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Chiquita Brooks La-Sure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: Comments on Requirements Related to Surprise Billing; Part II

Dear Administrator Brooks-LaSure,

Thank you in advance for considering our comments on the Requirements Related to Surprise Billing; Part II interim final rules to protect uninsured and self-pay consumers from surprise medical bills. We support the objectives of the No Surprises Act and appreciate your efforts to provide uninsured and self-pay patients with advanced billing information to increase access and control over their medical care as well as ease concerns about unexpected medical bills.

The Committee on Operating Rules for Information Exchange (CORE), an initiative of CAQH, is a non-profit, national multi-stakeholder collaborative that drives the creation and adoption of healthcare operating rules that support standards, accelerate interoperability, and align administrative and clinical activities among providers, payers, and consumers. [CAQH CORE Participating Organizations](#) represent more than 75 percent of insured Americans, including health plans, providers, electronic health record (EHR) and other vendors/clearinghouses, state and federal government entities, associations, and standards development organizations.

CAQH CORE is designated by the Secretary of the Department of Health and Human Services (HHS) as the author of federal operating rules for HIPAA administrative healthcare transactions. Operating rules, which are required by the Affordable Care Act, are defined as “the necessary business rules and guidelines for the electronic exchange of information that are not defined by a standard or its implementation specifications.” Operating rules are developed by CAQH CORE Participants via a multi-stakeholder, consensus-based process.

CAQH CORE comments on the Requirements Related to Surprise Billing; Part II interim final rules are based on our history of working with stakeholders across the healthcare industry. Together, we work to promote interoperability, reduce administrative burden, and collaborate to coalesce around practical solutions to some of the most complex and onerous healthcare problems. Recent discussions with our healthcare partners have focused on the importance of the good faith estimate and advanced explanation of benefits (EOB) provisions of the No Surprises Act and the opportunity for industry to come together to avoid potential duplication of effort or inconsistent implementation of these requirements. Our comments on areas that HHS has asked for additional guidance will focus on the need for standardized processes and workflow adjustments to meet the good faith estimate requirements without creating undue burden for patients and providers. Our remarks specifically address the following areas which HHS is seeking comments:

- The approach on how providers and facilities will provide a good faith estimate to individuals not enrolled in a plan or coverage or not seeking to have a claim submitted
- Publicly available resources, methods, and potential standardized formatting or design that could facilitate the communication of good faith estimate information in a clear and understandable manner
- How required methods for providing a good faith estimate may affect small or rural providers or facilities
- Methods and standardized processes that could facilitate accurate and efficient transmission of good faith estimate information from co-providers or co-facilities to convening providers or convening facilities
- Potential benefits and challenges of using a standardized form that could serve as a base for the good faith estimate for uninsured or self-pay individuals

In addition, CAQH CORE offers our assistance as the agencies develop future regulations to implement the No Surprises Act.

CAQH CORE Advanced Explanation of Benefits Advisory Group

We are pleased to share that CAQH CORE launched an Advanced Explanation of Benefits Advisory Group in August 2021 to bring industry stakeholders together to coalesce on how industry can implement requirements of the No Surprises Act, leveraging standards to support a uniform approach. The group includes over 60 participants representing over 30 healthcare stakeholders including providers, health plans, clearinghouses, vendors, associations, standards development organizations, and government entities. The initial focus of the group was to develop recommendations pertaining to messaging standards, connectivity protocols, and related data content to support the exchange of good faith estimates between providers and payers. After extensive discussion, research, and surveying, the group agreed to the following recommendations:

- **Messaging Standards:** Use of X12 837 Professional Pre-Determination X291, X12 837 Professional Pre-Determination X292, and HL7 FHIR.
- **Connectivity Methods:** Use of CAQH CORE Connectivity and HL7 FHIR APIs.
- **Uniform Data Content:** Establish uniform data elements pertaining to indicators, patients, providers/facilities, and services.

Additional detail around these published recommendations can be found [here](#).

CAQH CORE’s Advanced Explanation of Benefits Advisory Group will continue to apply its consensus-based approach to engage in industry discussions, assess additional use cases, evaluate operating rule opportunities, and consider pilot projects to drive the industry forward to support price transparency. Tentative next steps for the group include developing recommendations for a comprehensive advanced explanation of benefits data set that will enable common information flow and format across all advanced explanation of benefits, and recommendations for provider communications related to charges for items and services performed during a period of care. Any advanced explanation of benefits data set developed by the group could also inform a data set for the good faith estimate for uninsured and self-pay patients. Our work may be helpful as the agencies consider related regulations and we invite the Centers for Medicare & Medicaid Services (CMS) to continue participating in the Advisory Group and the other agencies to join.

