DRAFT
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Items in red require additional input

November 15, 2022

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9900-NC
P.O. Box 8013
Baltimore, MD 21244-8013

Re: File Code CMS-9900-NC
Request for Information re No Surprises Act

Submitted electronically to https://www.regulations.gov

Dear Administrator Brooks-LaSure:

The undersigned health systems welcome the opportunity to respond to the Request for Information (RFI) on the rulemaking for the advanced explanation of benefits (AEOBs) and good faith estimate (GFEs) requirements of the No Surprises Act. At the outset, we are pleased to see that the Departments have recognized some of the complexities inherent in preparing GFEs and AEOBs for insured patients and have deferred enforcement of the statutory provisions until such time as a full rulemaking process is completed. The statutory requirements, while undoubtedly well-intentioned, pose challenges for providers, facilities, payors, and regulators and will require significant financial investments for the development and acquisition of new technologies, the establishment of new workflows and the hiring of additional staff to implement and carry out numerous new requirements. We trust that our comments provide some insight into the challenges we face and offer some constructive suggestions for consideration.

A. Transferring Data from Providers and Facilities to Plans, Issuers, and Carriers (p. 8)

There appears to be an assumption underlying the questions that all electronic health record (EHR) systems are compatible, and providers and facilities routinely transfer data electronically to each other and payors; the reality is that not everyone has a sophisticated, compatible EHR system and not all payors have real time eligibility (RTE) capabilities. In some areas of the country, providers without electronic billing systems continue to rely on paper processes. Much of the patient data and financial information flows through email and spreadsheets. There is no standard for electronic claims, denials and payment transmission and communication. We believe the only way to meet the requirements of the No Surprises Act is for all the required data to be transferred electronically, but this will increase costs significantly. A technical solution that is standard and ready for implementation, at a low cost for all parties, is needed to facilitate the data exchange.

The administrative burden facing all parties is significant. To produce an accurate AEOB, insurers will need to be aware of all upcoming scheduled procedures for their members. Many insurers continue to refuse to accept data via a 278 interface and still require providers and facilities to call them to notify them when their patients are admitted. If insurers do not participate in an electronic exchange of information, thus requiring providers to perform a manual notification of all scheduled procedures, this will consume far more resources than most providers or facilities will be able to dedicate to the process. The regulations will need to include requirements for insurance plans to finally adopt the ANSI/EDI requirements from the 1996 HIPAA regulations regarding electronic transfer of data. Based on our experiences, different payors utilize different HIPAA codes and data standards. In addition to merely notifying insurers of upcoming procedures for their members, accurate charging information will also need to be shared from provider to insurer, in order to guarantee the most accurate AEOB possible. If no electronic exchange of information requirements is built into the regulations, it is impossible to predict the scale of the additional burden this would place on the providers and facilities to manually communicate this information to the insurer within the statutorily proscribed timeframes. Furthermore, privacy concerns will be exacerbated with items lost in the mail or emails and faxes gone astray.

Another privacy concern surrounds the special care and consideration due to minors with protected diagnoses or treatments when information is transferred to the plan holder. We encourage the Departments to carefully consider how to handle these situations and provide guidance for providers and facilities.

Burdens/Barriers on Small and/or Rural Providers/Facilities (p.11)

The EMR and technology costs, as well as the limited availability of internet access, pose significant challenges for small and/or rural providers and facilities, making compliance with industry-wide, standards-based API technology requirements beyond the reach of many. Providing exceptions to these requirements for small and/or rural providers and facilities, or at least allowing a phased in approach with delayed enforcement, is necessary. How to accomplish this will require considerable thought and input from all affected parties.

The challenges faced by these providers and facilities could impact larger providers and facilities in the convening/co-provider context. Communication between providers can be as challenging as communication between providers and payors. To alleviate these burdens and unnecessary complications, each provider/facility should submit their own GFE to the self-pay/uninsured patient. Furthermore, we urge the Departments not to require a convening provider to secure all GFEs for co-providers for insured patients – it is too unwieldy in the short time frames allowed and payors are experienced in coordinating this information on their own.

