September 7, 2021

The Honorable Xavier Becerra
Secretary
U.S. Department of Health & Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

The Honorable Janet Yellen
Secretary
U.S. Department of the Treasury
1500 Pennsylvania Avenue, NW
Washington, D.C. 20220

The Honorable Martin J. Walsh
Secretary
U.S. Department of Labor
200 Constitution Avenue, NW
Washington, D.C. 20210

The Honorable Chiquita Brooks-LaSure
Administrator
Center for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-9909-IFC; Requirements Related to Surprise billing; Part I

Submitted via *Federal eRulemaking Portal at www.regulations.gov*

Dear Secretary Becerra, Secretary Walsh, Secretary Yellen, and Administrator Brooks-LaSure:

On behalf of our collectively more than 55,000 physician and medical student members, the Texas Medical Association (TMA), Texas Orthopaedic Association, Texas College of Emergency Physicians, Texas Radiological Society, Texas Society of Pathologists, and Texas Society of Anesthesiologists (hereinafter the "Associations") appreciate this opportunity to comment on the interim final rules on the Requirements Related to Surprise Billing; Part I, as published in the July 13, 2021 edition of the *Federal Register*.

Our organizations have a keen interest in legislative and regulatory efforts relating to "surprise" out-of-network balance bills. The Associations supported surprise billing legislation in Texas (i.e., SB 1264, 86th Regular Session), as passed, due to our commitment to helping patients address "surprise" out-of-network balance bills.

The Associations also support many of the patient protection measures included in the No Surprises Act and the interim final rules (such as protections reinforcing the prudent layperson standard for emergency care and the application of cost-sharing amounts to the in-network deductible and out-of-pocket maximum); however, we have grave concerns with others portions of the rule, such as the "qualifying payment amount" definition in the context of the independent dispute resolution (IDR) process. Our specific comments are set forth in more detail, below.

I. Definitions

A. "Health care facility" and "Independent freestanding emergency department"

1. "Health care facility"

The definition of "health care facility" in the interim final rules is as follows in the context of nonemergency services: (1) a hospital (as defined in section 1861(e) of the Social Security Act; (2) a hospital outpatient department; (3) a critical access hospital (as defined in section 1861(mm)(1) of the Social Security Act; and (4) an ambulatory surgical center described in section 1833(i)(1)(A) of the Social Security Act.

The Departments solicit feedback on whether additional facilities should be included in this definition and request feedback related to urgent care centers and retail health clinics. As the preamble states,

> [t]he Departments recognize that state regulation of urgent care centers varies significantly, as does the type of services they are permitted to provide under state law. Under these interim final rules, emergency services provided at urgent care centers that are licensed in a manner that brings them within the definition of independent freestanding emergency department would be subject to cost-sharing and balance billing protections, among others. However, given significant variation in state law definitions, urgent care centers are not included within the definition of health care facilities, in the context of nonemergency services.[1]

The Associations strongly agree with ***not*** including urgent care centers in the definition of a "health care facility." As acknowledged by the Departments, state regulation of urgent care centers varies widely (as do the services provided at urgent care centers). Some states license urgent care centers and treat them as a facility. Others, like Texas, do not license urgent care centers and regulate them not as facilities but as physician practices (focusing on physician licensure and oversight by the state medical board). It is imperative that the Departments not interfere with these existing and long-standing state regulatory frameworks.

The risk of surprise billing is not the same at an urgent care center as it is as at a hospital or other traditional health care facility for multiple reasons, including that (1) a facility fee is not charged; and (2) urgent care centers typically perform a wide variety of services that are lower acuity than emergency care (where surprise billing scenarios are more likely to occur). In contrast to a freestanding emergency care facility (which in Texas are licensed to provide emergency care),

[1] Federal Register Vol. 86, No. 131 at 36882 (July 13, 2021).

urgent care centers often function as walk-in or after-hours care for patients with nonemergent conditions. Since care provided at urgent care centers is lower acuity, there is more of an opportunity to shop for care and avoid a surprise out-of-network bill.

Notably, the Texas Legislature did not include urgent care centers in its definition of a "health care facility" under Texas' comprehensive surprise billing legislation (i.e, SB 1264, Texas Legislature, 86th Regular Session), thereby recognizing that: (1) surprise billing legislation should be focused on scenarios where surprise billing is most likely to occur (i.e., certain licensed facilities) and (2) urgent care centers in Texas are not those facilities. **We urge the Departments to do the same and refrain from broadening the definition of a "health care facility" to encompass urgent care centers.**

The Associations also oppose any proposed inclusion of retail health clinics in the definition of a "health care facility" for purposes of surprise billing legislation. Retail health clinics are not licensed as health care facilities in Texas and should not be performing emergency services; thus, there is not the same risk for surprise bills in these locations (which may schedule care and provide a smaller range of services than in licensed facilities) as in the facilities encompassed in the Departments' current definition of a "health care facility." Surprise billing legislation and regulation is typically directed at avoiding scenarios where patients are likely to be surprised that care is out-of-network, not in circumstances under which patients choose care at a particular location or with a particular provider for convenience.

In summary, the Associations contend that the itemized list in the interim final rule definition of "health care facility" encompasses sufficient facilities for the purposes of implementing the law's surprise billing protections. Thus, the Associations oppose any proposed inclusion of urgent care centers or retail health clinics in the definition of a "health care facility."

2. Independent freestanding emergency department

Next, the Departments define an "independent freestanding emergency department" as "a health care facility (not limited to those described in the definition of health care facility with respect to non-emergency services) that—(1) is geographically separate and distinct and licensed separately from a hospital under applicable State law; and (2) provides any emergency services described in §54.9816-4T(c)(2)(i)."

