

October 13, 2026

Submitted electronically via: www.federalregister.gov.

The Honorable Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
7500 Security Blvd
Baltimore, MD 21244

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

Dear Administrator Oz,

Timely access to safe and effective medical technologies is a critical patient safety and healthcare access issue. ECRI supports the Centers for Medicare & Medicaid Services' (CMS's) goal of reducing the longstanding gap between Food and Drug Administration (FDA) authorization and Medicare coverage of medical devices.

The concept of the Regulatory Alignment for Predictable and Immediate Device (RAPID) coverage pathway is sound. ECRI advocates for regulatory pathways that enable the safest, most effective devices to get to market as quickly as possible, with sufficient evidence supporting their safety and efficacy.

Summary of ECRI's Key Recommendations

- Support the pathway's goal of accelerating Medicare beneficiary access to Breakthrough Devices, conditioned on coverage decisions remaining grounded in evidence sufficient to demonstrate meaningful clinical benefit and safety for the Medicare population.
- Require that studies supporting Breakthrough Device designation and RAPID eligibility adequately represent Medicare-age and comorbid populations and increase transparency around how FDA and CMS jointly define agreed-upon clinical endpoints.
- Mandate a defined post-market and active-surveillance infrastructure (e.g., registry enrollment tied to NEST or a RAPID-specific registry) as a condition of any accelerated National Coverage Determination, not an optional or assumed safeguard.
- Require post-authorization evidence obligations address clinical effectiveness, not safety alone, consistent with the established purpose of Coverage with Evidence Development.
- Address patient accessibility concerns in pivotal studies.

- Clarify how RAPID's post-market evidence obligations will replace the multi-year, gap-driven evidence-development structure lost with the pause of new candidates into the TCET pathway.

Aligning FDA and CMS Evidence Standards to Improve Patient Access

FDA and CMS should work collaboratively to identify a core set of clinically meaningful outcomes relevant to Medicare beneficiaries, including appropriate study endpoints, patient populations, comparators, and follow-up periods. Generating evidence in these populations would provide a stronger foundation for evaluating device performance in routine clinical practice, improve the relevance of evidence for downstream coverage decisions, and support more timely and predictable patient access to beneficial technologies.

ECRI recommends that FDA and CMS further harmonize the Breakthrough Devices Program with Medicare coverage requirements by placing greater emphasis on device availability in the best interest of patients and on reducing disparities in health and health care, consistent with Sections III.B.2.d and III.B.3.d of FDA's final Breakthrough Devices Program guidance. Studies used to support FDA's review of safety and effectiveness should include patient populations representative of Medicare beneficiaries, including adults aged 65 years and older and individuals with comorbid medical conditions, who are frequently underrepresented in premarket studies.

ECRI recommends that CMS clarify that any post-authorization evidence obligations under RAPID continue to evaluate clinical effectiveness and functional patient outcomes, consistent with the established purpose of Coverage with Evidence Development (CED), rather than being narrowed to safety or adverse-event monitoring alone.

Improve Speed without Compromising Standards

ECRI supports efforts to align FDA and CMS review timelines, provided that such alignment strengthens efficiency without compromising evidence-based decision making. Earlier coordination of evidentiary expectations can reduce duplicative evidence generation, improve predictability for manufacturers, and enable CMS coverage determinations to proceed in parallel with FDA review while maintaining rigorous standards for safety, effectiveness, and beneficiary benefit.

To support this objective, ECRI recommends that CMS and FDA develop a publicly available shared evidence framework that clearly identifies where regulatory and coverage evidence requirements overlap and where they differ. Such a framework would provide greater transparency for manufacturers, facilitate more efficient study design, and reduce avoidable review delays. Importantly, alignment should not be interpreted as a lowering of the evidentiary threshold for Medicare coverage. CMS should continue to ensure that evidence supporting coverage decisions is sufficient to demonstrate meaningful clinical benefit for the Medicare population, particularly for higher-risk Class III devices where residual evidence gaps may appropriately warrant additional evidence development strategies.

