

October 6<sup>th</sup>, 2025

Dr. Mehmet Oz, Administrator  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, Maryland 21244

**RE: Agency Information Collection Activities: Proposed Collection; Comment Request: CMS-R-131**

Dear Dr. Oz,

Please accept the comments of the American Clinical Laboratory Association (ACLA) on the proposed updates to CMS-R-131: Advance Beneficiary Notice of Non-coverage or “ABN.” ACLA is the national trade association representing leading laboratories that deliver essential diagnostic health information to patients and providers. ACLA members are at the forefront of driving diagnostic innovation to meet the country’s evolving health care needs and provide vital clinical laboratory tests that identify and prevent infectious, acute, and chronic disease. ACLA works to advance the next generation of health care delivery through policies that expand access to life-saving testing services.

We appreciate that the Centers for Medicare & Medicaid Services (CMS) is updating the ABN forms to increase plain language, improve usability, and reduce burden for providers. To ensure that these goals are achieved, particularly for clinical laboratories and the ordering providers, we provide recommendations around the disclosure statement requirements and the timeline for implementation of the updated form and instructions below.

**Disclosure Statement Requirements:**

The proposed updates to the ABN Form Instructions, included with the updated ABNs, “Disclosure Statement” section are of particular concern to our members. The updates include that “the disclosure statement may be printed on a separate page, or the notice may be printed as a double-sided document.” We anticipate that the change from the current requirement (*i.e.*, footnotes on a single-page ABN document) will cause administrative and records keeping issues for laboratories and other ancillary providers. Some laboratories have systems which currently scan a single page document and will routinely miss piece-meal ABNs that are submitted. Additionally, if the laboratories are asked to produce a copy of the ABN at a later date, the lack of the full disclosure statement could be used to invalidate the entire ABN. **We recommend that either the language be changed to require the disclosure be included on the single, front-page ABN document or that CMS retain the current requirement for the Disclosure Statement: “The disclosure statements in the footer of the notice are required to be included on the document.”**

**Timeline for Implementation:**

ACLA laboratories are concerned that they will need additional time to address the formatting updates and roll over to the new forms by the effective date of January 1, 2026. In particular, laboratories anticipate that there will be issues with incorporating the formatting updates into their manual paper forms and need time to work through this hurdle.

Additionally, clinical laboratories will need to develop their new, updated version of the ABN and then will

need to work with their ordering providers to recall the old, previously distributed forms and deploy the new forms. Many laboratories provide services to ordering providers nationally and deploying the new forms will constitute a substantial burden. **We request that CMS provide at least a 6-month grace period following the effective date when old versions of the ABN form will continue to be accepted while providers shift over to the new form.**

Thank you for your attention to this request. We would be happy to engage in a collaborative discussion with you and your team on this issue. Please contact me at (202) 637-9466 or [sthibaultsennett@acla.com](mailto:sthibaultsennett@acla.com) with any additional questions or to set up a call with our member laboratories to discuss this issue further.

Best,

A handwritten signature in black ink, appearing to read 'Satz'.

Sarah Thibault-Sennett, PhD  
Senior Director, Reimbursement Policy  
American Clinical Laboratory Association (ACLA)