For consistency with the underlying statutory language in the No Surprises Act and to aid physicians and providers in assessing which facilities fall within the definition, the Associations recommend that the rules be amended to refer solely to facilities licensed as independent freestanding emergency departments under state law. However, should the Departments move forward with a more expansive definition (as currently reflected in the interim final rules), the Associations agree with ***not*** expressly including urgent care centers in this definition, because (as noted above) the services provided at urgent care centers and the regulation of urgent care centers varies widely under state laws. The Associations also support the separate licensure requirement contained in the current definition of "independent freestanding emergency department." As noted, above, Texas does not license urgent care centers and thus, our understanding is that Texas urgent care centers, therefore, would not fall within the definition of an independent freestanding

emergency department under the interim final rules. This approach would be consistent with Texas law, which exempts physician offices and clinics from the freestanding emergency medical care facility licensure requirements.

B. "Participating Health Care Facility" and "Participating Emergency Facility"

Next, in the definition of "participating facility," the interim final rules provide that "a single case agreement between a health care facility and a plan or issuer, used to address unique situations in which a participant, beneficiary, or enrollee requires services that typically occur out-of-network constitutes a contractual relationship for purposes of this definition, and is limited to the parties to the agreement with respect to the particular individual involved." The practical effect of including this language in the "participating health care facility" definition is that when nonparticipating physicians or other providers provide nonemergency care at a facility that has a single case agreement, the nonparticipating physician or provider would be subject to the surprise billing provisions of the interim final rules for that particular individual's care.

While the Associations understand the Departments' rationale for inclusion of this language as stated in the preamble (i.e., to address instances where the patient might expect the other providers to be in-network), we are concerned that this expansive definition of "participating facilities," will have two negative effects on patients and physicians. First, inclusion of this language will create compliance challenges for nonparticipating physicians and other providers. It will be more difficult for a physician or provider who is providing services at a facility to know whether such a single case agreement (to which they are not a party) is in place (and, therefore, whether the physician or provider is subject to the balance billing prohibitions and other requirements under the law). Given the steep penalties applicable for violations of the law, this compliance challenge could ensnare well-intentioned physicians and providers who, despite good faith efforts, may violate the law based upon a lack of knowledge of these single-case agreements.

Additionally, the single case agreement language essentially permits health benefit plan issuers and health care facilities to determine on a case-by-case basis whether an individual will fall within the No Surprises Act (for nonparticipating physicians or providers providing services at the facilities). This allowance may disincentivize health plans from developing robust networks (by giving them assurances that they can rely on these single case agreements with facilities as a backstop). **Thus, while inclusion of the single case agreement in the definition might benefit the individual whose care is affected by the agreement, it may seriously harm the composition of the network on a broader scale (resulting in patients having fewer choices of in-network physicians and other providers overall).**

The Associations, therefore, recommend that the Departments strike the last sentence regarding single case agreements from the interim final rules. Should the Departments move forward with the single case agreement language, over the Associations' objection, the Associations ask that the Department include language stating that the single case agreement must be in advance of the provision of services (to make it abundantly clear that an agreement after services have been rendered does not affect the application of the No Surprises Act to nonparticipating physicians or providers providing services at the single case agreement facility).

The Associations note that the same language regarding single case agreement is included in the interim final rules for "participating emergency facility." The Associations offer the same comments, as stated above, with regard to the "participating emergency facility" definition. The single case agreement language in both definitions goes beyond the language of the underlying law and is problematic for the reasons stated herein.

C. "Specified State Law"

Next, the rules define a "specified state law" as follows:

> a state Law that provides a method for determining the total amount payable under a group health plan to the extent such State law applies for an item or service furnished by a nonparticipating provider or nonparticipating emergency facility (including where it applies because the State has allowed a plan that is not otherwise subject to applicable State law an opportunity to opt in, subject to section 514 of the Employee Retirement Income Security Act of 1974). A group health plan that opts into such a specified State law must do so for all items and services to which the specified State law applies and in a manner determined by the applicable State authority, and must prominently display in its plan materials describing the coverage of out-of-network services a statement that the plan has opted into the specified State law, identify the relevant State (or States), and include a general description of the items and services provided by nonparticipating facilities and providers that are covered by the specified State law).

1. Comments on "a method for determining the total amount payable"

The Associations appreciate the Departments' consistency with underlying statutory language in the first portion of the definition of "specified state law" in the interim final rules and the explanatory language in the preamble on that portion of the definition; however, the Associations have some remaining concerns with the ERISA language and believe that additional guidance likely will be needed on the interaction between state and federal law (particularly for physicians and providers who are licensed and practicing in multiple states with surprise billing laws).

Determining whether a particular state law addressing surprise billing qualifies as a "specified state law" under the No Surprises Act and regulations will be critical for compliance efforts by the regulated community (as it is clear from the federal law and the rules that the cost-sharing amount, payment, and independent dispute resolution provisions of "specified state laws" are not preempted). Varying interpretations of the application of state and federal law may result in enforcement efforts taken against providers who are making good faith attempts to navigate the interaction between state and federal law.

For this reason, we are particularly appreciative of the Departments' guidance in the preamble, which states as follows:

> The Departments interpret the statutory phrase 'a State law that provides for a method for determining the total amount payable under such a plan, coverage, or

> issuer, respectively' broadly as referring not only to state laws that set a mathematical formula for determining the out-of-network rate, or that set a predetermined amount for an out-of-network item or service. Rather the Departments interpret that language to also include, for example, state laws that require or permit a plan or issuer and a provider or facility to negotiate and then to engage in a state arbitration process to determine the out-of-network rate. Such state laws provide a process for determining the total amount payable, and in such instances, the timeframes and processes under such a state law related to negotiations and arbitration would apply, as opposed to the timeframes and IDR processes under the No Surprises Act.[2]

The Associations **strongly agree** that the statutory language should be interpreted broadly to effectuate Congress' intent of not preempting state surprise billing laws. In particular, we strongly agree that state laws, such as Texas' law (i.e., SB 1264, 86th Regular Session) that require or permit a plan or issuer and provider or facility to negotiate and then engage in a state arbitration process to determine the out-of-network rate qualify as a "specified state law." Clearly by using language that references a "method for determining," Congress did not intend the "specified state law" language to be limited to state laws that set a fee schedule or mathematical formula for assessing the total out-of-network payment. This is the only rational reading of the statutory language.

