Catholic Health Association of the United States

A Passionate Voice for Compassionate Care®

September 7, 2021

Laurie Bodenheimer
Associate Director
Healthcare and Insurance
Office of Personnel Management

Douglas W. O'Donnell
Deputy Commissioner for Services and Enforcement
Internal Revenue Service

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

Ali Khawar
Acting Assistant Secretary
Employee Benefits Security Administration
Department of Labor

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services

Re: Requirements Related to Surprise Billing; Part I
File Code CMS-9909-IFC

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

On behalf of the Catholic Health Association of the United States (CHA), the national leadership organization of more than 2,200 Catholic health care systems, hospitals, long-term care facilities, service providers and organizations, I am writing to share our comments on the initial round of rulemaking on the No Surprises Act, enacted as part of the Consolidated Appropriations Act, 2021, the interim final rule entitled Requirements Related to Surprise Billing; Part I (86 Fed.Reg. 36,872).

CHA and our members strongly support protecting patients from surprise bills. Patients should not be subjected to financial consequences when they have unexpected and unavoidable encounters with out-of-network health care facilities and providers, and they should not get caught in negotiations among facilities, providers and insurers over payment. We are pleased that the No Surprises Act provided protection to patients with gaps in their health care coverage that could result in unanticipated bills. We appreciate the hard work of your departments in issuing this first set of implementing rules under tight timelines, especially given the demands of the continuing public health emergency due to COVID-19.

We also appreciate the efforts that have been made to reach out to stakeholders and we urge that the departments continue that engagement. While the concept is simple – protect patients from

medical bills for unexpected out-of- network care beyond their control – successful implementation of the No Surprises Act is complex and subject to an abbreviated timeline. We are grateful for the departments' intention to provide enforcement discretion is some areas, as expressed in the August 20, 2021, "Frequently Asked Questions" and we urge the departments to exercise such discretion in other areas as well as discussed below. Given that this set of regulations do not address all of the requirements of the No Surprises Act and some of the provisions will also be affected by subsequent rulemaking, we ask the departments allow additional time for comment on topics that require further rulemaking, such as the qualifying payment amount (QPA) and good faith estimates. It is essential that the regulations implementing the No Surprises Act create a structure that successfully protects patients without creating unintended barriers to access or unnecessary burdens for providers and facilities. To that end, we urge the departments to partner with stakeholders to address barriers to implementation, to provide comprehensive guidance, education and technical assistance, and to exercise enforcement discretion to allow sufficient time for compliance.

- **Scope of the New Surprise Billing Protections**

The No Surprises Act and the regulations define emergency services consistent with the Emergency Medical Treatment and Labor Act (EMTALA) with two modifications. As under EMTALA, emergency services include an appropriate medical screening examination and any such further examination and treatment required to stabilize the patient. The regulation expands the definition of emergency services by including such services provided by a freestanding emergency department and by including services provided after stabilization.

Emergency Services
The departments acknowledge concerns about some plans and issuers determining whether an episode involved an emergency medical condition based solely on the final diagnosis and confirm that these practices are inconsistent with the emergency services requirements of the No Surprises Act as well as the Affordable Care Act's (ACA) prudent layperson standard. The regulations expressly state that plans may not: restrict coverage of emergency services by imposing a time limit on the onset of symptoms and when the person presented in the emergency department; restrict coverage of an emergency service because the patient did not experience a sudden onset of the condition; or restrict access to emergency services based on a general plan exclusion.

We thank the departments for the express clarification that the practice of denying coverage for certain emergency medical services is inconsistent with the prudent layperson standard established under the ACA, as well as with the No Surprises Act and urge them to continue oversight and monitoring to ensure compliance and prevent the creation of loopholes or workarounds.

Post-stabilization Services
The law includes post-stabilization services in the definition of emergency services. The regulations address the period of post-stabilization services as extending until the patient is transferred to an in-network facility or consents to be balance billed. However, the regulations do not say what would happen if a patient remained in a facility until discharge, that is, the patient neither meets the conditions for transfer nor consents to be billed for post-stabilization services. **We request the departments confirm that health plans and insurers are responsible for covering emergency services through any one of the following: discharge, appropriate transfer, or patient consent to be balance billed. In addition, we ask that the Departments make clear that health plans and issuers must work in a timely manner and with providers to facilitate transfers**. Our members report frequent delays in insurers responding to requests for transfer, during which a patient's condition can deteriorate and the out-of-network hospital must continue care for the patient. There is also the distinct possibility that a patient may both decline to be transferred and refuse to consent to be balance billed. In these instances, we request clarification about the requirements on both providers and plans.

