

October 13, 2026

Mehmet Oz, MD

Administrator

Centers for Medicare & Medicaid Services

7500 Security Boulevard

Baltimore, MD 21244

**Re: Medicare Program; Regulatory Alignment for Predictable and Immediate Device (RAPID) Coverage Pathway (CMS-3487-NC)**

Dear Administrator Oz:

Research!America appreciates the opportunity to comment on the proposed Regulatory Alignment for Predictable and Immediate Device (RAPID) Coverage Pathway. With more than 300 organizational members, the nonprofit, non-partisan [Research!America](#) alliance advocates for science, discovery, and innovation to achieve better health for all.

RAPID reflects the importance of harmonizing FDA and CMS decision-making to ensure that safe and effective medical advances reach patients without unnecessary delay. Greater coordination between the two agencies can help maximize the return on the federal government's longstanding commitment to medical research and innovation. Time saved during FDA review should not be lost to avoidable delays in Medicare coverage that postpone opportunities to prevent suffering, improve health, and save lives.

Beyond encouraging CMS to continue working with FDA to coordinate and align decision-making as appropriate, our comments focus on two aspects of the proposed RAPID pathway that have implications for medical research and innovation and the patients who stand to benefit from it.

**First, we are concerned that the proposed exclusion of diagnostic tests from RAPID would disadvantage an area of medical innovation that is fundamental to improving patient outcomes.** Timely and accurate diagnosis is often the essential first step toward effective treatment. The consequences of diagnostic errors are profound. A 2023 [study](#) published in *BMJ Quality & Safety* estimated that diagnostic errors contribute to approximately 795,000 deaths or cases of permanent disability in the United States annually. Beyond the human toll, delayed or inaccurate diagnoses contribute to avoidable health care costs, including unnecessary testing, treatment delays, and preventable complications.

Excluding diagnostic tests from an accelerated coverage pathway risks skewing incentives away from diagnostics research and development, potentially slowing progress in an area where innovation is urgently needed. We encourage CMS to reconsider this exclusion and explore an approach that would support timely access to innovative diagnostic technologies.

**Second, we urge CMS to ensure that RAPID does not come at the expense of other national coverage determinations.** Prioritizing RAPID applications without additional resources risks

further delaying coverage decisions for other medical advances, including technologies that patients are already waiting to access. Accelerating access to one category of innovation should not mean delaying access to another. We encourage CMS to ensure that RAPID has the resources needed to succeed without diverting capacity from other national coverage determinations.

Research!America strongly supports efforts to ensure that the benefits of medical research and innovation reach patients as quickly as possible. We believe that addressing these two concerns would help RAPID achieve its objectives while reinforcing the broader goal of translating scientific progress into better health for all Americans.

Thank you for your consideration.

A handwritten signature in cursive script that reads "Eleanor Dehoney". The signature is fluid and elegant, with a large initial "E" and a long, sweeping tail on the "y".

Eleanor (Ellie) Dehoney  
Senior Vice President, Policy & Advocacy  
Research!America