ECRI recommends that CMS clarify in the final notice that "aligned" evidence requirements are not a lowered bar, particularly for Class III devices where evidence gaps may be more likely and CED becomes the fallback.

Include Human Factors Evaluation

ECRI additionally recommends that FDA and CMS explicitly incorporate human factors engineering (HFE) considerations into the evidence framework for Breakthrough Devices. While the proposed approach emphasizes clinical outcomes, it does not clearly address usability, workflow integration, or risks associated with human-device interaction. For devices that rely on clinician, caregiver, or patient use, real-world performance depends not only on safety and effectiveness, but also on the ability to use the technology correctly in routine care settings.

FDA and CMS should encourage prospective evaluation of use-related risks, usability across diverse patient populations, and integration into clinical workflows. Incorporating HFE evidence would strengthen understanding of device performance in real-world practice and help identify potential safety and effectiveness concerns before widespread deployment and coverage. Faster authorization does not reduce the risk of use-error; if anything, compressed timelines increase the chance that human factors issues surface only after wider deployment.

IDE Pre-Submission Stage & Temporary Eligibility

ECRI recommends against a broad transitional allowance for devices already underway in an IDE study, because retrofitting RAPID's agreed-upon endpoints, Medicare-representative enrollment, and human factors evaluation onto an in-progress trial risks accepting evidence that was not designed to meet these standards. If CMS creates a transitional process, it should be narrowly limited to devices whose IDE protocols can still be amended, with FDA and CMS concurrence, to incorporate Medicare-relevant endpoints, adequate representation of Medicare beneficiaries, and applicable human factors evaluation before enrollment is complete.

Address RAPID Pathway Ownership

The notice indicates a collaborative effort between FDA and CMS, but beyond indicating that pathway initiation begins with contacting an FDA TAP advisor, it is unclear which agency and what role within that agency will own the pathway and coordinate the participating parties through the proposed RAPID process. ECRI recommends CMS and FDA clearly define ownership of ongoing coordination, escalation, and endpoint-dispute resolution throughout the pathway, not just at initiation.

Healthcare Accessibility

ECRI acknowledges that there are potential patient accessibility benefits associated with the RAPID coverage pathway via the inclusion of Medicare populations. For example, the pathway may provide earlier national coverage of Breakthrough Devices that might have previously only been available to those patients who are privately insured.

However, the pathway's potential for exacerbating systemic disparities must not be ignored. For instance, the evidence gathered to support decision-making should include pivotal studies with underrepresented racial minorities, women, and rural populations. Further, Medicare patients who could benefit from this pathway are still subject to potentially access-limiting social determinants of health, such as transportation and provider access, healthcare literacy, and adequate caregiver support.

Respectfully submitted,

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ECRI

About ECRI

ECRI is an independent, nonprofit organization dedicated to improving patient safety and reducing preventable harm. For more than six decades, ECRI has provided trusted device and technology-related guidance to healthcare leaders and policymakers. ECRI is the only organization worldwide to conduct independent medical device evaluations and is designated as one of the few Evidence-based Practice Centers by the U.S. Agency for Healthcare Research and Quality.

ECRI's engineers and clinical specialists conduct hands-on testing and evaluation of medical devices to provide unbiased insights that help healthcare organizations reduce risk and protect patients. ECRI applies evidence-based, clinically informed evaluation methods to help ensure that healthcare technologies are safe, effective, usable, and aligned with the needs of patients, clinicians, and healthcare organizations.

ECRI also brings extensive expertise in human factors engineering to device evaluations, focusing on how people interact with tools, technologies, processes, and environments within healthcare systems. ECRI's human factors engineers identify barriers to healthcare quality and safety and develop solutions that improve workflows, enhance technology integration, minimize risks, and support healthcare professionals in delivering safer, more effective care.