessarily know what type of coverage the patient has prior to billing the plan or issuer as this information is not always apparent either on the insurance card or when running an eligibility check. For example, the provider or facility may not know if the plan is considered a short-term limited duration plan and therefore not subject to the rules; whether the particular service is outside of the scope of the patient's benefits; or whether the plan is regulated by the federal government or the state. To further confuse matters, in the instance where a state law exists and allows for federally-regulated plans to opt in, the provider may not know if the patient's plan or issuer has opted in. **For these reasons, hospitals and health systems should not be expected to flag on claims to plans and insurers when these provisions apply. Instead, plans and issuers are in a much better position to determine which protections, if any, apply.**

INTERACTION WITH STATE LAW

In general, the law and regulations apply to all forms of comprehensive group and individual market commercial coverage except in instances where states have surprise medical billing protections in place for state-regulated plans. The interaction between federal requirements and state law is very important and very complicated. **The AHA recommends that the departments more clearly articulate when state laws apply, as well as modify the regulations to disallow a split process (where a single episode of care may be subject to both state and federal laws). In these instances, only one set of policies should prevail, and we recommend that the departments apply the federal protections and related policies.**

Permitting both state and federal laws to apply to a single episode of care will not be operationally feasible. To illustrate this, we rely on one of the examples provided in the regulation in which a patient in a state-regulated health plan receives both emergency and post-stabilization services from an out-of-network facility. The care is provided in a state that has balance billing protections for emergencies services only and not post-stabilization services. The regulations require for the state's balance billing protections and reimbursement policies to apply to the emergency services and the federal government's protections and reimbursement policies to the post-stabilization services.

This scenario would result in substantial patient confusion and potentially double the administrative cost and burden for plans and issuers and providers and facilities. While not an exhaustive list, the following are some of the operational concerns we have with this approach:

- The patient will receive multiple disclosure forms and providers must be prepared to explain how the two different policies may interact.
- Plans and issuers must calculate cost-sharing in two different ways, doubling their burden.
- A provider or facility seeking to challenge the total payment amount must engage in two separate processes.
- The patient's cost-sharing is determined without regard for the final payment amount by the plan or issuer for the post-stabilization services but their cost-sharing could change after a dispute for the emergency services, if permitted by the state. In fact, we question whether a state's law would even be deemed sufficiently comprehensive if it allowed for patient cost-sharing to change after reimbursement was determined.

We urge the departments to apply the federal protections and requirements in any instance where an episode of care spans both state and federal policies.

In addition, we note that not all potential scenarios are addressed in the rule. For example, the rule and the separate notice and consent standard form say that if a state law conforms to the No Surprises Act requirements, then the state's notice and consent law could prevail. Providers and facilities are not in a position to evaluate a state's compliance with the federal statute. **At a minimum, we recommend that the**

departments work with the National Conference of State Legislatures, the National Governors Association, and the National Association of Insurance Commissioners in developing guidance to states, plans and issuers, and providers and facilities on the interaction of state and federal laws. Such guidance could include a crosswalk of state law and the federal provisions and definitively identify where a provider or facility should (or must) rely on state law. In addition, we strongly urge enforcement discretion while questions remain about which jurisdiction prevails, for example, if an important deadline is missed due to confusion about whether state or federal law applies.

OVERSIGHT

The law and regulations established a shared responsibility for oversight and enforcement of the No Surprises Act between federal and state authorities. We recognize there may be substantial challenges in standing up these oversight processes by Jan. 1, 2022, due to the complexity of the policies, the lack of comprehensive guidance to-date on all components of the law, and inherent challenges with information sharing across different levels of government. This shared approach to oversight and enforcement will likely lead to substantial variation across the country as well as states will have different priorities and capacity levels to engage in oversight. Further intensifying this challenge will be how states with their own surprise billing policies conduct oversight of two different sets of policies – sometimes, as discussed above, for the same episode of care.[3]

In general, we urge the departments to:

- **Clearly articulate which components of the law will be overseen by the federal government and which by the states;**
- **Provide a crosswalk between the federal and state laws and a clear assessment of which states meet the standards for compliance on relevant provisions, e.g., notice and consent and protections against balance billing;**
- **Set clear standards for what constitutes adequate state oversight and an articulation of how the federal government plans to determine whether oversight is adequate; and**
- **Establish a data submission process with standards for states to report complaints and outcomes to the federal government for tracking and oversight.**

Additional comments on specific components of oversight and enforcement follow.

[3] The regulations provide one example where a patient receives out-of-network emergency and post-stabilization services in a state with a surprise billing law that applies only to emergency services. According to the regulations, the state law will apply for purposes of the emergency services whereas federal law will apply for purposes of post-stabilization services.