- **Determination of the Cost-Sharing Amount and Payment Amount**

Cost-sharing Amount: Qualified Payment Amount
The No Surprises Act provides that patient cost-sharing is to be based on an amount determined by an applicable All-payer Model Agreement, the amount determined under applicable state law, the qualifying payment amount (QPA) or the billed amount if less than 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 independent dispute resolution (IDR) process, which will be established in a future regulation. The statute defines the QPA as the insurance issuer's median in-network rate for a particular service trended forward from 2019. In the case of a self-insured group health plan, the administering entity may be treated as the issuer.

This approach insulates the patient from payment negotiations between the payer and the provider or facility by establishing a methodology to determine cost-sharing without waiting for a final payment determination, a goal we support wholeheartedly. We do however have some comments on the implementation of the QPA.

We share the concerns expressed by our members and other stakeholders that a thorough assessment of the methodology to be used by payers for determining the QPA and its implications is not possible without understanding the full scope of how it will be used. The QPA is one of the factors to be considered during the IDR process but the regulations establishing that process have not yet been released. The departments chose a QPA methodology with the goal of limiting patient cost-sharing, a goal we share. However, an artificially low QPA could have a substantial impact on access to care if it is weighted too heavily in the IDR process. **We strongly urge the departments to release the regulations governing the IDR process as quickly as possible and include a new solicitation of**

comments on the QPA methodology once stakeholders have a complete understanding of its intended use.

To avoid unintended consequences on the ability of providers to obtain fair and reasonable reimbursement, **we urge the departments to clarify that the QPA may not to be used by plans and issuers as the initial payment rate or out-of-network rate** (unless both the plan or issuer and the provider or facility agree to it through negotiation). **We also urge the Departments to refrain from establishing IDR regulations that give, or allow the arbiter to give, the QPA too much weight in the IDR process.**

Plans and issuers are to share the QPA with providers and facilities for the purpose of determining cost-sharing amounts. They are not required to share any meaningful information about how the QPA was calculated and if they were, providers and facilities would have little ability to assess the accuracy of the information. **Thus, it is important that the departments conduct regular and comprehensive oversight of QPA calculations by plans and issuers.** Because providers and facilities will not be in a position to determine whether QPA determinations are correct, **we urge the departments to make clear that providers and facilities will be held harmless for using an inaccurate QPA** and the plans and issuers will be responsible for any negative consequences, such as making patients whole if the use of an inaccurate QPA results in a patient paying too much. **Finally, if a QPA later found to be inaccurate was used in the IDR process, there should be mechanism for reviewing the IDR result**.

Specified State Law
The interaction between the No Surprises Act and state laws in states with surprise billing protections applicable to state-regulated plans is going to be very complex and getting it right will be very important, for both patients and providers of care. Under the statute and regulations, state laws with methodologies that determine payment for out-of-network surprise bills with respect to a particular item or service, provider and plan will continue to apply.

While the regulations include a few examples, **we urge the departments to provide very clear guidance on when state laws would apply and provide comprehensive resources analyzing the applicably of state and federal law.** To that end, we recommend the departments collaborate with states through the National Governors Association, National Conference of State Legislatures and the National Association of Insurance Commissioners in developing guidance for states, plans, issuers, providers and facilities on the interaction of state and federal laws. Until there is more clarity, we ask the departments to exercise enforcement discretion when confusion about which jurisdiction prevails leads to inadvertent compliance failures. **We also urge that in situations where both state and federal law potentially apply to aspects of a single episode of care, the regulations provide that federal law governs the entire episode**.

The laws and regulation give federal and state authorities shared responsibility for oversight and enforcement of the No Surprises Act. Given the complexities of these policies, the current reality

of incomplete guidance on the law and the significant challenges posed by the need to share data across different levels of government and among different types of health care entities, this will likely lead to significant variation across the country in oversight and enforcement of the statute. This is of particular concern to our members that are multi-state integrated health systems. To address these challenges and ensure uniform enforcement of federal law, **we recommend that department clarify which components of the law will have state or federal oversight; assess whether states meet federal standards for compliance on relevant provisions; set standards for state oversight and how the federal government will determine whether states meet those standards; and create a standard data submission process for states to report complaints and outcomes to the federal government for tracking and oversight.**

- **Additional Plan and Issuer Requirements Regarding Making Initial Payments or Providing a Notice of Denial**

Plans or issuers must send an initial payment or denial of payment notice no later than 30 calendar days after receiving a clean claim from a non-participating provider or facility protected services. The initial payment is the intended payment in full *prior* to the start of an open negotiation period, not a payment installment. The departments seek comment on whether a minimum payment amount, rate or other payment methodology for the initial payment should be established in future rulemaking. The Departments also encourage providers and facilities to include on the claims whether the surprise billing protections apply

Because of potential confusion between the QPA, the initial payment and the final out-of-network reimbursement rate, we reiterate our request for a clear statement of the difference between the three and that the QPA is neither the initial payment amount nor the out-of-network rate unless agreed to by the parties.