B. Other Policy Considerations (p.11)

Should a nonparticipating provider of nonemergency services be required to inform a plan, issuer, or carrier, as part of or concurrently with the GFE, whether the requested or scheduled items or services would be furnished with respect to the individual's visit to a participating facility? (Background begins on p.12 – question on p. 13)

One system says no, another says how do you get a reliable GFE without it, but it's too complex and expensive to do. I propose that we say nonparticipating providers of nonemergency services should file their own GFEs with the plan, issuer, or carrier and not rely upon the participating facility to file it for them. (It needs to be filed because the payor must count the cost sharing toward any in-network deductibles and out-of-pocket maximums.

Suggestions?

Notice and Consent (p.13)

The Departments pose questions about whether nonparticipating providers and nonparticipating facilities should be required to inform payors when they have provided notice and received consent to balance bill an out-of-network patient. The No Surprises Act is quite definitive on the content of the notice, when and how it is to be prepared, and the requirement that a signed copy be provided to the participant, beneficiary, or enrollee by mail or email (as chosen by the participant, beneficiary, or enrollee.) The statute does not require the notice and consent form to be provided to a payor. Imposing such a requirement would create additional work for the provider or facility, requiring the establishment of a new workflow and communication process to provide the information within the tight statutory timeframes required to complete the GFE. If the payor questions whether its insured was provided notice and gave consent, the payor can ask the insured for copy of the form. There is no reason to place additional reporting requirements on the nonparticipating providers/facilities who have no contractual relationship with the payor.

State Specific Requirements (p. 14)

The RFI asks how the AEOB should reflect the way in which the No Surprises Act's or a State's surprise billing and cost-sharing protections affect an individual's benefits related to the items or services specified in an AEOB, and the individual's financial responsibility for these items or services. AEOBs should include state-specific information where applicable. Providers and facilities must take a state's surprise billing laws into account where the state laws control. This should be reflected in the AEOB provided by payors as well.

Regulations should require that the AEOB validate that the authorization, eligibility, and coverage criteria have been met. Patients need to know if the item or service is subject to a medical management technique such as concurrent review, prior authorization and step-therapy or fail-first protocols. AEOBs should clearly identify the patient cost share for each provider.

Transparency in Coverage Requirements (p.15)

As confusing as AEOBs can be, we do not believe the internet-based self-service price transparency requirements of the Transparency in Coverage (TiC) rules are sufficient to detail complex benefit calculations and the underlying pre-requisites such as eligibility, medical necessity and authorization requirements that should be included in an AEOB.

AEOBs (p. 16)

We strongly support requiring plans, issuers, and carriers to provide a copy of the AEOB to the providers and facilities that submitted GFEs. Information from the AEOB is necessary for

providers and facilities to see medical necessity determinations, coverage, and the patient's out of pocket costs.

The RFI asks what, if any burdens or barriers should be considered if plans, issuers, and carriers were allowed to communicate a covered individual's request for an AEOB to a particular provider or facility to secure GFE information. If this is allowed, there must be an electronic mechanism in place to solicit such information - including all procedures and codes that are being contemplated in the request for the GFE. This is a complicated process, and any such requirement would contribute to additional expenditures for labor and technology.

(p. 17)

It seems that commercial payors should account for secondary or tertiary payors, including those for which the AEOB regulations would not apply, when providing an AEOB to the patient.

There also needs to be some mechanism in place to ensure that patients who might qualify for Medicaid or other types of financial assistance are able to access that information before making decisions based solely on information provided in a GFE (if uninsured) or an AEOB prepared based on a GFE (if insured).

(Discussion on p. 17, questions p. 18)

The RFI seeks input on the items and services with low utilization or significant variation in costs for which modification of the timing of the AEOB might be permitted. The items and services that are most challenging for providers and facilities to prepare GFEs are the complicated surgical procedures, oncology treatment plans and implants. As an example, receiving correct dosage of chemotherapy drugs based on real time information (such as weight) and scans is not something that can be done in advance. Relaxing the tight time constraints for both GFEs and AEOBs in these situations would allow for more accurate estimates.

