



October 12, 2026

The Honorable Mehmet Oz, M.D.
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-3487-NC
P.O. Box 8010
Baltimore, MD 21244-8010

Electronically Submitted: <https://www.federalregister.gov/documents/2026/08/11/2026-16368/medicare-program-regulatory-alignment-for-predictable-and-immediate-device-rapid-coverage-pathway>

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

Dear Administrator Oz:

The American College of Radiology (ACR), representing more than 40,000 physicians practicing diagnostic radiology, interventional radiology, radiation oncology, and nuclear medicine, as well as medical physicists and other radiology allied health professionals, appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) notice with comment period for the Regulatory Alignment for Predictable and Immediate Device (RAPID) Coverage Pathway.

ACR supports CMS's goal of expanding patient access to innovative medical technologies that demonstrate meaningful clinical benefit for Medicare beneficiaries. Radiology is often at the center of medical innovation, including imaging-enabled devices, artificial intelligence, software, image-guided interventions, and other technologies that may improve diagnosis, treatment planning, patient safety, and outcomes. A predictable Medicare coverage pathway can reduce delays between Food and Drug Administration (FDA) authorization and Medicare coverage when the evidence supports such coverage.

At the same time, accelerated coverage pathways must preserve the integrity of Medicare's reasonable and necessary standard, ensure transparency for patients and clinicians, and avoid diverting limited CMS coverage resources away from other important national coverage determination (NCD) requests. As CMS refines the program, we encourage the agency to provide additional clarity regarding the relationship between RAPID participation, Medicare coverage, and Medicare payment. ACR therefore offers the following recommendations to strengthen RAPID while supporting appropriate access to beneficial technologies.

Summary of ACR Recommendations

Issue	ACR recommendation
Patient access	Finalize a pathway that expands timely access when technologies demonstrate improved health outcomes for Medicare beneficiaries.
Transparency	Increase transparency around both FDA Breakthrough Device designation and CMS RAPID acceptance so stakeholders can assess whether accelerated national coverage is appropriate.
NCD prioritization	Do not automatically prioritize RAPID NCDs over traditional NCDs, reconsiderations, or other pending coverage issues. CMS should use a balanced, transparent queue.
Eligibility	Support CMS's proposal to limit RAPID participation to devices in the Investigational Device Exemptions (IDE) pre-submission stage. Devices already in IDE studies or already authorized should use traditional NCD, LCD, or claim-by-claim pathways.
Evidence standards	Require Medicare-relevant clinical health outcomes, adequate Medicare beneficiary representation, and specialty clinician input before a proposed RAPID NCD is released.

ACR supports faster access to innovative technologies that improve Medicare beneficiary outcomes.

ACR supports CMS's effort to better align FDA and CMS evidence expectations earlier in the device development process. The proposed RAPID pathway could help reduce the historic gap between FDA market authorization and Medicare coverage by allowing CMS to issue a proposed NCD on the day of FDA authorization and target a final NCD within approximately 60 days for eligible Class II devices and 90 days for eligible Class III devices.

This policy can be particularly important when a technology addresses a serious disease, fills an unmet clinical need, and generates evidence showing improved outcomes in the Medicare population. For radiology, this could include imaging-enabled devices or software that demonstrably improves patient selection, diagnosis, treatment planning, procedural outcomes, safety, function, survival, or other clinically meaningful outcomes.

Faster coverage should not mean automatic coverage, however CMS should make clear in any final notice that RAPID does not change the statutory Medicare coverage standard, replace rigorous evidence review, or permit coverage based solely on FDA authorization, product novelty, or diagnostic performance measures that are not tied to patient outcomes.



CMS should address transparency concerns associated with Breakthrough Device designation and RAPID acceptance.

ACR remains concerned that FDA Breakthrough Device designation decisions are not generally publicly disclosed due to confidential commercial information. As a result, stakeholders may have limited visibility into the rationale for device selection and RAPID eligibility determinations. CMS should identify opportunities to enhance transparency while respecting applicable confidentiality requirements.

Breakthrough Device designation, which is granted before market authorization, is based on preliminary information and FDA's determination that the statutory criteria at 21 U.S.C. § 360e-3(b) have been met. For the criterion in § 360e-3(b)(1), FDA assesses whether there is a "reasonable expectation" that the device could provide more effective treatment or diagnosis based on literature or preliminary data. That designation is only valuable for specific types of premarket manufacturer-FDA interactions on device development and authorization pathway-related questions. The designation itself is not a determination that the device will have clear practical utility, can be readily integrated into real-world clinical workflows, or is reasonable and necessary for Medicare beneficiaries.

RAPID eligibility begins with Breakthrough Device designation. Therefore, before a device receives accelerated NCD consideration, CMS should require manufacturers to publicly disclose information beyond what FDA may independently release. Specialty societies, clinicians, patients, and payers need sufficient information to understand the clinical condition being addressed, intended Medicare population, health outcomes determined appropriate by FDA, and remaining evidence gaps.

