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Mark J. Mazur
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Assistant Secretary
Employee Benefits Security
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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 lowering 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.

Calculating the QPA in Instances Where Sufficient Information is Not Available

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 emergency 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.

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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,

/s/

Stacey Hughes
Executive Vice President