(Discussion on p.18, question p. 19)

As to whether diagnosis codes should be required for the calculation of the AEOB, providers are not always able to provide the "final" diagnosis code on the GFE as the scheduled treatment is often designed to determine the "final" diagnosis, and, thus, is not known at the time the GFE is prepared. Diagnosis codes often change and include additional services based on findings at the time the initial services are rendered.

Enrollment Status (p. 19-20)

The Departments ask if providers and facilities should be required to verify an individual's enrollment status in a health plan or coverage for a scheduled (or requested) item or service or if they already routinely conduct such verifications. The No Surprises Act does not place this responsibility on providers and facilities; the statute merely requires providers and facilities to inquire if patients are insured. Requiring providers and facilities to verify insurance coverage would require us to stand up the infrastructure to coordinate with multiple payors and providers. Not all plans have real-time eligibility and contacting payors can take hours. Currently there may be instances where providers or facilities may attempt to verify an insurance provider, but may

not necessarily verify if the insured has coverage for each item or service that would be expected to be included.

The health plan must be responsible for verifying the individual is insured and determining the coverage available. Providers and facilities cannot rely on the patient's representation regarding enrollment because patients do not have full and complete understanding of their insurance. Patients may provide limited or incorrect information thereby increasing the amount of work and the amount of time required to verify. There may be pre-authorization requirements. If providers and facilities are required to rely upon the patient's representations, the provider and facility should not be negatively impacted by an inaccurate GFE due to a patient's error.

Unique Barriers and Challenges for Underserved and Marginalized Communities (Discussion on p. 20, questions p. 21)

It would be good to offer something specific to underserved/marginalized communities here rather than the generalized comments below.

Insurers should be required to provide more education to their insureds regarding coverages under policy, including a plain language summary in the patient's primary language. Patients need to understand that GFEs and AEOBs are estimates and that there may be services or treatments provided that are unanticipated at the time of the GFE and AEOB that may increase the costs. Other services might change during the procedures, such as anesthesia time and operating room time.

C. Economic Impacts (p. 22)

The Departments seek information on the costs for purchasing and implementing a standards-based API for the real-time exchange of AEOB and GFE data from a third-party vendor, compared to building standards-based API functionality in-house. We believe few facilities would have the resources to build these APIs internally and would rely on outside vendors, such as EPIC, to create standard APIs to make the data interoperable, similar to the USCDI data set APIs. The USCDI elements could be updated to include standardized vocabulary and definitions as these standards are developed.

Additionally, if we are to assume that insurers will be required to comply with an electronic exchange of data with providers, then we must also consider the burden on our Information Technology (IT) teams in creating these interfaces. While the manual burden might be alleviated through EDI compliance, this will still create a new workload for IT teams who must create and maintain the interfaces of appointment and charging data for all patients.

For some facilities, preparing GFEs for uninsured/self-pay patients alone has already resulted in increased staffing requirements in all areas of patient access. We are preparing GFEs for patients who decide to defer care or go elsewhere and for patients who receive our services and then either cannot or do not pay. Expanding this requirement to insured patients will substantially increase staffing costs.

Some facilities have added staff to deal with the complexities involved in collecting charge information for uninsured patients from external providers required to meet the requirements placed on convening providers for self-pay/uninsured patients. External providers are often unwilling to share their charge data with convening providers causing significant delays in patients receiving their GFEs. If this requirement is expanded to include insured patients and external providers are expected to share their insurance contract data, this process will prove even more difficult to manage in the required timeframes. The convening provider would have to develop infrastructure and IT systems with the capability to produce GFEs taking into consideration managed care contractors for numerous external providers. We urge the Departments not to extend the unwieldly convening/co-provider requirements to insured patients.

Finally, the Departments should consider regulations to reduce the burden, time requirements and costs for obtaining pre-authorizations. The pre-authorization requirements currently in place make it difficult to ensure that patients receive the necessary care in a timely manner.

We hope this information is helpful as you develop regulations to implement the remaining provisions of the No Surprises Act. Please feel free to contact Diane Turpin, General Counsel, Strategic Health Care, at diane.turpin@shcare.net or the signatories below with any questions.

Sincerely,