Comments on Requirements Related to Surprise Billing; Part II

The interim final rules require a statement of a good faith estimate of expected charges to an uninsured or self-pay individual who schedules an item or service at least three business days before the date of such item or service and no later than one business day of scheduling. The rules further state that when an uninsured or self-pay individual requests a good faith estimate of expected charges, but the item or service has not been scheduled, a good faith estimate must be delivered within three business days of their request. Additionally, the interim final rules introduce the concept of a “convening health care provider or facility,” responsible for providing the good faith estimate to the uninsured or self-pay individual and “co-providers and co-facilities” that provide components of the items or services for which a good faith estimate is requested. The convening provider must contact all applicable co-providers and co-facilities no later than one business day after the request for the good faith estimate is received or after the primary item or service is scheduled to request expected charges for the good faith estimate.

Providing uninsured individuals with a good faith estimate in advance of an item or service will help inform care decisions and patient planning. However, CAQH CORE is concerned about how these requirements will be operationalized by industry and how they may relate to future requirements for the advanced EOB and appreciates the enforcement discretion related to the inclusion of charges from co-providers and co-facilities. The provider-to-provider data exchange needed to meet these requirements present a unique challenge as they require new workflows and interactions between disparate entities. CAQH CORE research indicates there is no simple solution that can be quickly implemented that meets all requirements and urges industry to avoid disparate, proprietary, and non-standardized approaches that create more burden and

confusion than value for patients and providers. More detailed guidance from the agencies on definitions and expected workflow processes is needed. Specifically, CAQH CORE's recent conversations with industry stakeholders have highlighted the need for additional direction on initiation, design, and required elements of a good faith estimate with the understanding that provider capabilities and current workflows may not align, as well as the need for patient education on the use and applicability of a good faith estimate. Among various specific workflows that need further guidance, one issue that needs to be addressed is more guidelines for the scope of when a good faith estimate is required.

Additional guidance will help the industry move forward with consensus-based approaches and ensure patients receive meaningful and understandable good faith estimates without overburdening convening and treating providers' resources and systems.

Need for Standardization to Reflect Expectations for the Good Faith Estimate Requirements

Uniformity across common data sets, electronic transmission methods, and format/layout for the provider-to-provider, and provider-to-patient workflows is vital to successful industry implementation of the requirements in the interim final rules. At CAQH CORE, we see firsthand the importance of applying uniform standards and operating rules across the entire healthcare industry to enable consistent automation and interoperability. We encourage the agencies to consider standardization across the provider-to-provider and provider-to-patient workflows, including use of standard agnostic operating rules, where possible, to support the requirements in the interim final rules and to avoid proliferation of proprietary or manual efforts that only increase administrative burden.

There are a variety of implementation approaches the industry can consider when determining how to support the exchange of good faith estimates between providers and from providers to uninsured or self-pay individuals. Establishing standards for messaging is particularly challenging because there is not a HIPAA transaction that exists today that can address the provider-to-provider exchanges necessary to meet the requirements in the interim final rules without altering the intended use of the transaction.

We are concerned that given the lack of an established messaging standard for provider-to-provider exchanges, proprietary and non-standardized solutions, such as DIRECT Messaging, will be the primary method for exchanging the information necessary to garner a good faith estimate to uninsured and self-pay individuals. There is a need for standardization that does not place undue burden on the industry and meets provider organizations where they are along the technology adoption spectrum to reduce disruption to patient care. CAQH CORE and its Advisory Group have launched an environmental scan to better understand the challenges and potential solutions for how to exchange charge information between convening providers and co-providers using a uniform approach, such as establishing a common format for secure email or DIRECT Messaging.

Need for Workflow to Reflect Expectations for the Good Faith Estimate Requirements

Existing practice management systems are not designed to include the intersystem communication in the workflow required for providers to create a good faith estimate. The process of developing, testing, and implementing necessary updates to practice management systems to accommodate intersystem communication will take time to ensure appropriate workflow changes and resourcing.

This process will be especially burdensome to convening providers if a good faith estimate is required for all items and services for which a patient requests an estimate. Supplying the patient with the most accurate good faith estimate after each discussion regarding cost will require consistent and comprehensive data collection and staff time. We encourage the agencies to address these workflow issues and consider additional guardrails or guidance that could reduce the burden of this process including a phased implementation approach, more clarity on when a good faith estimate is required, and/or limiting the scope of items and services for which a patient can request a good faith estimate to higher cost items and services.