Further, state laws that have an arbitration process like Texas' arbitration process do set forth "a method for determining the total payment amount." In Texas, there is a defined method for determining the enrollee's cost sharing (which is based upon the amount initially determined payable by the plan or if applicable, a modified amount determined under the plan's internal appeal process) and there is a defined method of determining the total payment amount (with the arbitrator limited to selecting between certain amounts in baseball style arbitration after determining the reasonable amount for the services or supplies). Thus, a surprise billing law that is similar to Texas' should (very clearly) qualify as a "specified state law" under the No Surprises Act.

Some law articles have raised questions as to whether the "total payment amount" language in the statute requires the arbitration under a state law to be binding. The Associations note that the arbitration determination under Texas's surprise billing law is, in fact, "binding." Thus, such a distinction should not affect the qualification of Texas' law as a "specified state law." As reflected in SB 1264, the Texas Legislature used the word "binding" **seven** different times in the statute to describe the arbitration determination. Most expressly, the Texas Legislature states in Section 1467.089 that "[a]n arbitrator's decision under Section 1467.088 is binding." Texas law does permit a narrow window of 45 days for a party not satisfied with the decision to file an action to determine the payment due to an out-of-network provider, but this is a very limited review under a substantial evidence standard of review. Thus, this review should not be construed as altering the binding nature of the award for purposes of the specified state law analysis.[3]

[2] *Id*. at 36887.

[3] Anecdotally, the Texas Medical Association has also been told that when a provider has won under the substantial evidence standard of review, the court has stated their recourse was to go back through arbitration to determine the award.

In any event, the Associations also contend that the "total payment amount" determination should not be dependent upon whether an arbitration decision is "binding" or not, because a non-binding arbitration determination would still be a process for determining the total payment amount (thus strictly complying with the language of the No Surprises Act). The No Surprises Act statutory language does not state that any arbitration process has to be "binding" in order to fall within the "specified state law" provision nor does the Departments' explanatory language in the preamble. Such an additional requirement should not be read into the statutory language, thereby altering the plain meaning of the statute. Furthermore, the Associations agree with the Departments that the language should be broadly construed to effectuate Congress' intended deference to the states with surprise billing legislation.

The Associations note that some analyses have viewed 16 state laws as having comprehensive surprise billing laws and several more as having partial surprise billing laws. Yet, the preamble references 14 (unidentified) states as having established a method for determining payment for nonparticipating emergency and nonemergency services. This disconnect has caused some to raise concern as to whether their particular state's surprise billing law would qualify as a "specified state law." Thus, additional clarification could be beneficial to prevent any confusion among the regulated community as physicians and providers attempt to navigate state and federal law (particularly those who provide services physically in multiple states or via telemedicine). However, in issuing any such further guidance, the Associations urge the Departments, again, to be mindful of the interim final rule statement regarding broad construction of the statutory language and to avoid narrowing the scope of the "specified state law" definition. Specified state laws (including laws that apply comparable or additional requirements on plans), like Texas' clearly were not intended to be preempted by the No Surprises Act. The Departments should not alter this statutory intent.

The Associations also recommend that, given the risk for potential confusion over which law (state versus federal) applies in a particular scenario, the Departments provide for an opportunity for physicians and other providers acting in good faith who use the wrong process to correct the mistake without penalty. Furthermore, any timelines under state or federal law for initiating arbitration should also be deemed to have been satisfied if arbitration was initiated in the wrong forum (i.e., state versus federal). For example, if a provider initiates an arbitration under federal law within 90 days of receipt of initial payment (i.e., the timeframe applicable for initiating arbitration in Texas), but the arbitration should have been initiated under Texas' arbitration process, Texas should permit that arbitration to proceed in Texas even if the arbitration is shifted to Texas after the expiration of the 90-day arbitration initiation period. The same should apply with any deadlines applicable at the federal level for initiating arbitration.

2. Comments on the ERISA-Opt-In Component of the "Specified State Law" Definition

Next, the Departments add a statement in the definition of "specified state law" providing that a specified state law "includes where the state law applies because the State has allowed a plan that is not otherwise subject to applicable State law an opportunity to opt in, subject to section 514 of the Employee Retirement Income Security Act of 1974)."

The rules further specify that "a group health plan that opts into such a specified State law must do so for all items and services to which the specified State law applies and in a manner determined by the applicable State authority, and must prominently display in its plan materials describing the coverage of out-of-network services a statement that the plan has opted into the specified State law, identify the relevant State (or States), and include a general description of the items and services provided by nonparticipating facilities and providers that are covered by the specified State law)."

Although Texas' surprise billing law does not currently have an ERISA opt-in, the Associations **strongly agree** that for states that do have an ERISA opt-in a self-funded plan that chooses to opt-in should be required to opt in for all items and services to which the specified state law applies (in order to protect against the self-insured plan cherry picking the application of state law). It must be wholesale opt-in, not piecemeal or episodic opt-ins. Furthermore, health plan issuers should not be able to opt-in on a product-specific basis. Again, it should be wholesale or not at all.

We also agree that if ERISA opt-ins are permitted by self-funded plans, the ERISA opt-in must be in the manner determined by applicable state law. It is important for states to have the latitude (if granting ERISA opt-ins) to set the terms of those opt-ins (e.g., requiring plans to voluntarily agree to more than just the process for surprise billing, but also to the enforcement provisions and other attendant regulations (e.g., network adequacy requirements) under state law). Presumably, compliance with any additional requirements under state opt-in laws is part of what is contemplated by the interim final rule's statement regarding "in the manner determined by the applicable State authority." The Associations also contend that a self-funded plan should not be able to unilaterally dictate whether a physician or other provider is subject to a self-funded plan's opt-in.

3. Opt-Ins to State Law for Providers

Next in the interim final rules, the Departments expressly seek comment on whether the rules should provide flexibility for health plan issuers, physicians or providers to opt-in to a particular state's program when the issuer, physician or provider is not otherwise subject to a specified state law that provides a method for determining the total amount payable under a group health plan or group or individual health insurance coverage with respect to an item or service furnished by the nonparticipating provider.

