October 15, 2021

Sent electronically

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

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

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

SUBJECT: CMS-9907-P, Requirements Related to Air Ambulance Services, Agent and Broker Disclosures, and Provider Enforcement, Federal Register (Vol. 86, No. 177), September 16, 2021

Dear Secretaries Becerra, Yellen, and Walsh:

On behalf of our more than 400 member hospitals and health systems, the California Hospital Association (CHA) greatly appreciates the work the Departments of Health and Human Services (HHS), Labor, and Treasury (hereafter, tri-agencies) have done to protect patients when they receive care from out-of-network facilities in emergencies, or from out-of-network providers at in-network facilities, by developing regulations to implement the "No Surprises Act" (NSA).

CHA fully supports Congress' primary goal in passing the NSA — removing patients from billing disputes that arise when care is provided in covered situations. Therefore, our members seek to fully comply with the law's requirements as quickly as possible. However, we are concerned the tri-agencies are promulgating regulations related to enforcement actions before they have produced the full set of regulations required to implement the NSA's core provisions. Beyond making it difficult to fully comment on the enforcement provisions, this ambiguity raises significant questions about what activities a state

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will undertake if it elects to enforce the NSA requirements. We respectfully ask the tri-agencies to address these questions in a subsequent rule and provide an additional opportunity for stakeholders to comment on these issues.

CHA greatly appreciates the detail provided by the tri-agencies related to the federal enforcement process for providers and facilities (hereafter, "providers" unless otherwise specified). In this letter, we respectfully offer specific, technical recommendations to ensure that providers have an appropriate opportunity to respond to allegations that they are out of compliance with the NSA's requirements and that civil monetary penalties are not unduly assessed.

Finally, given the importance of the qualifying payment amount (QPA) in calculating the patient's cost-sharing in the independent dispute resolution (IDR), CHA appreciates the proposed rule's discussion of the tri-agencies' audit sample approach to ensure that health plans are accurately calculating the QPA. However, we are concerned that the audit sample size is insufficient, relative to the number of products offered by health insurance companies, to ensure that the QPA is not accidentally miscalculated. Therefore, we respectfully ask the tri-agencies to use the market conduct review process to increase the number of health plan QPA calculations sampled, and we request the tri-agencies confirm that providers can refer health plans to the relevant enforcement entity to have the QPA calculation reviewed.

Below, please find our specific recommendations for each of these items.

Ambiguous Relationship Between State and Federal Enforcement Efforts

States have primary enforcement authority over health plans for Public Health Service (PHS) Act requirements — including many of the NSA's provisions. The proposed rule specifies that states are the primary enforcement agents over providers that practice in their states, as well as over out-of-state providers that provide telehealth services to individuals in their states. The rule also clarifies that for both plans and providers, the Centers for Medicare & Medicaid Services (CMS) assumes the role of primary enforcement agent for the NSA provisions when a state notifies the agency that it cannot (or will not) enforce the PHS requirements, or if CMS determines that the state is failing to enforce the requirements.

Further, the rule defines the CMS/federal process for enforcement. This includes the:

- Process to notify providers of alleged non-compliance
- Providers' timeline to respond
- Documentation that can be submitted to demonstrate compliance
- Circumstances considered when determining whether to assess a civil monetary penalty (CMP) and the amount of CMP
- Appeals process

However, it is not abundantly clear if states are expected to follow the same processes, or if each state may develop its own unique process for investigating alleged non-compliance and (as appropriate) sanctioning providers. CHA believes it is the tri-agencies' intent to allow each state to develop its own processes. If that is correct, we are concerned that process fragmentation will increase the administrative burden on health systems with facilities in multiple states. **Therefore, we ask the tri-agencies to clarify their intent and provide a clearer outline for the processes that states are expected to follow if they elect to enforce the NSA's provider provisions.** Further, it is unclear if CMS will allow states that do not

have the legislative authority to sanction non-compliant providers to investigate an allegation of non-compliance, make a determination of non-compliance, and then refer the provider to the agency for assessment of CMPs. **Again, we ask the tri-agencies to clarify if this type of hybrid enforcement model is permissible and provide additional details as to how it will work. Finally, we ask CMS to maintain a list, available on a publicly available website, that describes who the enforcement agent is based on the insurance market type for each state so that it is clear for all stakeholders.**