ACR recommends requiring RAPID applicants to disclose a minimum set of information, which would be available on a public RAPID dashboard once a device is accepted into the pathway. ACR also supports CMS's proposal in section II.I to publicly identify participating manufacturers and devices and recommends publishing the following information on the CMS Approved IDE Studies webpage, the NCD Dashboard, or both:

- FDA pathway, device class, and participation in TAP;
- Medicare benefit category assessment status, including clear notice that preliminary review is not a final benefit category determination;
- Clinical condition, intended use, and anticipated Medicare population;
- Clinical health outcomes FDA and CMS agreed the IDE study will evaluate;
- Anticipated CMS coverage following evidence development for remaining gaps;
- Expected public milestones (including IDE approval) and NCD tracking sheet posting, proposed comment period, and final target date.

CMS should also establish a structured process to obtain specialty society input during the IDE pre-submission stage. Early input from clinicians who diagnose, treat, and manage Medicare beneficiaries can help CMS identify relevant outcomes, appropriate comparators,



implementation risks, real-world workflow concerns, coding and payment issues, and patient safety considerations before the proposed NCD is released.

CMS should not prioritize RAPID NCDs over traditional NCDs and reconsiderations.

ACR is concerned by CMS's proposal to prioritize RAPID NCDs over non-RAPID NCDs in the event the agency cannot address the full volume of NCD requests with available resources. Traditional NCDs, NCD reconsiderations, and other pending coverage actions often involve high-priority clinical issues, longstanding access barriers, outdated coverage policies, or technologies that already have mature evidence. In contrast, the FDA Breakthrough Device and Total Product Life Cycle Advisory Program (TAP) provide manufacturers with enhanced engagement and support during device development. TAP also facilitates interaction with external stakeholders, and RAPID may leverage TAP activities for participating devices. Nonetheless, participation in these FDA programs is intended to support device development and evidence generation and should not be interpreted as a comparative assessment or endorsement of a device's clinical value. Automatically moving RAPID NCDs ahead of non-RAPID NCDs could unintentionally delay access to services with greater utility, more established, and better stronger supporting evidence-supported services.

RAPID should be an accelerated pathway for eligible devices, not a mechanism that puts Medicare beneficiaries awaiting updates to existing coverage policies at a disadvantage. CMS should instead use a transparent and balanced NCD workload process that considers clinical urgency, strength of evidence, public health impact, beneficiary access, statutory deadlines, and stakeholder reliance on timely coverage decisions.

ACR recommends that CMS:

- Decline automatic prioritization of RAPID over non-RAPID NCDs;
- Publish queue-management principles that explain how CMS will balance RAPID NCDs, traditional NCDs, reconsiderations, and CED reviews;
- Apply the prioritization considerations reaffirmed in section II.H (including whether a technology represents a substantial clinical advance likely to significantly improve patient health outcomes) to RAPID and non-RAPID topics alike, rather than categorically prioritizing RAPID NCDs when resources are constrained;
- Identify resources needed to administer RAPID without delaying other coverage work;
- Regularly update stakeholders on the status of pending NCD requests, including impacts from RAPID implementation;
- Commit to maintaining access to the traditional NCD process for technologies that are not eligible for RAPID but have strong Medicare-relevant evidence.



RAPID eligibility should be limited to devices in the IDE pre-submission stage.

ACR supports CMS's proposed approach that devices beyond the Investigational Device Exemptions (IDE) pre-submission stage, including devices already market authorized or already being studied under an IDE, are not appropriate for RAPID. The core value of RAPID is early alignment among CMS, FDA, and manufacturers before pivotal evidence is generated. Once a study is underway or completed, CMS loses the ability to influence the protocol so that it includes Medicare beneficiaries, relevant subgroups, appropriate comparators, and health outcomes sufficient for Medicare coverage review. Thus, ACR supports limiting RAPID to devices in the IDE pre-submission. This approach will avoid retrofitting evidence into an accelerated coverage pathway after study design decisions have been finalized. Allowing devices already in active IDE studies to enter RAPID could create inconsistent standards, reward incomplete study planning, and undermine confidence in the pathway. CMS should define the "IDE pre-submission stage" to ensure RAPID eligibility is confined to points in device development where CMS can still meaningfully influence the pivotal evidence plan.

For devices that have progressed beyond the IDE pre-submission stage, CMS should direct manufacturers to existing coverage pathways, including the traditional NCD process, local coverage determinations, or claim-by-claim adjudication. If a manufacturer believes an already-authorized or already-studied device has sufficient evidence for national coverage, that evidence should be evaluated through the standard NCD process with the usual opportunity for public comment and stakeholder review. CMS should also clarify when an existing NCD is deemed to control coverage for RAPID eligibility. If an NCD only partially overlaps with a device's technology or indication, CMS should consider allowing RAPID participation in conjunction with targeted NCD reconsideration rather than automatically excluding an NCD.