The Associations contend that health plan issuers should not be able to unilaterally decide (or cherry pick) which claims go through federal versus state law (or which particular state law applies to particular items or services). However, there are circumstances where it makes sense for physicians and providers to have the **option** to have expanded access to a specified state law's process (rather than having to go through the federal law process). For example, it makes sense if there are services provided by a particular physician or provider on a single claim or for a single episode of care that are split between a specified state law and federal law arbitration process for the physician or provider to have the ability to opt-in to the state law for the items or services that would otherwise be subject to the federal process in order to avoid the administrative hassle of two separate processes (and the expense of two separate arbitrations).

To illustrate this point, this would make sense in the scenario described in Example 3 in the preamble on page 36886 of the interim final rules where a specified state law covers emergency care but does not cover post-stabilization care. Under most state surprise billing laws, post-stabilization services are not included in the definition of emergency services. Thus, if a patient has both emergency services and post-stabilization services, the provider would have to use two separate processes for these claims with the current drafting of the interim final rule. This split process adds additional and unnecessary expense and compliance burden for physicians and other providers.

Furthermore, it makes sense if a physician or provider is subject to a state surprise billing law for fully-insured plans for a particular item or service (e.g., provided on an emergency basis our out-of-network in an in-network facility), for the physician or provider to have the option to use the same state surprising billing law for those items and services under the same circumstances when those items or services are covered by a self-insured plan. Using one state independent dispute resolution (IDR) program may be much less administratively burdensome and costly for a physician than having to parse out which claims go through a state law IDR process and which go through the federal IDR process. Most physicians in Texas have historically practiced in small groups. It will be challenging for physicians in practices of all sizes (but especially in small practices) to navigate separating out each claim based upon the particular plan type. Thus, allowing physicians the flexibility to choose to utilize a single state-based process that would otherwise apply to them for fully-insured plans would accomplish the desired goals of the federal legislation while reducing costs and expenses to physician and provider practices. The Associations recommend that the Departments provide the physicians and other providers with this option**.** Health plans operate on a much larger scale and face fewer difficulties navigating multiple laws, **thus the state-only pathway should be at the physician or provider's choice.**

In Texas, the relevant stakeholders (physicians, hospitals, health plans, and consumer groups) all ultimately supported SB 1264, as passed. Texas' legislation was carefully crafted to provide a means of protecting patients from "surprise" out-of-network balance bills while providing physicians and providers with an IDR process to seek reasonable payment (thereby deterring plans from terminating long-standing physician contracts). The Texas system, which also includes network adequacy examinations conducted by the Texas Department of Insurance (TDI) at least each three years for state-regulated plans, has been working. If a state has an established program (and is consistent with the underlying goals of the No Surprises Act as is Texas' law), a physician or provider should be able to utilize that system more fully, if desired.

D. "Qualifying Payment Amount"

Under the No Surprises Act, the Departments are directed to establish through rulemaking the methodology that group health plans and health insurance issuers are required to use to determine the "qualifying payment amount" (QPA). The methodology is critical, because the QPA is used for two important purposes under the law: (1) (in circumstances when an All Payer Model Agreement or specified state law does not apply) to determine the recognized amount for patient cost-sharing responsibilities; and (2) for consideration by IDR entities when selecting between the plan and facility or provider's offer and determining the total payment for emergency services

furnished by a nonparticipating emergency facility or nonparticipating provider, or non-emergency services performed by a nonparticipating providers at participating facilities that are subject to the federal IDR process.

While the Associations support low cost-sharing for patients out-of-network (and appreciate the Departments efforts to this end), we have grave concerns with the current methodology used to establish QPA to the extent that it is considered in the IDR process (and represented as reflective of the market), because the methodology does not accurately reflect median contracted rates or the market. Our concerns with some of the specific elements of the QPA are detailed, below.

1. Median Contracted Rate

Under the law, the "qualifying payment amount" (QPA) for a particular item or service is the median of the contracted rates recognized by the plan or issuer 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 a geographic region in which the item or service is furnished, increased for inflation. The median contracted rate is determined with respect to all group health plans of the plan sponsor or all group or individual health insurance coverage offered by the health insurance issuer that are offered in the same insurance market, consistent with the methodology established by the Departments.

Under the methodology in the rule, the median contracted rate for an item or service is determined by arranging the contract rates in order from highest to lowest and selecting the middle number (or when there is an even number of rates, the average of the middle two rates). The rules further provide that "[i]n determining the median contracted rate, the amount negotiated under each contract is treated as a separate amount." Thus, each contracted rate for a particular item or service will be treated as a single data point when calculating the median contracted rate (so that group contracts are treated as a single data point and have the same weight as a single contract with an individual physician).

The Associations are very concerned with this approach as it is not reflective of market rates under typical contract negotiations and will artificially deflate the median contract rate. In the health insurance market, negotiations are entered into with a variety of physician practices of varying sizes (from solo practitioners to large group practices). In Texas, most physicians have historically practiced in small groups. But regardless of the size of a physician practice, each physician is a part of the market and affects market rates (even if the physician is part of a group contract).

Yet, the interim final rules fail to acknowledge the role each physician in the market and create a scenario wherein the median contract rate may discount contracts that are representative of a majority of physicians in the area (e.g., if three contracts are considered with the contracts representing a group practice of 50, a group practice of 5 and a solo practitioner, and the group practice of 5 is the median rate). While we understand that as a practical matter, large group practices may, in some instances have greater bargaining power (and more favorable rates) than solo practitioners, this is a part of normal market functioning. To weigh group contracts the same

as a single physician contract significantly distorts the market to skew it in favor of smaller contracts wherein physicians presumably have less bargaining power.

The rules also provide that the number of claims or services provided under the contract for the particular item or service will not be considered in determining the median contracted rate. The Associations note that as part of contract negotiations, physicians or providers may negotiate differently for particular services dependent upon the number of times they expect to perform that service. For low volume services, they may find lower rates more acceptable (knowing that they can make up the loss in fees for other services that are provided more frequently). For higher volume services, they may spend more time negotiating the rate because it has a greater impact on their practice's viability. Thus, failure to consider the volume of claims and weight contracted claims by frequency may also significantly distort the median contract rate determination**.**

2. Insurance Market

Under the interim final rules, the insurance market is defined as the individual market, small group market, or large group market (each as defined under section 2791(e) of the PHS Act (and are defined irrespective of state). The preamble to the rules further expounds on the definition of an insurance market.

