



October 13, 2026

Mehmet Oz, MD, MBA
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Medicare Program; Regulatory Alignment for Predictable and Immediate Device (RAPID) Coverage Pathway [CMS–3487–NC]

Submitted electronically via regulations.gov

Dear Administrator Oz:

The National Health Council (NHC) appreciates the opportunity to provide comments on the Centers for Medicare & Medicaid Services' (CMS) notice with comment period establishing the Regulatory Alignment for Predictable and Immediate Device (RAPID) coverage pathway. The NHC has long supported efforts to reduce unnecessary delays between Food and Drug Administration (FDA) market authorization and Medicare coverage of innovative technologies, including through the Medicare Coverage of Innovative Technology (MCIT) pathway, the Transitional Coverage for Emerging Technologies (TCET) pathway, and legislative proposals intended to provide more timely coverage of Breakthrough Devices.^{1,2,3} RAPID builds on many of the objectives of those earlier efforts by moving CMS engagement earlier in development, and aligning FDA and CMS consideration of evidence before pivotal studies are completed. It also provides eligible technologies with the possibility of a proposed National Coverage Determination (NCD) concurrent with FDA market authorization and a final NCD

¹ National Health Council, "NHC Comments – Medicare Coverage of Innovative Technology and Definition of Reasonable and Necessary," November 2, 2020, <https://nationalhealthcouncil.org/letters-comments/medicare-coverage-of-innovative-technology-and-definition-of-reasonable-and-necessary/>.

² National Health Council, "NHC Comments on Transitional Coverage for Emerging Technologies," August 28, 2023, <https://nationalhealthcouncil.org/letters-comments/nhc-comments-on-transitional-coverage-for-emerging-technologies/>

³ National Health Council, "NHC Comments on Request for Information on the Future of 21st Century Cures 2.0 Legislation," August 2, 2024, <https://nationalhealthcouncil.org/letters-comments/nhc-comments-on-request-for-information-rfi-on-the-future-of-21st-century-cures-2-0-legislation/>.

approximately 60 days later for eligible Class II devices and 90 days later for eligible Class III devices.⁴

The NHC unites nearly 200 national organizations—including leading patient groups, research institutions, providers, caregivers, and businesses across the health care sector—to drive patient-centered health policy. Representing 200+ million Americans with chronic diseases and disabilities, the NHC strengthens its members' collective influence to expand access to quality, affordable, and equitable health care. The NHC fosters collaboration to shape policies that reflect the needs of patients.

The NHC supports the fundamental objective of RAPID. For patients, FDA authorization has limited practical significance if uncertainty or delay in coverage prevents access to a beneficial technology, and earlier coordination between FDA and CMS can help address evidence needs while development programs remain sufficiently flexible to do so efficiently. CMS also appropriately recognizes that evidence generated for FDA authorization may not always adequately represent older adults, people with disabilities, people with multiple chronic conditions, and other populations served by Medicare. RAPID provides an opportunity to identify those evidentiary questions before authorization rather than after a product is already available.⁵ These objectives are consistent with the NHC's longstanding support for timely coverage of innovative technologies and our recommendations that patient input, relevant evidence, and coverage considerations be incorporated early enough to influence development rather than after key study decisions have been fixed.^{6,7}

As CMS moves from TCET to RAPID, however, several elements of the proposed pathway warrant modification. Most significantly, the NHC encourages CMS to remove the categorical exclusion of in vitro diagnostic (IVD) products. This exclusion is inconsistent with the approach the NHC previously recommended under TCET and could leave patients who rely on breakthrough diagnostics without access to a comparable expedited national coverage pathway. CMS should incorporate meaningful patient input while RAPID evidence requirements are being developed, apply evidence expectations in a manner appropriate to the clinical role of different technologies, establish a workable transition for technologies already in development, and ensure that Coverage with Evidence Development (CED) does not create unnecessary barriers to access. The agency should also provide sufficient capacity so that accelerated review of

⁴ Centers for Medicare & Medicaid Services, "Medicare Program; Regulatory Alignment for Predictable and Immediate Device (RAPID) Coverage Pathway," *Federal Register* 91, no. 153 (August 11, 2026): 51710–19, 51710–11.