ACR urges CMS to ensure that any temporary transition policy is narrow in scope, time-limited, and subject to strict safeguards. At minimum, CMS should require:

- A public rationale for why the device can meet RAPID standards despite being beyond IDE pre-submission
- An independent CMS and FDA assessment of whether the existing protocol captures Medicare-relevant outcomes
- An opportunity for specialty society input
- A determination that participation will not delay other NCD requests.

For the above reasons, ACR strongly believes RAPID should be reserved for devices still in IDE pre-submission.

CMS should require Medicare-relevant evidence and clinical input before issuing RAPID NCDs.

ACR supports CMS's emphasis on evidence demonstrating improved health outcomes for Medicare beneficiaries. For radiology-related technologies, evidence should not rely solely on technical performance, workflow efficiency, or diagnostic accuracy (unless these measures are linked to meaningful patient outcomes). Depending on the device, relevant outcomes may



include earlier or more accurate diagnosis that changes management, reduced morbidity, improved function, reduced fewer or less severe complications, improved survival, reduced need for invasive procedures, improved better treatment selection, improved survival, or other outcomes important to patients and clinicians. Understanding whether RAPID changes the scope or timing of evidence generation is critical to evaluating the program's potential impact on innovation and product development.

RAPID participants should be required to enroll a study population representative of Medicare beneficiaries and to specify how subgroup analyses will inform CMS's coverage decisions when outcomes may vary across clinically relevant populations. CMS should also establish prospective criteria for demonstrating adequate Medicare representation and the generalizability of study findings to the Medicare population. For RAPID NCDs that rely on coverage with evidence development, CMS should define the evidence development questions, endpoints, study duration, completion milestones, and pathway for reconsideration at the outset.

ACR supports CMS's commitment to time-limited CED NCDs and urges CMS to specify, in each RAPID NCD, the evidence requirements, study milestones, and clear criteria for initiating reconsideration and completing the CED cycle.

CMS should clarify separate payability and coordinate coverage, coding, and payment early.

Although RAPID is intended to accelerate NCDs and coverage predictability is important, coverage alone does not ensure patient access. New technologies may require code creation, valuation, payment classification, practice expense inputs, site-of-service policies, claims processing instructions, quality safeguards, clinician training, and workflow integration. CMS should use early RAPID engagement to develop a coordinated process for implementation including billing and reimbursement and avoid delays due to lack of appropriate coding, payment methodologies, and operational guidance.

Because separate payability is a RAPID eligibility criterion, CMS should also clarify how this requirement applies across Medicare payment systems and sites of service, including for devices subject to packaged or bundled payment, device-led combination products, and integral software or digital components. CMS should address these questions during premarket eligibility review so that the applicable coding and payment basis is understood before devices advances through RAPID.

ACR recognizes that RAPID is a pathway to coverage (not coding or payment). Nevertheless, all three are interdependent when determining whether beneficiaries have access to a technology. RAPID is designed to accelerate evidence development and potentially shorten the period between FDA authorization and NCD. Therefore, CMS should not defer consideration of separate payability, coding, or payment expectations until after a device has advanced through RAPID. Instead, CMS should explain how it will assess separate payability and establish mechanisms to coordinate relevant coding and payment questions across Medicare payment systems before the RAPID review proceeds. This coordination would recognize the



interdependence of coverage, coding, and payment, provide sufficient implementation time before coverage takes effect, and support successful adoption of covered technologies.

CMS should also ensure that final RAPID NCDs use clear coverage language that can be implemented consistently by Medicare Administrative Contractors, providers, and suppliers. Any limitations tied to FDA-authorized indications, patient selection criteria, clinician qualifications, imaging protocols, facility requirements, or participation in evidence development should be stated precisely enough to support accurate claims processing and minimize beneficiary confusion.

Conclusion

ACR appreciates CMS's efforts to improve patient access to innovative medical technologies and supports a more predictable and transparent coverage pathway for eligible devices. To ensure RAPID strengthens access without compromising Medicare's evidence standards, CMS should increase transparency, provide meaningful opportunities for clinical stakeholder input, clearly define eligibility and evidentiary requirements, and maintain sufficient resources for both RAPID and traditional NCD activities. ACR supports CMS's proposed limitation of RAPID participation to devices in the IDE pre-submission stage and encourages CMS to establish clear milestones and reconsideration criteria for RAPID-related CED determinations. These safeguards will help ensure timely access to innovation while preserving the rigorous evidence base needed to support Medicare coverage decisions.

ACR looks forward to continued engagement with CMS and FDA as the agencies refine the RAPID pathway. Please contact Alicia Blakey, Manager of Economic Policy, at ablakey@acr.org, with any questions.

Respectfully submitted,

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