We do not support the creation of a minimum payment amount. Congress chose not to take that approach in the No Surprises Act and the departments should respect the intent of Congress. Health plans and hospitals have a longstanding history of settling disputes over out-of-network payments and they should be allowed to continue to do so with recourse to the IDR process if necessary and as set forth in the statute. Establishing a minimum payment amount could create a de facto payment ceiling and disadvantage providers and facilities in the IDR process.

- **Notice and Consent Exception to Prohibition on Balance Billing**

The No Surprises Act's limitations on cost-sharing and prohibitions on balance billing do not apply to individuals who are provided notice and give consent for out-of-network non-emergency and post-stabilization services. In establishing policies and procedures for seeking consent, the departments sought to strike a balance between permitting a provider to refuse to treat an individual who will not accept their charges and ensuring the individual is not being pressured into waiving their protections. They also made it clear that the notice and consent exception is to be used in very limited circumstances with respect to post-stabilization patients.

While both the regulations and the guidance documents largely reflect the requirements as established in statute, they do present some logistical and operational challenges for providers**. We believe this is another area where it would be constructive to convene a provider advisory group in order to better understand the operational challenges in the notice and consent process and public disclosure requirements**. For facilities, in particular, the notice and consent process will require changes to information systems, management processes, and provider relations.

Post-stabilization
The regulations provide that the final determination as to when a post-stabilization patient can give consent for out-of-network care must be made by the treating provider or physician. **We agree that treating providers or physicians should have responsibility for determining when a patient is able to provide consent.** Because cultural factors and differences can create barriers to informed decision-making, we suggest that departments provide guidance for treating providers on addressing these differences and other factors that can undermine trust in communities that have experienced inequities in health care.

When consent is sought for post-stabilization patients at in-network facilities, the notice must include a list of in-network providers at the facility that are able to furnish the services. Providers are not the best source of this information. They will need to rely on plan provider directories (which are frequently inaccurate) or contact the plans directly. **We encourage the Departments to instead allow the notice and consent process to advise patients to consult their health plan to identify an alternative provider.**

We agree that certain out-of-network "ancillary" providers, as defined, should be able to use the notice and consent process in certain contexts. First, we agree that when the primary professional (e.g., a surgeon) is out-of-network and obtains notice and consent, the associated ancillary providers should also be allowed to seek notice and consent, if time allows. We also encourage the departments to clarify that certain types of providers listed as "ancillary" can and do sometimes deliver primary services. Certain pain management physicians that perform injection procedures, for example, also are anesthesiologists. When they provide pain management services, they are the primary provider, not an ancillary provider.

Good Faith Estimate
The notice must include a good faith estimate of the amount that a nonparticipating provider or facility may charge for the needed items or services, including those items reasonably expected to be provided by the nonparticipating facility or nonparticipating providers as part of the visit and must include relevant billing and diagnostic codes. To date, neither the regulations nor the standard form stipulates which codes are to be used for purposes of developing the good faith estimate. **CHA recommends the departments to expedite guidance explaining how providers should calculate good faith estimates and to incorporate guidance on the specific codes or code families to be used for these purposes**.

Language Access
Under the statute and the IFC, the notice must be made available in any of the 15 most common languages in the geographic region. Because the Departments intend to treat the adoption of the standard form as compliant with the law's notice and consent requirements, **we recommend that CMS provide translations of the standard form in the top 15 nationally known languages.** This would substantially reduce the administrative burden on facilities and providers, while avoiding unnecessary duplication of efforts and resource expenditures.

Consolidating Notice and Consent
The regulations state 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. We assume this means 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. **We recommend that the Departments clarify that facilities can choose which out-of-network providers they plan to work with as part of their management of the notice and consent process and that the standard notice form clearly states that it may not encompass all potential out-of-network providers**.

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. Acknowledging that getting this specific health plan policy information may prove challenging, the departments would allow providers and facilities to adopt a general default statement that informs the patient that such limitations may apply. **CHA strongly supports allowing providers and facilities to use the default statement, given the complexities involved with fully ascertaining the patient's health plans or issuer's policies.**

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 so the health plan or issuer can accurately calculate the patient's cost-sharing. However, neither the regulations nor the separately issued standard form provide any guidance on how the signed notice nor consent documents should be transmitted to the plan. **Because there is currently no standard electronic transaction for this exchange of information, CHA recommend 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.** In addition, CMS should expedite the adoption of standard electronic transactions for the exchange of this information between the provider, facility and plan, and modify the standard form to reflect these transaction standards.

In closing, thank you for the opportunity to share these comments in regard to the initial round of rulemaking on the No Surprises Act. If you have any questions about these comments or need

more information, please do not hesitate to contact me or Kathy Curran, Senior Director Public Policy, at 202-721-6300.

Sincerely,

Lisa A. Smith
Vice President Public Policy and Advocacy