⁵ CMS, "RAPID Coverage Pathway," 51712–14.

⁶ National Health Council, "NHC Comments on Transitional Coverage for Emerging Technologies," August 28, 2023.

⁷ National Health Council, "NHC Comments on Coverage with Evidence Development Proposed Guidance," August 21, 2023, <https://nationalhealthcouncil.org/letters-comments/nhc-comments-on-coverage-with-evidence-development-proposed-guidance/>.

RAPID technologies does not result in additional delays for other NCDs important to Medicare beneficiaries.

Summary of Recommendations

- Remove the categorical exclusion of IVD products and establish criteria for considering appropriate Breakthrough-designated diagnostics for RAPID or a comparably timely and predictable national coverage pathway.
- Apply fit-for-purpose evidence expectations that reflect how different technologies produce clinical benefit, including the role diagnostics may play in informing subsequent clinical management and treatment decisions.
- Provide a structured opportunity for patients and patient organizations to help identify relevant clinical outcomes and evidence gaps during early FDA-CMS alignment, while preserving the efficiency of the RAPID process.
- Establish a reasonable transition process for otherwise eligible technologies that have progressed beyond IDE pre-submission and ensure that the pause in accepting new TCET candidates does not create gaps in access to expedited coverage.
- Use CED selectively and transparently, with clear evidence questions, minimal duplication of FDA requirements, feasible participation expectations, and defined pathways for completing evidence development and reconsidering coverage.
- Ensure that RAPID implementation does not materially delay other high-priority NCDs and provide greater transparency regarding CMS capacity, pathway performance, and prioritization decisions.

Remove the Categorical Exclusion of In Vitro Diagnostics

The NHC encourages CMS to remove RAPID's categorical exclusion of IVD products and permit appropriate Breakthrough-designated diagnostics to be considered for the pathway based on their clinical role, evidence needs, and implications for Medicare beneficiary access. CMS acknowledges that IVDs, including diagnostic laboratory tests, fall within the statutory definition of a medical device, but states that diagnostics are a highly specialized area of coverage policy development. Agency also notes that it has historically delegated review of many such products to specialized Medicare Administrative Contractors (MACs), and that the majority of Breakthrough-designated IVD coverage determinations should continue through existing local pathways. CMS therefore provides that IVD products "will not be accepted" into RAPID.⁸

The NHC has previously addressed this issue directly. In our 2023 comments on TCET, we encouraged CMS to clarify that diagnostics should be eligible for that pathway when

⁸ CMS, "RAPID Coverage Pathway," 51714.

appropriate, noting the significant effect that diagnostic advances can have for patients, including people with rare diseases for whom reaching an accurate diagnosis may itself be one of the most difficult parts of the patient journey.⁹ Those comments also raised concerns about relying on local coverage where a national approach is warranted, observing that MAC-by-MAC decision-making can result in geographic differences in access that do not serve patients well.¹⁰ The categorical exclusion proposed for RAPID would move away from that principle at the same time CMS is pausing TCET for new candidates. The NHC's position also has broad cross-sector support. In August 2025, the NHC joined AdvaMed and dozens of patient and health care organizations—including Alliance for Aging Research, the Alzheimer's Association, the Alzheimer's Impact Movement, the American Cancer Society Cancer Action Network, the American Diabetes Association, the Arthritis Foundation, and Breakthrough T1D—in urging CMS to establish a streamlined breakthrough coverage pathway that expressly included diagnostics.¹¹

The NHC recognizes the specialized expertise that MACs, including contractors with substantial experience evaluating molecular and other diagnostic technologies, contribute to Medicare coverage policy. That expertise does not establish that diagnostics should be categorically ineligible for earlier FDA-CMS evidence alignment or for expedited national consideration where the circumstances warrant it. CMS should distinguish between the proposition that many diagnostics can appropriately remain subject to local coverage and the much broader proposition that no diagnostic can appropriately participate in RAPID. The notice provides support for the former but does not adequately establish the latter.

