AMERICAN CLINICAL LABORATORY ASSOCIATION

November 14, 2022

Ms. Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
Attn: CMS-9900-NC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: Request for Information: Advanced Explanation of Benefits and Good Faith Estimate for Covered Individuals (CMS-9900-NC)

Dear Administrator Brooks-LaSure,

Please accept the comments of the American Clinical Laboratory Association (ACLA) on the above-referenced Request for Information (RFI).[1] ACLA is the national trade association representing leading laboratories that deliver essential diagnostic health information to patients and providers. ACLA works to advance the next generation of health care delivery through policies that expand access to lifesaving testing services.

We appreciate the opportunity to provide feedback and to share our concerns with the Departments of Treasury, Labor, and Health and Human Services (the "Departments") about the advanced explanation of benefits (AEOB) and good faith estimate (GFE) requirements of the No Surprises Act (the "Act"). We offer comments and recommendations on the following five areas: (1) data transfer issues and economic burdens; (2) defining smaller, rural, or other entities; (3) a requirement to include a diagnosis code in a GFE; and (4) the structure of AEOBs and the verification on enrollment in a health plan.

I. Data Transfer Issues and Economic Burdens

Practicality of Uniform Data Standards. In order to meet their responsibilities under Sec. 2799B-6 of the Public Health Services Act, providers and plans must exchange data quickly and efficiently. ACLA supports and encourages widespread interoperability of health data, but the reality is that not every provider, facility, and plan will be able to adopt one uniform data exchange standard without significant financial burdens. ACLA is concerned about the costs associated with requiring the adoption of a Fast Healthcare Interoperability Resources (FHIR)-based API to comply with the Act. Most clinical laboratories currently use HL7 Version 2 standards to transmit laboratory orders and results. Laboratories would be forced to incur significant financial costs if they are required to use FHIR for data transfer, including the purchase of a new FHIR server, employee training, and software development. For smaller laboratories, this transition could be prohibitively expensive.

The Departments should allow trading partners the flexibility to use data exchange

[1] 87 Fed. Reg. 56905 (Sept. 16, 2022).

processes that already are in place, at least during a transition period. It would be inefficient and unnecessary to "rip and replace" entities' established workflows. If the Departments do require the use of a FHIR-based API to transmit data to comply with the GFE and AEOB requirements, we recommend that laboratories and other entities be given sufficient time to integrate FHIR into their systems and that the Departments work closely with the Office of the National Coordinator for Health Information Technology (ONC) to ensure that any applicable FHIR-based API receives ONC Certification. It is ACLA members' experience that EHR vendors are reluctant to implement APIs that are not required for ONC Certification.

Incomplete Information. Achieving real-time transfer of information about GFEs between laboratories and plans is unlikely to be possible in the near term. A patient who schedules a service with a laboratory may not have an order in hand that specifies the exact tests and diagnosis codes, and the order may not have been sent to the lab by the ordering health care practitioner directly. The very short time frame for a laboratory to furnish a plan with a GFE does not account for the time needed for an ordering health care practitioner to send pertinent information in response to a request by a laboratory, especially if the practitioner does not have a mechanism in place already for real-time data exchange with the laboratory. The laboratory would not be able to provide a GFE to a plan unless and until it receives information from the practitioner.

Leveraging Existing Data Transfer Mechanisms. Laboratories regularly transfer data and information to plans for utilization management approvals, such as for prior authorization. There is considerable overlap between the information transferred to the plan for these purposes with the information required by the Act. We urge the Departments to promulgate policies that would encourage providers, facilities, and plans to leverage existing data transfer mechanisms. Doing so would reduce the already substantial administrative burdens faced by all the entities involved in data exchange for purposes of developing GFEs and AEOBs.

II. Defining Smaller, Rural, or Other Entities

We appreciate that the Departments are considering flexibilities for small, rural, and other providers to comply with the Act. We urge the Departments and OPM to do so; any flexibilities would further health equity in underserved and underrepresented communities. As the Departments craft a definition for these entities, we recommend referencing the Small Business Administration's current Table of Size Standards,[2] which indicates that for medical laboratories (NAICS Code 621511), a small business is defined as having annual revenues up to $36.5 million. To reduce administrative and financial burdens on small and rural entities, ACLA urges the Departments not to force providers and facilities to use one reporting standard for data exchange, particularly one that may be expensive and resource-intensive to implement.

III. Including a Diagnosis Code in a GFE

The Departments received feedback that it is not always possible to provide a diagnosis code to develop a GFE. We urge the Departments to be flexible with respect to this requirement. Rather than requiring a diagnosis code "only where one is required for the calculation of the GFE"[3]

[2] Available at https://www.sba.gov/document/support-table-size-standards.
[3] 87 Fed. Reg. 56910.

(as the Departments stated is the policy in the context of a GFE for an uninsured or self-pay patient), a diagnosis code should be required only when the entity furnishing the GFE knows the diagnosis code. When a laboratory has an order from a health care practitioner that includes one or more diagnosis codes, only then would it be possible to include this information in a GFE without a considerable burden on the laboratory to try to obtain this information from the ordering practitioner.

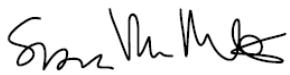
IV. Structure of AEOB and Verification on Enrollment in a Health Plan

Structure of the AEOB. ACLA recommends that the Departments consider how the AEOB should be structured if a plan must notify a patient that a service or item is not covered. ACLA is concerned that if a plan declines to cover an item or service, the plan will show the entire cost as a patient responsibility on the AEOB. That information could lead patients to forego testing altogether.

Verification of Enrollment in a Health Plan. Providers and facilities should be able to rely on an individual's representation about enrollment in a health plan. Requiring laboratories and others to verify whether a patient's representation is accurate would add to administrative burdens needlessly.

Thank you for your consideration of ACLA's comments and recommendations on these important policy issues.

Sincerely,



Susan Van Meter, President
American Clinical Laboratory Association