The Associations appreciate the Departments' clarification in the preamble that Medicare Advantage and Medicaid managed care plans must not be included in any insurance market for purposes of determining the QPA. We strongly agree that Medicare Advantage and Medicaid managed care (as well as Medicaid fee-for-service and Medicare) should be *excluded* from calculating the median contracted rates. Inclusion of these products (which are not commercial products) is not contemplated by the No Surprises Act and would inappropriately distort the QPA determination.

We are concerned, however, that the interim final rules "permit sponsors of self-insured group health plans to allow their third-party administrators to determine the QPA for the sponsor by calculating the median contracted rate using the contracted rates recognize by all self-insured group health plans administered by the third-party administrator (not only those of the particular plan sponsor.)" [4]

While we understand the stated rationale for this decision (i.e., to reduce the burden imposed on the sponsors and to have fewer instances of insufficient information to calculate a median contracted rate for a given item or service), we are very concerned that this flexibility will permit TPAs to calculate the QPA in a manner that is most advantageous for them (i.e. creates the lowest QPA) and is not reflective of the plan sponsor or the relevant network.

3. Same or Similar Item or Service

Next, in the interim final rules, the Departments define "same or similar item service" for purposes of the QPA as a health care item or service billed under the same service code, or comparable code

[4] *Id*. at 36890.

under a different procedural code system. The interim final rules include specific requirements concerning modifiers. For example, the rules provide that:

> … plans and issuers must calculate separate median contracted rates for CPT code modifiers that distinguish the professional services component ("26") from the technical component ("TC"). This will result in separate median contracted rates being calculated for services when billed by a facility versus a provider. In addition, where a plan or issuer's contracted rates otherwise vary based on applying a modifier, the plan or issuer mut calculate a sperate median contracted rate for each such service code-modifier combination.[5]

The Associations are concerned that the interim final rules' language on determining same or similar service does not appear to account for the effect of downcoding by health plans on the QPA. If plans are permitted to calculate median contracted rates on the downcoded claims rather than on the level of claim submitted for payment, they can reduce the median contract rate through their own initiative (thereby deflating the appropriate contracted rate for QPA purposes). We also agree with the AMA's prior comments stating that: (1) the contracted rates used to calculate a median rate should not incorporate modifiers that reduce payments and (2) the departments "should consider using an outlier methodology that excludes $0 paid on claims, as well as inappropriately low payments, that may result in inappropriate skewing of the median."

4. Same or similar specialty provider

Next, the interim final rules provide that the median contracted rate must be calculated separately for each provider specialty if a plan or issue has contracted rates for a service code that vary based on provider specialty. Under the rules, "provider in the same or similar specialty" is defined as "the practice specialty of a provider, as identified by the plan or issuer consistent with the plan's or issuer's usual business practice … ." If the plan or issuer uses separate identifications of specialty for contracting purposes and other business needs, the plan is supposed to be required (as stated in the preamble) to use the specialty classification that the plan uses for contracting purposes.

The Associations are concerned that the definition and explanatory language in the preamble appear to defer significantly to the plan's classification of the physician or provider's specialty. The plan's classification also should have to accurately reflect the physician or provider's self-designation of specialty (and not unilaterally be determined by the plan in order to prevent plans from skewing the results of the applicable rates); otherwise, this could negatively affect the QPA determination. We also note that for a truly apples-to-apples comparison, it is vital for the same or similar specialty provider to be the same or similar specialty provider with the same licensure type (i.e., physicians of the same or similar specialty should be compared to other physicians of the same or similar specialty). The education, training, and experience of a provider affects negotiated contract rates.

5. Geographic Regions

[5] *Id*. at 36891.

In order to narrow and more accurately reflect the markets, the No Surprises Act requires plans to calculate the median contracted rate for an item or service using contracted rates for the similar item or service provided in the geographic region where the item is furnished. The Associations are concerned that under the interim final rules, geographic areas are defined very broadly as one region for each metropolitan statistical area in a state and one region for all other portions of the state.

We agree with prior comments from the AMA that geozips are the most appropriate tool to define the geographic area. Under Texas law (SB 1264, 86th Regular Session), geozips are the relevant market for consideration in the IDR process. The Associations understand that this may result in more instances of insufficient data for each calculation, but it would be more appropriately tailored data that is reflective of the local market, which could also be beneficial for calculating cost-sharing in the QPA computation. Furthermore, under the current rules the threshold for having sufficient information to calculate the median contracted rates is not high (i.e., it is currently if the plan or issuer has at least three contracted rates on January 31, 2019).

6. Non-Fee-For-Service Contractual Arrangements

In the interim final rules, the Departments acknowledge that there are many arrangements that are non-fee-for-service (e.g., bundled payments or capitation arrangements). The Departments state that when a plan or issuer uses an alternative payment model that isn't fully fee-for-service, the plan or issuer is required to calculate a median contracted rate for a given item or service using the underlying fee schedule rates that the plan uses for cost-sharing for the relevant items or services, if such a schedule is available. If such a schedule isn't available, the plan or issuer must use a derived amount (which the plan or issuer assigns for the purpose of internal accounting reconciliation as set forth in the rules). The rules further specify that "when calculating median contracted rates, plans and issuers must exclude risk sharing, bonus, or penalty, and other incentive-based and retrospective payments or payment adjustments." The Associations are concerned that failure to include bonus or other incentive-based payments distorts the median contracted rate and makes it not reflective of the market.