This distinction matters because diagnostic technologies can improve patient outcomes by helping clinicians make more informed care decisions. Accurate and timely test results can guide diagnosis, treatment selection, and monitoring, resulting in downstream health benefits. Literature has long recognized that clinical utility of diagnostics therefore extends beyond analytical performance or diagnostic accuracy to whether use of a test changes management and ultimately improves outcomes relative to the available alternative.¹² Depending on the clinical context, the evidence supporting that relationship may include direct patient outcomes, changes in management linked to

⁹ National Health Council, "NHC Comments on Transitional Coverage for Emerging Technologies," August 28, 2023.

¹⁰ National Health Council, "NHC Comments on Transitional Coverage for Emerging Technologies," August 28, 2023.

¹¹ AdvaMed et al., letter to Mehmet Oz, Administrator, Centers for Medicare & Medicaid Services, August 2025, https://www.advaMed.org/wp-content/uploads/2025/08/Stakeholder-Letter-Encouraging-Breakthrough-Rule_August-2025.pdf.

¹² Patrick M. M. Bossuyt et al., "Beyond Diagnostic Accuracy: The Clinical Utility of Diagnostic Tests," *Clinical Chemistry* 58, no. 12 (2012): 1636–43, <https://doi.org/10.1373/clinchem.2012.182576>.

well-established treatment effects, observational evidence, or other fit-for-purpose approaches rather than a single evidentiary design.^{13,14}

CMS should therefore establish criteria for considering appropriate Breakthrough-designated IVDs for RAPID rather than retaining a categorical exclusion. Relevant considerations could include whether the diagnostic addresses a serious condition or substantial unmet need; whether it is integral to selecting, initiating, or modifying treatment; whether access to another clinically appropriate intervention depends on timely access to the diagnostic; whether local coverage could create meaningful geographic differences in beneficiary access; and whether early coordination between FDA and CMS could materially improve the ability of the evidence-development program to satisfy Medicare coverage requirements. These criteria would allow CMS to preserve specialized diagnostic expertise and existing local pathways for the many tests for which they are appropriate while providing a route to expedited national consideration where the patient-access rationale is compelling.

CMS could also consider incorporating specialized MAC expertise into RAPID review of an eligible diagnostic rather than treating that expertise as a reason for exclusion. CMS and FDA could draw on appropriate diagnostic coverage expertise during early evidence alignment to preserve the advantages of specialized review while providing the predictability and national coordination RAPID is intended to achieve.

Ensure Evidence Expectations Reflect How Different Technologies Produce Clinical Benefit

The NHC supports CMS' focus on evidence that demonstrates meaningful health outcomes for Medicare beneficiaries but encourages the agency tailor evidence expectations to the technology and clinical question being evaluated. The relevance and strength of different forms of evidence can vary considerably by condition, patient population, intended use, and type of technology. The NHC has previously encouraged CMS to use evidence standards appropriate to the question being addressed rather than applying an overly rigid hierarchy to different forms of evidence.^{15,16}

This flexibility is particularly important for diagnostics because analytical validity, clinical validity, clinical utility, changes in clinical management, and downstream patient

¹³ Patricia A. Deverka and Susanne B. Haga, "Comparative Effectiveness Research and Demonstrating Clinical Utility for Molecular Diagnostic Tests," *Clinical Chemistry* 61, no. 1 (2015): 142–44, <https://doi.org/10.1373/clinchem.2014.223412>.

¹⁴ Wylie Burke, "Genetic Tests: Clinical Validity and Clinical Utility," *Current Protocols in Human Genetics* 81 (2014): 9.15.1–9.15.8, <https://doi.org/10.1002/0471142905.hg0915s81>.

¹⁵ National Health Council, *The National Health Council Rubric to Capture the Patient Voice: A Guide to Incorporating the Patient Voice into the Health Ecosystem* (Washington, DC: National Health Council, June 2019), <https://nationalhealthcouncil.org/additional-resources/patient-engagement-rubric/>.

