



October 06, 2025

Dr. Mehmet Oz, Administrator
Centers for Medicare and Medicaid Services
P.O. Box 8013
Baltimore, Maryland 21244-8013

**RE: Agency Information Collection Activities: Proposed Collection; Comment
Request: Advance Beneficiary Notice of Non-Coverage (ABN) Contained in 42 CFR
411.404 and 411.408 (CMS-R-31)**

Dear Dr. Oz:

Quest Diagnostics appreciates the opportunity to comment on the proposed updates to CMS-R-31, Advance Beneficiary Notice of Non-Coverage (ABN). Quest Diagnostics is among the world's leading providers of diagnostic information services with the purpose of working together to create a healthier world, one life at a time. The work we do has a profound impact on patients. Diagnostic testing accounts for only two to three percent of healthcare spending but drives up to 70 percent of healthcare decisions. Quest Diagnostics serves one in three adult Americans and about half of physicians and hospitals in the United States annually. We have over 7,400 patient access points, including phlebotomists in physician offices and 2,000 patient service centers. Quest Diagnostics is passionate about providing patients with accurate, timely, and affordable insights into their health.

We recognize that the Centers for Medicare and Medicaid Services (CMS) is updating the ABN form(s) to increase plain language, improve usability, and reduce burden on providers. To ensure these goals are achieved, particularly for clinical laboratories and ordering providers, Quest Diagnostics supports the recommendations submitted by the American Clinical Lab Association (ACLA) regarding the disclosure statement requirements and implementation timeline for the updated form and its instructions.

In furtherance of the goals surrounding continued process improvements, we would additionally support using an ABN-equivalent process for Medicare Advantage (MA) enrollees given that, for MA plans, there is currently no ABN process. It is our position that the existing organization determination (OD) requirements in MA plans impede access to care and create an unnecessary burden on providers and beneficiaries. **Quest Diagnostics strongly urges CMS to adopt an ABN-equivalent process that would provide MA enrollees with the same rights as fee-for-service (FFS) Medicare beneficiaries, allowing them to elect to move forward with**

receiving laboratory testing without the delay or administrative burden of having to first receive an OD.

As a general matter, it is impractical for a laboratory to seek an OD on an MA enrollee's behalf after receiving a test order from the enrollee's physician but prior to performing the test. Oftentimes, the laboratory does not receive an order until either after the date of service (i.e. the date the patient's blood was drawn in the physician's office) or at the time of service (if the patient has their blood drawn at a lab's patient service center). A laboratory cannot delay testing to seek an OD on behalf of an enrollee due to specimen integrity issues and testing turnaround time requirements.

Moreover, an MA plan has up to 14 days after receiving a request to respond to standard ODs, and CMS regulations permit only an enrollee or a physician to request an expedited OD. For reasons stated above, the laboratory is unable to withhold performing the test during the 14 day period the MA plan has to respond to any such requests. Further, ODs are provided only if they are requested by the beneficiary or the provider and in many cases, ordering providers are not obtaining ODs when ordering non-covered testing.

In the case of clinical laboratory testing, electronic test ordering systems can predict eventual Medicare claim denials with very high accuracy at the point of care for commonly ordered and routinely covered services that will not be covered in the beneficiary's specific case due to indications presented at the encounter. This process can be applied to MA plans, which we strongly believe would give MA enrollees: 1) the ability to acknowledge likely non-coverage; 2) the option to proceed with critical laboratory testing and downstream care without delays associated with the OD process; 3) the ability to maintain appeal rights in the case of denial; and 4) parity with their FFS Medicare counterparts.

We note that the current ABN process prohibits the routine use of ABNs in most situations and may only be used when the provider has strong indication of likely denial. **Quest Diagnostics supports this as an important tenet that should be maintained in using an ABN-equivalent process in MA to ensure a meaningful, transparent decision point for the beneficiary at the point of care.**

Quest Diagnostics urges CMS to adopt an ABN-equivalent process for MA, ensuring:

- 1. MA enrollees receive advance notice when coverage is uncertain;**
- 2. Equity between traditional Medicare and MA is restored, consistent with statutory parity requirements; and**
- 3. MA enrollees maintain their appeal rights if the provider's claim is denied.**

Thank you for considering Quest Diagnostics' comments on the proposed updates to CMS-R-131. Please do not hesitate to contact me should you have any questions or concerns and/or if you require further information.

Sincerely,

A handwritten signature in black ink that reads "Michael Prevoznik". The signature is fluid and cursive, with "Michael" on the top line and "Prevoznik" on the bottom line.

Michael Prevoznik, Senior Vice President and General Counsel
Quest Diagnostics