7. Eligible Databases

The No Surprises Act sets forth that in cases of "insufficient information," the QPA is determined through the use of any database determined by the Departments rule to not have conflicts of interest and to have information sufficient to reflect allowed amounts paid to a health care provider or facility for the particular service in the relevant geographic region. The interim final rules provide criteria for these databases under the definition of "eligible databases." The Associations have numerous concerns with this definition.

i. State all-payer claim databases

First, the interim final rules provide that state all-payer claims databases are categorically eligible databases. While the Associations have been supportive of all-payer claims databases (and supported recent Texas legislation to create an all-payer claims database in our state), we are concerned with the categorical eligibility language. Some states may not have a robust set of data

in their all-payer claims databases or have data that has not been properly audited and verified and those states' databases, therefore, may not have sufficient information or sufficiently valid information for the median contracted rate calculation. Also, many states may not have self-funded data (due to ERISA preemption issues). Thus, the data taken from these databases may not be reflective of the market.

The Associations, therefore, strongly recommend that the Departments establish minimum requirements for all-payer claims databases to qualify as "eligible databases." These requirements should include the following: include commercial plans only; include in-network claims only; exclude zero and negative allowable rates; and include only facility claims (based on revenue code). For anesthesia services, it is important that data in the all-payer claims database includes the time units involved and that claims reflect 15-minute increments for all observations. It also will be important for all-payer claims databases to include self-funded claims as much as possible. All-payer claim databases need to truly be reflective of market data if they are to be used to calculate median contracted rates and the Associations strongly contend that the Departments need be more involved in assessing all-payer claims databases to ensure their use is appropriate.

ii. Other databases

For other databases that may be used, the interim final rules establish three basic criteria. First, the database or organization maintaining the database must be not affiliated with or owned or controlled by any health insurance issuer or health care provider, facility, or air ambulance provider (or any member of the same controlled group as, or under common control). While the Associations appreciate the Departments' effort to place some guardrails on this provision from a conflict-of-interest perspective, we are concerned that the rules do not go far enough and that databases that have other conflicts might be used under the rules. We also are concerned that, in order to avoid a conflict of interest, the interim final rules do not currently prohibit use of databases that are affiliated with, or controlled or owned by, plan sponsors or third- party administrators.

Precisely defining a conflict of interest is a difficult task, because it will likely be fact specific. Thus in Texas, the Legislature prohibited affiliations with certain entities but also included a more general statutory prohibition on any other conflict of interest for the database selected by the Texas Department of Insurance for purposes of calculating certain amounts (50^{th} percentile of rates paid to participating providers and 80^{th} percentile of billed charges) considered in Texas' arbitration process for surprise bills. We recommend that the Departments not limit their conflict analysis to the conflicts specifically identified in current rules.

The second criterion for the database under the current rules is that it must have sufficient information to reflect the in-network amounts paid by group or individual health coverage to providers, facilities, or air ambulance providers for the relevant items or services furnished in the geographic region. However, the interim final rules do not provide a particular definition for when that threshold for sufficient information is satisfied. We are concerned that the lack of guidance on this issue will result in databases that are not reflective of the market being used.

The third criterion is that the database must have the ability to distinguish amounts paid to participating providers by commercial payers from other claims data (such as nonparticipating

providers and amounts paid by government payors – e.g., Medicare). While this is an important component, we are concerned that this criterion (in conjunction with the other two criteria) remains insufficient to prevent inappropriate databases from being used by payers and third-party administrators.

Given the foregoing concerns with the "eligible database" criteria, the Associations contend that payers should not be given such wide discretion to use any database that is determined to meet these basic criteria. **Instead, we strongly recommend that the Department engage in a vetting and selection process for eligible databases (allowing for stakeholder input) to ensure that an appropriate database is used (and that it truly has no conflicts of interest), as well as to prevent a plan from choosing the database that has the most favorable rate from the plan's perspective**.

We note that the Departments include some language regarding consistent use of a selected database and that choosing another database cannot be related to rates (but for other reasons such as sufficiency of data), but we are still concerned with potential cherry picking in this area. Further action, as suggested herein, is needed on the Departments' part to prevent payer abuse of the current eligible database criteria.

iii. Recommendations for Addressing the QPA in the IDR process

Based upon all of the foregoing, it is clear that the QPA (while useful for limiting patient cost-sharing) will not be reflective of the actual median of contracted rates in the commercial market for the geographic area of the particular items or services at issue. And misrepresenting the QPA as reflecting the market in the IDR process is likely to have a very detrimental impact on physician practice viability and patient access to care.

More specifically, outsized IDR consideration of a skewed QPA is likely to result in health plans exerting more pressure to lower in-network rates (effectively creating a race to the bottom) and health plan termination of long-standing physician contracts. This will compromise patient access to ***in-network*** care and is likely to lead to forced consolidation of physician practices to survive the payment cuts. Physician practices in Texas are already facing practice viability challenges in the midst of the COVID-19 pandemic. According to TMA's COVID-19 Practice Viability Survey of Texas Physicians, 63% of physician respondents reported their revenue had decreased 51% to 100% during the pandemic. Many small practices may simply be unable to keep their doors open under this added strain.

Both Congress and the Texas Legislature have expressed concerns regarding health care consolidation, as consolidation can lead to increased costs. In recognition of consolidation concerns, the Texas Legislature included measures in its surprise billing legislation (and other legislation passed that same legislative session) that were designed to help create a more balanced process to settle payment disputes and promote network adequacy. More specifically, under SB 1264 (86th Regular Session), the Texas Legislature established ten exclusive factors that must be considered in determining the "reasonable amount" for services in its arbitration process.

While one of those ten factors is the 50th percentile of rates for the service or supply paid to participating providers in the same or similar specialty and provided in the same geozip area as reported in a nonconflicted database selected by the Texas Department of Insurance (TDI), the Texas Legislature balanced that factor by also requiring consideration, among other things, of the 80th percentile of all billed charges for the service or supply performed by a health care provider in the same or similar specialty and provided in the same geozip as reported in the TDI selected database. **Thus, the Texas Legislature took into consideration amounts primarily set by the plan (i.e., contract rates) and amounts primarily set by the physician or provider (billed charges). Inclusion of billed charges was a critical factor to a fair process under the Texas bill.**

The federal legislation does not have the critical counterbalance of the 80th percentile of billed charges for QPA in the arbitration process (nor did the federal legislation include network adequacy examinations by the Departments as is required under Texas law by TDI at least once every three years); thus, a very skewed calculation of QPA is likely to have an even greater impact on the outcomes of federal IDR (causing physicians and other providers to lose more frequently). The QPA has great potential to negatively impact network adequacy, practice viability, consolidation, and health care costs.