QPA Audits

In the regulation, the departments discuss the process for ensuring compliance with the QPA requirements. The departments note that enforcement responsibilities will be split between states and the federal government, with the Departments of Labor, Treasury, and Health and Human Services and the Internal Revenue Services and Office of Personnel Management all playing an enforcement role based on existing authority. For the purpose of auditing and enforcing the QPA requirements, the departments note that they "will generally use existing processes to ensure compliance." **The AHA is deeply concerned that the existing oversight mechanisms are insufficient to monitor plan and issuer behavior and a more robust structure is needed to enforce the QPA requirements.**

Current enforcement mechanisms have failed to prevent widespread inappropriate behavior by plans and issuers, including reducing beneficiaries' access to care by narrowing networks, creating delays through increased use of burdensome prior authorization requirements, and changing coverage policies mid-year. For example, a 2018 HHS Office of the Inspector General (OIG) report found that 75% of appealed Medicare Advantage (MA) prior authorization or payment denials were overturned during internal appeals. In addition, independent reviewers at higher levels of the appeals process overturned additional denials in favor of beneficiaries and providers. Unfortunately, the report notes that beneficiaries and providers only appealed 1% of denials to the first level of the appeals process between 2014 and 2016. Many patients therefore were likely not granted access to care that should have been covered. These findings indicate gross health plan and issuer abuse that is curtailing patient access to needed care and creating more waste in the system. The report concluded that CMS needs to enhance its oversight of MA plans to prevent such misuse of utilization management tools; however, such updates have yet to be implemented.

We know from our members that these types of tactics are not exclusive to MA plans and that commercial health plans and issuers regularly institute similar policies impacting access. Often in these types of situations, regulations exist to protect patients from plan and issuer abuses but oversight is lacking to ensure compliance. Instead, the enforcement authorities rely on self-reported data or inadequate complaint mechanisms to track inappropriate behavior. Though patients and providers continually push back on these practices, greater oversight is clearly needed to monitor and curtail such actions. Given the persistent and growing concerns with existing oversight mechanisms, we do not believe that these mechanisms will be sufficient to ensure compliance with the QPA requirements.

The consequence of inadequate oversight could be the depression of the QPA, which could have substantial repercussions if the QPA is heavily weighted in the IDR process. Such a result may result in lower patient cost-sharing at the outset, but it would undoubtedly create other problems for patients. Specifically, the more plans and issuers can rely on an artificially low rate through the QPA, the less likely they are to maintain comprehensive and adequate networks of providers. This will further restrict where their

enrollees can access care and put enormous financial pressure on providers – not all of which may be able to keep their doors open as a result.

Complaint Process

The regulations establish a process through which the departments can collectively receive and resolve complaints about potential violations of all of the consumer protection and balance billing requirements included in the No Surprises Act. This single complaint process will apply to health plans and issuers, providers and facilities, and providers of air ambulance services, and will serve as the basis for informing the government of potential violations of the No Surprise Act. The regulations lay out the initial steps that the departments will take to investigate complaints and either offer resolution, initiate investigation for enforcement action, or refer the complaint to another state or federal agency for resolution or enforcement. The departments did not institute a statute of limitations on the timeframe for submitting a complaint through this process.

While the AHA supports the premise of this streamlined complaint process, we are concerned that there is not a statute of limitation for submitting complaints. As the departments note, they may seek additional information during their investigation from any of the stakeholders involved, including the person submitting the complaint, the health plan or issuer, or the provider or facility. Providing such information will become impossible after a certain point, as maintaining records indefinitely is untenable. Instead, AHA recommends setting a statute of limitation of five years to bring the complaint or to start the complaint process to align with the document retention policies stipulated in the notice and consent requirements. Specifically, the regulations require that providers maintain notice and consent documents for seven years. Given that there will be a period of time between when a complaint is filed and additional documentation is requested, there must be a buffer period between the statute of limitation and the documentation retention period.

In addition, greater detail is needed on the process following the initial complaint investigation to ensure proper enforcement. The departments note the next steps could include “referring the complainant to another appropriate state or federal resolution process, referring a complainant to the state or federal regulatory authority with enforcement jurisdiction, or initiating an investigation for enforcement action.” **The departments should make clear to the public which federal and state authorities have jurisdiction over the different potential No Surprises Act violations.**

Moreover, additional guidance is needed for how complainants and those subject to the complaint track when a complaint has been referred to another federal or state authority. Specifically, the departments should provide a mechanism for complainants to follow where their complaint is in the process and ensure that complainants have an appropriate point of contact at each point in the process. From there, the complainant should be notified of updates regarding any additional investigation and the eventual outcome.

Finally, there also should be a process – which is not enumerated currently – for the departments to step in should the state or alternative federal agencies fail to conduct appropriate oversight.

CONCLUSION

Protecting patients from surprise medical billing is of utmost importance, and we are pleased to work with the departments on implementation of this important law. Please contact me if you have questions or feel free to have a member of your team contact Molly Smith, AHA's group vice president for policy, at mollysmith@aha.org.

Sincerely,

Stacey Hughes
Executive Vice President