The Role for Standard Agnostic Operating Rules

Regardless of the standards used, industry needs consistency in the data content, infrastructure, connectivity, and format to prevent entities from using the same standard in different ways. Historically, CAQH CORE Operating Rules have addressed these gaps, aligning data and infrastructure expectations across standards for the same business process. This concept can be applied to the development of good faith estimates.

Data content and infrastructure operating rules can help define uniform expectations for good faith estimates and have the potential to accelerate the success of implementing the proposed requirements by capitalizing on existing value in backend systems, facilitating ease of technology transition, and supporting small or rural provider practices with fewer resources. Standard agnostic CAQH CORE Operating Rules include built-in flexibility to update requirements as the industry evolves and matures, providing structure for providers to interoperate, regardless of where they are on the technology adoption spectrum.

The most recent version of the [CAQH CORE Connectivity Rule vC4.0.0](#) includes requirements for the exchange of information using both SOAP and REST technologies to support the exchange of clinical and administrative data. This creates a standard agnostic approach to exchange information in a uniform manner. For example, entities may:

- Use CORE Connectivity vC4.0.0 to exchange the HIPAA-mandated X12 transactions
- Use CORE Connectivity vC4.0.0 to exchange the HL7 FHIR standard to support good faith estimates via a REST API

As mentioned previously, the CAQH CORE Advisory Group is conducting an environmental scan to determine options for supporting the provider-to-provider exchange including connectivity method(s) and how operating rules may help. We encourage the agencies to review any guidance produced by this Advisory Group and consider naming or requiring development of the specific standards, methods, and associated operating rules recommended to support the transmission of the good faith estimate.

Using HIPAA to Drive Standard Provider to Patient Data Exchange to Support the Good Faith Estimate

CMS already has authority to mandate operating rules for standards under Section 1104 of the Affordable Care Act. We encourage HHS and CMS to consider using its existing authority under the Administrative Simplification provisions in the HIPAA and expanded under the Affordable Care Act (45 C.F.R. § 162.910-930) to drive industry-wide adoption of standards and operating rules to support the exchange of good faith estimates between providers and between providers and health plans. Specifically, Section 1172 of the Social Security Act states:

The Secretary shall adopt standards for transactions, and data elements for such transactions, to enable health information to be exchanged electronically, that are appropriate for--"(A) the financial and administrative transactions described in paragraph (2); and "(B) other financial and administrative transactions determined appropriate by the Secretary, consistent with the goals of improving the operation of the health care system and reducing administrative costs.

This authority can be used to update existing standards and advance new and emerging standards for additional administrative functions, such as transmission of good faith estimate and advanced EOB information. In an industry-driven process, the National Committee on Vital and Health Statistics (NCVHS) hears industry feedback on new and emerging standards, and operating rules through comment letters and testimony to make a recommendation to the HHS Secretary on adoption. The process, which is enforceable by CMS, is open to the public, and as such, moves the entire industry forward together.

Next Steps: Bringing Industry to Consensus

There is a need for an overarching strategy to consider how the requirements in the interim final rules will support the creation and transmission of a good faith estimate to an uninsured or self-pay patient without creating unnecessary burdens. Multiple stakeholders will need to collaborate across the healthcare industry to ensure successful implementation and comprehensive good faith estimates.

Development of a uniform approach for the good faith estimate and its implementation that does not create undue burdens on providers will likely take longer than the current one-year enforcement discretion. CAQH CORE encourages the agencies to continue to consider industry feedback and collaborate with stakeholders like CAQH CORE to develop standardized approaches and appropriate timelines for implementation that reduce the burden of this process and ensure lasting value for patients.

CAQH CORE looks forward to supporting this work and helping industry to agree on specific recommendations and rules to bring together current, emerging, and new workflows to meet the spirit of the law without inhibiting industry innovation and progress.

Thank you for considering our comments in response to the Requirements Related to Surprise Billing; Part II of the No Surprises Act. These comments should also be considered any upcoming or future rules addressing the good faith estimate for the advanced explanation of benefits. Should you have any questions, please contact me at atodd@caqh.org.

Sincerely,



April Todd
Senior Vice President, CAQH CORE & Explorations

CC:

Secretary, Department of Health and Human Services

Secretary, Department of Labor

Secretary, Department of the Treasury

Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget

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