Given all the foregoing, the Associations, therefore, urges the Departments to take measures to address concerns related to the QPA methodology and to ensure that a skewed QPA is not given an outsized role in decisionmaking by the IDR entity.

The Associations understand that, under the No Surprises Act, the QPA must be provided to the IDR entity; however, it is imperative that the QPA be provided in context so that is not inappropriately weighted by the IDR entity. **More specifically, the Associations strongly recommend that the Departments take the following three steps (without the physician or provider having to request the steps to be taken).**

1. **Require the IDR entity (and the physician or provider) to be provided with direction that the IDR entity is *not* to weigh the QPA more than any other submitted information when picking a party's offer.**

Congressional intent, as reflected in this June 17, 2021 letter was "to ensur[e] a balanced process to settle payment disputes between health plans and providers." As the letter continues to state:

> Providers and payors are able to bring relevant information with the exception of billed charges and public payor information for consideration, and the certified IDR entity shall consider:
>
> • Median in-network rates
> • Provider training and quality of outcomes
> • Market share of parties
> • Patient acuity or complexity of services
> • Teaching status, case mix, and scope of services of the facility
> • Demonstrations of previous good faith efforts to negotiate in-network rates

• Prior contract history between the two parties over the previous four years

The No Surprises Act instructs the certified IDR entity to consider each of these listed factors, as well as any allowable information brought by either party or requested by the certified IDR entity. **To match Congressional intent, your implementation of the law should ensure an IDR process that captures the unique circumstances of each billing dispute and does not cause any single piece of information to be the default one considered.**

The Associations concur with the above assessment regarding the weighing of QPA and believe that it is important for this information to be properly communicated to the IDR decision-maker.

2. **Provide the IDR entity (and the physician or provider) with a clear and conspicuous disclaimer that: (a) the QPA was calculated primarily for the purpose of determining/limiting patient cost-sharing amounts, and (b) that the Departments recognize that the QPA is *not* necessarily reflective of a true median of contracted commercial rates in that market for that item or service.**

Given all the aforementioned concerns related to the QPA, it also is critical that an express and standard disclaimer be provided to the IDR entity to properly explain the purpose of the QPA (which is focused on limiting patient cost-sharing responsibility) and to inform the IDR entity of the limitations of the QPA. The QPA will not reflect actual market conditions or rates and this fact needs to be conveyed to the IDR decision-maker.

3. **Require Payers to Provide the IDR entity (and the physician or provider) with additional information relevant to the calculation of the QPA.**

In the interest of transparency and to properly place the QPA in context, the IDR entity (and the physician or provider) also should be provided with additional information from the payer regarding the computation of the QPA, including:

- the type of specialties and subspecialties of the physicians or providers that have contracted rates included in the dataset used to determine the QPA;
- the number of contracts used to determine the median contracted rate (including the number of physicians or providers represented by those contracts);
- if the QPA is based on a claim that has been downcoded by the payer, an explanation of why it was downcoded and what the QPA would have been for the item or service if it were not downcoded;
- information pertaining to the use of any modifier in calculating the QPA and what modifiers were used, if any; and
- information regarding the use of alternative payment models, bonuses and other supplemental payments paid to providers within the payers' networks; and
- if the claim is denied, what the QPA would have been based on the original claim.

While the Associations appreciate the other information that is required to be provided to physicians by issuers and plans related to the QPA under the interim final rules, we assert that the above-listed additional information is also important to the open negotiation and IDR processes and should be provided without the physician or provider having to request the information.

II. Initial Payments

A. Initial Payment Amounts

Next, the Departments solicit information on whether they should set a payment standard for the health plan's initial payment. **The Associations are opposed to the Departments setting an initial payment amount or standard (particularly any payment standard based on Medicare or in-network rates), because: (1) we are concerned that such a standard will have a negative impact on physician contracting and financial viability; and (2) the No Surprises Act does not establish an initial payment amount or contemplate the Departments setting an initial payment amount.**

As has been noted by physician stakeholders repeatedly, Medicare rates are not reflective of rates in the commercial market, do not reflect the cost of providing care, and have not kept pace with inflation. Medicare rates are based on political and budgetary considerations. And, in-network rates are significantly discounted rates that reflect other considerations (e.g., patient steerage and prompt payment) that are not present in out-of-network scenarios. Thus, neither of these amounts is an appropriate basis for setting an initial payment amount.

In the interim final rules, the Departments noted that an initial payment "does not refer to a first installment" and "should be an amount the plan or issuer reasonably intends to be payment in full based on the relevant facts and circumstances and as required under the terms of the plan or coverage [.]" We appreciate the Departments' statement of intent and agree that, in order to have IDR be the backstop (and not the default), it is imperative that health plans act consistently with this stated intent.

To ensure that this occurs, the Associations recommend that the Departments require the plan's initial payment be considered the plan's final offer in the IDR. This will encourage health plans to provide reasonable initial payments and prevent health plans from providing "low ball" initial payments only to subsequently shift their conduct in the IDR. The IDR process will entail time and expenses for physicians and other providers to pursue. It is important that health plans not drive all payment resolutions to IDR (and ultimately add wasteful, unnecessary costs to the healthcare system). Physicians should not have to engage the IDR process to obtain a fair payment.

In the alternative, should the Departments not accept our recommendation for the plan's initial payment to be considered the plan's final offer in the IDR, we recommend ***at the very least*** that the Departments require the plan's last offer in negotiation be considered their final offer in the IDR. This measure will help ensure that the plans use the negotiation period in good faith, moving towards a payment resolution.

B. **Other Initial Payment Issues**

In the interim final rules, the Departments provide that if a plan or issuer knows or reasonably should know that the notice and consent (required to exercise the exception to the balance billing prohibition) were not properly and timely given and received (despite the provider's assertions to the contrary), the plan or issuer "should apply the cost-sharing and other requirements set forth in these interim final rules and applicable state law by, among other actions, reprocessing any claims that were not processed consistently with those requirements."[6]

The Associations are concerned that the rules appear to permit the plans to make a unilateral assessment as to the appropriateness of the notice and consent. Moreover, the rules do not set forth any requirement for the plan to inform the provider or enrollee of this determination or for the physician to challenge or appeal this determination. The Associations oppose the Departments providing this delegation of authority to the plans.