¹⁶ National Health Council, "NHC Comments on Coverage with Evidence Development Proposed Guidance," August 21, 2023.

outcomes represent related but distinct evidentiary questions. A diagnostic test generally influences outcomes by providing information that enables clinical decisions about patient care. Peer-reviewed literature has long described clinical utility through this relationship between testing, informed care decisions, and patient benefit.¹⁷ A substantial body of work on molecular and genomic testing likewise recognizes that evidence of clinical utility can be developed through different methodologies. The appropriate approach depends on the clinical context and the strength of the evidence connecting the test result to an effective intervention.^{18,19}

If CMS permits appropriate diagnostics to participate in RAPID, the agency should clarify how it will assess this chain of evidence. It should also explain when evidence showing a change in diagnosis or management, combined with established evidence regarding the consequences of that change, may contribute to demonstrating a Medicare-relevant health benefit. This would not weaken the reasonable-and-necessary standard; it would align evidence assessment with how technology benefits patients.

CMS should apply similar flexibility to the requirement for Medicare-relevant evidence. Representation of Medicare beneficiaries is important where age, disability, comorbidity, functional status, or other characteristics may affect benefits and risks, and the NHC supports RAPID's effort to identify those questions prospectively. However, the degree and form of Medicare-specific evidence necessary to answer a particular question may vary. The NHC has previously emphasized that evidence should be evaluated according to the question being addressed, the available evidence, the population, and the methodology, particularly where conventional study expectations may not be feasible or necessary.^{20,21} CMS and FDA should therefore identify when direct enrollment of Medicare beneficiaries is necessary to answer an unresolved question and when scientifically appropriate evidence of generalizability may be sufficient, supplemented by postmarket evidence where needed.

Integrate Patient Input Before Evidence Requirements Are Fixed

RAPID creates a significant opportunity for more patient-centered evidence development precisely because CMS is moving coverage discussions earlier. Under the proposed process, CMS and FDA will engage with manufacturers before completion of the pivotal IDE study to determine which clinical health outcomes must be evaluated to support Medicare coverage. CMS describes these outcomes as direct measures of how

¹⁷ Bossuyt et al., "Beyond Diagnostic Accuracy," 1636–43.

¹⁸ Deverka and Haga, "Comparative Effectiveness Research," 142–44.

¹⁹ Burke, "Genetic Tests," 9.15.1–9.15.8.

²⁰ National Health Council, "Rubric to Capture the Patient Voice."

²¹ National Health Council, "NHC Comments on Coverage with Evidence Development Proposed Guidance."

patients feel, function, or survive.²² Yet the notice offers considerably more detail about interactions among FDA, CMS, and manufacturers than about how patients or patient organizations will be able to provide feedback on which outcomes are meaningful before the evidence plan is finalized.

The NHC has consistently encouraged CMS to involve patients at this stage of evidence development. In our comments on both CED and TCET, the NHC recommended that patients be consulted on study design, study burden, barriers to participation, and outcomes relevant to subsequent coverage decisions, emphasizing that patients should not be limited to serving as research participants after fundamental study-design decisions have already been made.^{23,24} These principles are also reflected in the NHC's broader patient-engagement work, which emphasizes patient partnership, transparency, representativeness, inclusion of outcomes patients identify as important, appropriate patient-centered data sources and methods, and timely incorporation of patient evidence.²⁵

CMS and FDA should incorporate a proportionate patient-engagement mechanism into RAPID's early evidence-alignment process. The NHC does not envision a new formal proceeding for every candidate or a sequential requirement that delays development. Depending on the technology and disease area, appropriate engagement could include consultation with relevant patient organizations, consideration of existing patient experience data or patient preference information, use of prior FDA-led or externally led patient engagement, or targeted engagement where important questions remain regarding meaningful outcomes, study feasibility, access, burden, or representativeness. CMS should also provide sufficient transparency when publishing a proposed RAPID NCD so that patients and other stakeholders can understand how patient-relevant evidence and perspectives informed the evidence-development process.

Preserve an Appropriate Pathway as CMS Pauses TCET

CMS states that TCET will be paused for new candidates while the agency focuses on RAPID implementation.²⁶ The NHC recognizes the value of simplifying and improving Medicare coverage pathways, but RAPID does not have the same eligibility structure as TCET and may therefore leave some technologies without access to a comparable expedited pathway.