In addition to the ambiguity related to state enforcement of the NSA, the regulatory framework necessary to implement it — the good faith estimate and advanced explanation of benefit for insured individuals — is still incomplete. In light of that, CHA again asks CMS to exercise regulatory discretion when enforcing the NSA's provisions and instruct states to do the same. At this juncture, given the incomplete regulatory framework and ambiguity about the enforcement process, we believe it would be appropriate in almost all situations[1] for the agency (and states) to educate providers about incidents of non-compliance. In this unsettled regulatory environment, we do not believe it would be appropriate in most cases to assess a CMP. **Therefore, during the first 12 months after the issuance of the last final rule necessary to fully implement the NSA's transparency requirements and patient protections, we respectfully ask CMS to educate providers deemed non-compliant by issuing warning letters and requiring corrective action plans (CAP).**

Federal Facility and Provider Enforcement Efforts

The proposed rule includes regulations implementing the enforcement process for provider and facility compliance with the NSA when CMS is the enforcement entity. This process is like that used by the agency to ensure health plan compliance with the PHS Act requirements.

When the agency identifies an alleged violation, CMS will issue a notice to the provider describing what triggered the investigation and indicating that the inquiry may result in a CAP and/or CMPs. The proposed rule states that CMS would generally allow 14 days for providers to respond to the notice with the requested documentation. However, in circumstances that warrant a more rapid response, such as complaints involving urgent medical issues or allegations of fraud and abuse, CMS may shorten the time frame for the provider or facility to provide the requested documentation but does not anticipate requesting responses within less than 24 hours.

CHA is deeply concerned that CMS anticipates providing only 14 days to respond to an investigation notice. This limited time frame is not sufficient for the provider to conduct an internal investigation, collect evidence of compliance with the NSA's requirements, and develop a response. **CHA respectfully asks that the agencies allow a minimum of 30 business days for a provider to respond to a notice of investigation.** We believe this is the minimum amount of time required to allow for a comprehensive response to an allegation of non-compliance. Given the risk of substantial CMPs, we believe the agency should afford providers this time to ensure they can comprehensively demonstrate their compliance with the NSA's requirements.

The rule also proposes that providers that receive a notice of investigation may request an extension to respond to the notice. The agency will consider extensions for "good cause," such as limited staffing

[1] The exception is when CMS or a state has clear and overwhelming evidence of a pattern of systematic, willful non-compliance by a provider with the NSA's patient protections.

resources and requests for clarification of the allegation. **CHA greatly appreciates and supports CMS' proposal providing for "good cause" extensions of the response deadline.** We ask that, in addition to the "good causes" cited in the proposed rule, the agency also provide extensions when the geographic area in which the provider is located is operating under an emergency declaration. Further, we ask that CMS not create a comprehensive list of "good causes" for an extension but make a list available to provide examples of circumstances under which the agency would merit an extension.

The proposed rule allows providers to submit and would require CMS to consider "relevant documentation" in determining whether to impose a CMP. Examples of "relevant documentation" described in the proposed rule include:

- Medical claims, bills, and notice and consent forms
- Other evidence refuting the allegation of noncompliance
- Evidence that the provider did not know or (could not have known) of the violation
- Any corrective actions taken in light of an inadvertent violation
- Documentation of internal policies or procedures to ensure compliance
- Records of previous compliance
- Good faith efforts to submit missing information, including implementation of a corrective action plan

CHA supports the proposed list of "relevant documentation" CMS will consider when it evaluates an allegation of non-compliance with the NSA's requirements. We greatly appreciate that CMS recognizes, by allowing for "other evidence" to be submitted, that each alleged violation will be unique. Therefore, it will be difficult to create an exhaustive list of relevant documentation for all circumstances. We respectfully ask that CMS include the following as items of "relevant documentation" it will consider evidence that:

- The patient did not provide accurate or sufficient information to identify themselves (or their source of insurance coverage).
- At the time the patient registered, their insurance coverage lapsed (due to non-payment of premium), but that after the provider billed the patient, coverage was reinstated as a result of "catching up" on back premiums.
- A provider that is not employed by a facility was unaware that the facility was in-network for the patient.