Next, the Departments provide that 30 calendar-day period for the initial payment generally begins on the day the plan or issuer receives information necessary to decide a claim for payment for such services (i.e., a clean claim). It is not clear, however, under the interim final rules what information will be needed to decide a claim for payment (and there may be variations in plan requirements). Thus, to avoid delays in payment and potential health plan abuses of this timeframe, it is critical that, if the claim is rejected, the Departments require the plans to clearly communicate the precise information needed to correct the claim. This clear communication from the plans needs to occur on the first rejection (with all the relevant information to enable the provider to address any purported deficiencies and move the claim along).

III. Notice and Consent

Next, the Associations appreciate the Departments' language in the preamble, which provides further information as to the intended functioning of the notice and consent provisions. However, we agree with the comments made by the American Medical Association (AMA) regarding the need for additional clarification of certain components of the notice and consent process.

More specifically, we agree that the requirement for plans and issuers to pay physicians and providers directly should extend to scenarios in which notice and consent are provided and received (when the patients seeks coverage for out-of-network care). Health plan practices of sending out-of-network payment to the patient and requiring the patient to remit full payment to the provider often creates confusion and additional burden for the patient and results in payment delays for the provider. Removing this unnecessary step in the process would be beneficial to patients and providers alike.

The Associations also agree with AMA's expressed concerns regarding the interim final rule's language in the "ancillary" services provision, which states that the notice and consent exception is not available for "items and services provided by a nonparticipating provider if there is no participating provider who can furnish the item or service at such facility."

[6] *Id.* at 36900.

Although the Texas Department of Insurance (TDI) included a similar requirement for Texas' notice and disclosure process (i.e., that "the enrollee [have] a meaningful choice between a participating provider for a health benefit plan issuer or administrator and an out-of-network provider,") the TMA and other physician organizations opposed this requirement, which we believe goes beyond the statutory language of Texas' surprise billing legislation.

In our comments to TDI, the TMA and other physician organizations stated that we opposed the language because it makes the out-of-network provider's satisfaction of the exception dependent upon third parties over whom the out-of-network provider has no control, namely health plans and health facilities. More specifically, the language effectively shifts responsibility for health plan network inadequacies from the plans to the out-of-network providers (which was not the Legislature's intent). The out-of-network provider cannot control whether there is choice between an in-network provider and out-of-network provider in any given scenario. In striking contrast, the health plan can. Yet, the out-of-network provider would be the one that is forced to forego collecting his or her full fee in this scenario. The burden (and additional financial responsibility) should be placed on the health plan in this scenario. And, the enrollee should be complaining to the health plan regarding its inadequate network (asking the health plan to make him or her whole).

Also as the TMA and other physician organizations stated to TDI when the Texas rules were proposed, for services performed in a facility, whether there is a choice between a participating provider and an out-of-network provider will be dependent upon the facility (in addition to the health plan), not the out-of-network provider. The out-of-network provider does not control the scheduling or assignment of procedures, the credentialing of providers at the facility, or the contracting practices of the facility; yet, all of these factors may impact whether there is a participating provider available to furnish an item or service at the facility. For these same reasons, the Associations are concerned with this provision in the Departments' interim final rule.

Finally, the Associations recommend that the Departments clarify that pain management services (including when furnished by anesthesiologists) qualify for participation in the notice and consent exception to the balance billing prohibition. Although the statute excludes from the notice and consent exception items and services related to certain "ancillary" services, including anesthesiology, pain management services (including when performed by anesthesiologists) should not be subject to this exclusion, the Associations agree with the American Society of Anesthesiologists that pain management services provided in non-urgent scenarios where a patient selects an anesthesiologist in advance (and otherwise satisfies the notice and consent provisions) should be distinguishable from "anesthesiology" in this context. Making this distinction would encourage patient choice and access to pain management care.

IV. Prudent Layperson

Finally, the Associations are generally supportive of the Departments' efforts to reinforce the prudent layperson standard. We note that in the preamble, the Departments states the following:

> These interim final rules make clear that if a group health plan, or a health insurance issuer offering group or individual health insurance coverage, provides or covers

> any benefits with respect to services in an emergency department of a hospital or with respect to emergency services in an independent freestanding emergency department, the plan or issuer must cover emergency services without limiting what constitutes an emergency medical condition (as defined in these interim final rules) ***solely*** on the basis of diagnosis codes. When a plan or issuer denies coverage, in whole or in part, for a claim for payment of a service rendered in the emergency department of a hospital or independent freestanding emergency department, including services rendered during observation or surgical services, the determination of whether the prudent layperson standard has been met must be based on all pertinent documentation and be focused on the presenting symptoms (and not **solely** on the final diagnosis). This determination must take into account that the legal standard regarding the decision to seek emergency services is based on whether a prudent layperson (rather than a medical professional) would reasonably consider the situation to be an emergency. (emphasis added).[7]

We are concerned, however, that plans may misconstrue and misapply the "solely" language in the rule. We strongly contend that presenting symptoms, not final diagnosis codes, should be the focal point of any review and urge the Departments to monitor for any abuses of this language.

V. Delayed Implementation

Finally, while the Associations greatly appreciate the Departments' efforts to quickly publish Part 1 of the rules implementing the No Surprises Act, we are concerned that there are still two other parts of the rules that need to be published before the end of the year. Thus, there will be a very short turnaround for physicians and other providers to implement changes to their policies and procedures. The Associations, therefore, respectfully request a one-year delay in implementation to enable more time for compliance efforts.

The Associations thank the Departments for the opportunity to comment. If you have any questions, please do not hesitate to contact Kelly Walla, Associate Vice President and Deputy General Counsel of the Texas Medical Association, at kelly.walla@texmed.org.

Sincerely,

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[7] *Id*. at 36879.

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