²² CMS, "RAPID Coverage Pathway," 51714–18.

²³ National Health Council, "NHC Comments on Coverage with Evidence Development Proposed Guidance," August 21, 2023.

²⁴ National Health Council, "NHC Comments on Transitional Coverage for Emerging Technologies," August 28, 2023.

²⁵ National Health Council, "The National Health Council Rubric to Capture the Patient Voice," 2019.

²⁶ CMS, "RAPID Coverage Pathway," 51718.

This concern is particularly clear for diagnostics. In 2023, the NHC expressly encouraged CMS to allow diagnostics to participate in TCET when appropriate.²⁷ The shift from a pathway that could include appropriate diagnostics to one that categorically excludes IVDs warrants additional explanation, particularly a CMS is simultaneously pausing the earlier pathway. More broadly, CMS should identify categories of technologies that could have received early engagement through TCET but cannot satisfy RAPID eligibility criteria and explain which existing pathway will provide timely coverage consideration for those technologies.

The NHC also supports establishing the temporary transition process CMS is considering for otherwise eligible technologies that have progressed beyond IDE pre-submission. CMS should assess whether an existing IDE study already addresses the Medicare-relevant outcomes necessary for RAPID or whether feasible modifications could resolve remaining evidence gaps. CMS should not exclude a technology solely because of its state of development when the pathway was announced.²⁸

Use Coverage with Evidence Development Selectively and With Clear Exit Criteria

The NHC supports RAPID's effort to identify possible postmarket evidence needs before FDA authorization and to align CED requirements with FDA-required post-approval studies where possible, thereby reducing unnecessary duplication.²⁹ The NHC has also consistently recognized that CED can provide an appropriate route to coverage where clinically promising technologies require additional evidence relevant to Medicare beneficiaries.

CED can, however, restrict practical access when coverage depends on participation at a limited number of research sites, when participation imposes significant travel or other burdens, or when the population able to participate does not reflect the broader Medicare population. In our 2023 comments on CED, the NHC specifically urged CMS to consider geographic barriers, effects of delayed access, beneficiary and caregiver experience, study burden, and participation barriers and to involve patients in study design and selection of outcomes.³⁰ These concerns are shared by NHC members; in 2024, Alliance for Aging Research and 17 other organizations warned that CED-related payment and site restrictions can reduce the number of participating sites and disproportionately restrict access for rural communities and communities of color.³¹

²⁷ National Health Council, "NHC Comments on Transitional Coverage for Emerging Technologies," August 28, 2023.

²⁸ CMS, "RAPID Coverage Pathway," 51715.

²⁹ CMS, "RAPID Coverage Pathway," 51714–17.

³⁰ National Health Council, "NHC Comments on Coverage with Evidence Development Proposed Guidance," August 21, 2023.

³¹ Alliance for Aging Research et al., letter to Chiquita Brooks-LaSure, Administrator, Centers for Medicare & Medicaid Services, September 9, 2024, re: "Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems (CMS-1809-P),"

CMS should therefore use CED within RAPID where the remaining evidence question is material to coverage and the proposed evidence-development plan is reasonably capable of resolving it; align requirements with FDA postmarket studies wherever scientifically appropriate; provide clear evidence questions and milestones at the outset; and specify the criteria and expected timing for reconsidering the NCD and removing the CED requirement. The NHC previously recommended this type of defined reevaluation process, including revising the NCD to provide full coverage when the evidence supports removal of CED, because clear exit criteria promote predictable and consistent beneficiary access.³²

Ensure RAPID Does Not Shift Coverage Delays Elsewhere

CMS proposes to prioritize RAPID NCDs over non-RAPID NCDs on the existing wait list when available resources are insufficient to address the total volume of coverage work.³³ The NHC appreciates that CMS cannot promise an accelerated pathway without dedicating sufficient resources to meet its timelines, but RAPID should improve the overall functioning of Medicare coverage rather than accelerate some coverage decisions by delaying others.

