
October 13, 2026

Mehmet Oz, MD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3487-NC
7500 Security Boulevard
Baltimore, MD 21244

Re: Medicare Program; Regulatory Alignment for Predictable and Immediate Device (RAPID) Coverage Pathway (CMS-3487-NC; Docket CMS-2026-2674)

Dear Administrator Oz:

Patients Rising is a national patient advocacy organization working on behalf of people living with serious, chronic, and rare conditions, including cancer, so that they can get the care their doctors recommend without needless delay. Thank you for the opportunity to comment on the RAPID coverage pathway, and thank you to CMS and FDA for taking on a problem patients have lived with for a long time. We have joined a coalition letter from patient and provider organizations on this notice. We write separately to add the perspective of the patients who will either benefit from RAPID or be left waiting outside it.

FDA authorization and Medicare coverage are separate decisions, and for the most novel technologies the space between them has been measured in years. A study of devices and diagnostics authorized between 2016 and 2019, published in *JAMA Health Forum* in 2023, found that only 44 percent of the truly novel technologies had reached even nominal Medicare coverage by the end of 2022, and that the median time to get there was 5.7 years. The same study found no statistically significant relationship between the strength of a device's clinical evidence and how quickly it reached coverage. That finding matters to patients because it tells us the wait has not been the price of careful review; it has been the cost of a process. A proposed national coverage determination (NCD) on the day of FDA authorization, finalized within two to three months, would transform that experience. We support finalizing RAPID, and we offer the recommendations below so that it reaches the patients who need it most.

1. Open the temporary process for devices already in study, and set a clock for devices already on the market

CMS asks whether it should establish a temporary process allowing devices currently studied under an investigational device exemption (IDE) to enter RAPID. Our answer is yes. Patients have no say in when the sponsor of a device they need began its pivotal study, and a device that started enrolling shortly before RAPID was announced may be exactly what a person with a serious cancer needs next year. We urge CMS to establish the process, keep it open at least long enough to cover devices whose pivotal studies were underway when the pathway was

announced on April 23, 2026, and allow sponsors to add Medicare-relevant outcome measures through protocol amendments rather than starting over.

For devices that FDA has already authorized, the notice points sponsors to a conventional NCD request or to local coverage. Those are the routes that produced the multi-year wait in the first place. We ask CMS to commit to a published timeline for acting on NCD requests for authorized Breakthrough Devices, so that patients and their doctors know when a decision will come. We also support the Ensuring Patient Access to Critical Breakthrough Products Act (H.R. 5343 / S. 1717) as the durable complement to RAPID, because it would reach devices that are already in patients' hands.

2. Make room for rare and small-population conditions

RAPID requires an IDE study that enrolls Medicare beneficiaries and demonstrates improved outcomes in that population. For many conditions that is a sensible expectation. For rare diseases, and for some cancers, the number of eligible Medicare beneficiaries may be too small to support a separate analysis, or the condition may be diagnosed mostly in younger people who later age into Medicare or qualify through disability. The notice itself recognizes that the Medicare population includes people with disabilities and end-stage renal disease, not only adults over 65. We ask CMS to state in the final notice that, for small-population conditions, it will accept appropriately designed evidence such as analyses pooled across age groups, natural history data, and registry or real-world data to establish the Medicare-relevant outcome, rather than a Medicare-only enrollment target that may be impossible to meet. Without that flexibility, the pathway risks being least available to the patients with the fewest alternatives.

3. Give patients a voice in choosing the outcomes that matter

RAPID turns on clinical outcomes that FDA and CMS agree on in advance, which the notice defines as direct measures of how a patient feels, functions, or survives. We welcome that definition. Patients are the people best placed to say which of those measures matter most in a given condition, and FDA already has established methods for collecting patient-reported outcomes and patient preference information. We ask CMS and FDA to state that this evidence will be considered when setting RAPID endpoints, and that CMS will seek input from patients and patient organizations in the relevant condition when it establishes outcome expectations for a type of device.

4. Keep coverage with evidence development accessible and time-limited

Patients Rising supports collecting evidence in the Medicare population. We do not support making patients wait for that evidence to be complete before they can be treated, and coverage with evidence development (CED) is the right tool for striking that balance. But when participation in an approved study is a condition of coverage, a device can end up available only at a small number of study sites, often academic centers far from rural and underserved communities. We ask CMS to design RAPID's CED requirements so that patients can take part where they already receive care, through registries and data collection that travel with the patient; to ensure that study participation adds no out-of-pocket cost for the beneficiary; and

to publish an expected end date for each CED requirement, consistent with CMS's 2024 guidance that coverage under CED should be time-limited.

5. Turn goals into commitments, and report against them

We support CMS's proposal to make public the manufacturers and devices in the pathway. We ask CMS to go one step further and publish, for each device, the dates on which it entered the pathway, received IDE approval, received FDA authorization, and received its proposed and final NCD, along with an annual summary of how many devices entered, how many completed, and how long each stage took. The notice describes the 60-day and 90-day final decisions as goals. We join our coalition partners in asking CMS to set an outside limit and report publicly on whether it is met. Patients have heard promises of streamlined pathways before; published timelines are how they will know this one is working.

6. Do not leave diagnostics, or patients already waiting, behind

We share the coalition's concern about the exclusion of in vitro diagnostics. In cancer especially, a test that finds disease earlier often determines whether any treatment that follows arrives in time, and we ask CMS to design a route for Breakthrough diagnostics rather than exclude them. We also ask that prioritizing RAPID decisions not lengthen the wait for patients whose technologies are already on the NCD Wait List, and that CMS seek the resources to do both.

RAPID is the most promising step CMS has taken on this problem since 2021, and we appreciate the administration's willingness to take it on. Because a procedural notice can be paused or reversed, as TCET has just been paused, we hope CMS will finalize the pathway quickly and work with Congress to make its core promise permanent. Patients Rising would welcome the opportunity to help CMS hear directly from patients as the pathway is implemented. Please contact me at terry@patientsrising.org with any questions.

Yours in Advocacy,



Terry Wilcox
Co-Founder and CEO
Patients Rising