CMS proposes that if a violation is confirmed it may levy a CMP of up to $10,000 per violation. In calculating the CMP, the agency proposes to consider the:

- Nature of claims of noncompliance and the circumstances
- Degree of culpability of the provider
- Provider's history of prior violations
- Frequency of the violation
- Level of financial and other impacts on affected individuals
- Other matters as justice may require
- Mitigating and/or aggravating circumstances

As discussed above, CHA asks that CMS educate providers during the period that begins on January 1, 2022, and extends until after 12 months the last regulations necessary to implement the NSA have been published. During this time, unless CMS or a state finds a clear and overwhelming evidence of a pattern of systematic, willful non-compliance by a provider with the NSA's patient protections, we ask the agency to require CAPs in validated instances of non-compliance. This approach is consistent with other enforcement areas, like the Medicare Conditions of Participation, where the agency takes a measured and graduated approach to enforcement that allows providers to address performance deficiencies before CMS sanctions them.

Further, the proposed rule permits CMS to waive the penalty if the provider does not knowingly violate and should not have reasonably known it violated a requirement, as long as the provider or facility withdraws any erroneous bill and, if necessary, reimburses the plan or enrollee, within 30 days of the violation plus interest. **CHA strongly supports this provision.** Providers are diligently putting the systems and processes in place to ensure compliance with the NSA's requirements. However, despite best efforts by the provider, a patient may be inadvertently balance billed in a covered situation. In this scenario, the first time that the provider becomes aware of this issue may be when it receives the allegation notice from CMS (or state enforcement agency). **Therefore, we ask that the agency toll the 30 days to retract bills issued for services covered by the NSA (and refund any payments received) when the provider receives an allegation notice from CMS (or state enforcement agency).**

In instances where CMS assesses a CMP against a provider, the rule proposes to allow 30 days from the from the date of such notice to request a hearing with an administrative law judge (ALJ) to appeal the proposed determination. This is aligned with the time frame provided to non-federal governmental plans and issuers for appeals in states where CMS directly enforces PHS Act requirements. However, CHA notes that, in other instances, CMS allows providers 60 days to file an appeal of a CMP to an ALJ[2,3,4]. **Given that CMS allows 60 days to file appeals of CMPs in other circumstances, CHA respectfully asks the agency to allow providers 60 days to file an appeal with the ALJ if they have allegedly violated a provision of the NSA.** We believe this will reduce the complexity of the NSA enforcement provisions by aligning the time frame for providers with other areas enforced by CMS.

CMS Enforcement of Insurance Requirements

The proposed rule also includes a regulatory amendment ensuring HHS has the ability to conduct audits of claims data from not more than 25 health plans to verify compliance with the NSA's QPA requirements. The number of plans to be audited is prescribed in the NSA's statutory language. The QPA plays an important role in the NSA. It is used both to calculate patient out-of-pocket costs and to serve as one piece of evidence considered in the IDR process. **Given the importance of the QPA, we respectfully ask CMS to use its authority to initiate market conduct examinations to significantly increase the number of health plan claims audits to ensure QPA accuracy.** Considering the number of issuers, CHA strongly believes that limiting audits to just 25 health plans is insufficient to ensure that the QPA is accurately calculated. We do not believe this concern is unmerited or the request unreasonable,

[2] https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-A/part-402
[3] https://www.law.cornell.edu/cfr/text/42/422.1020
[4] https://www.law.cornell.edu/cfr/text/42/498.40

given past instances where health plans have manipulated payment amounts calculated in a "black box[5]" environment or skewed data that impact payment[6] to their financial advantage. Further, providers operating in a given market will have the best ability to identify instances where a health plan is not calculating the QPA for a given service accurately. **Therefore, we ask CMS to confirm in the final rule that providers may collaborate with the relevant enforcement agency by referring health plans that may not be accurately calculating the QPA for a given service for further investigation.**

CHA appreciates the opportunity to offer comments to the tri-agencies on issues related to the No Surprises Act. We look forward to partnering with the tri-agencies and health plans to develop and implement a regulatory framework that achieves the Act's goals. If you have any questions about the comments, please contact me at (202) 270-2143 or cmulvany@calhospital.org.

Sincerely,

/s/
Chad Mulvany
Vice President, Federal Policy

[5]https://www.mssny.org/MSSNY/Resources/Legal_Matters/Class_Action_Settlements/United_Healthcare_Settlement/MSSNY/Practice_Resources/Legal_Matters/Class_Action_Settlements/United_Healthcare_Settlement.aspx?hkey=52f280ad-c706-4fe9-92cd-26fb332d9860
[6] https://oig.hhs.gov/oei/reports/OEI-03-17-00474.asp