This concern is consistent with the NHC's prior comments on TCET. When CMS estimated that available resources would support only approximately five TCET candidates annually, the NHC cautioned that capacity constraints could delay access to promising technologies solely because of timing and recommended that CMS work with patients and industry to expand capacity while being transparent about the resources necessary to do so.³⁴ The same principle applies to RAPID at a potentially larger scale.

CMS should ensure that RAPID implementation is accompanied by adequate staffing, clinical and methodological expertise, and operational capacity. The agency should also continue to prioritize coverage questions according to their consequences for Medicare beneficiaries rather than relying solely on RAPID status when competing needs cannot all be addressed. Additionally, CMS should report aggregate information on the RAPID workload, the non-RAPID NCD backlog, average review timelines, and any measurable effects of RAPID on other NCD activity.

<https://www.agingresearch.org/wp-content/uploads/2024/09/20240909-FY2025-OPPS-ASC-Sign-on-Letter.pdf>.

³² National Health Council, "NHC Comments on Coverage with Evidence Development Proposed Guidance," August 21, 2023.

³³ CMS, "RAPID Coverage Pathway," 51718.

³⁴ National Health Council, "NHC Comments on Transitional Coverage for Emerging Technologies," August 28, 2023.

Strengthen Transparency and Evaluate Whether RAPID Improves Patient Access

The NHC supports CMS' proposal to publicly identify manufacturers and devices participating in RAPID.³⁵ Because much of the consequential work under RAPID will occur before the conventional public NCD process begins, additional transparency will be important to understanding whether the pathway is functioning as intended.

CMS should publish aggregate information regarding applications, acceptances, withdrawals, pathway milestones, use of CED, time from FDA authorization to proposed and final NCDs, and effects on other NCD timelines, along with sufficient information for stakeholders to understand how Medicare-relevant evidence and patient input influence decisions. Over time, CMS should evaluate RAPID based on whether it reduces the interval between FDA authorization and meaningful beneficiary access, improves the relevance and representativeness of evidence available for Medicare coverage, and resolves evidence questions earlier. The agency should also assess whether these improvements occur without creating new inequities or shifting delays to other patients.

Conclusion

The NHC supports CMS and FDA's effort to create a more coordinated and predictable pathway from medical product development to Medicare coverage and believes RAPID has considerable potential to address longstanding delays that can prevent patients from benefiting from innovative technologies. The NHC's support for accelerated coverage pathways has remained consistent across MCIT, TCET, and related legislative proposals, as has our emphasis on meaningful patient engagement, appropriate evidence development, and national coverage approaches that minimize unnecessary geographic variation.

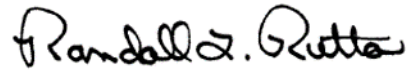
As CMS finalizes RAPID, the NHC encourages the agency to build on those principles by removing the categorical exclusion of IVDs and permitting appropriate Breakthrough-designated diagnostics to participate. CMS should apply evidence expectations that reflect how different technologies produce clinical benefit, engage patients before consequential evidence-development decisions are fixed, and preserve continuity as TCET is paused. The agency should also provide a workable transition for technologies already in development, use CED selectively with clear exit criteria, and ensure that sufficient CMS has sufficient capacity so that acceleration for RAPID technologies does not result in delays elsewhere in the Medicare coverage system.

The NHC appreciates the opportunity to provide these comments and looks forward to continuing to work with CMS, FDA, patients, patient organizations, clinicians, researchers, developers, and other stakeholders to ensure that Medicare beneficiaries have timely access to innovative technologies supported by evidence that is relevant to their needs.

³⁵ CMS, "RAPID Coverage Pathway," 51718.

Please do not hesitate to contact Jennifer Dexter, Senior Vice President, Policy & External Affairs, or Shion Chang, Assistant Vice President, Policy & Regulatory Affairs, if you or your staff would like to discuss these comments in greater detail.

Sincerely,

A handwritten signature in black ink that reads "Randall L. Rutta". The signature is written in a cursive, flowing style.

Randall L. Rutta
Chief Executive Officer