PORTAL
Program On Regulation, Therapeutics, And Law

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Dr. Mehmet Oz, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-8010
Attn: Lori Ashby, Coverage and Analysis Group

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

Dear Ms. Ashby and Administrator Oz:

As members of the Program On Regulation, Therapeutics, And Law (PORTAL), we appreciate the opportunity to submit comments to the Centers for Medicare and Medicaid Services (CMS) on the notice to accelerate Medicare coverage through the proposed Regulatory Alignment for Predictable and Immediate Device (RAPID) coverage pathway for new innovative technologies.

Based in the Division of Pharmacoepidemiology and Pharmacoeconomics at Brigham and Women's Hospital and Harvard Medical School, PORTAL is one of the largest academic research centers in the United States dedicated to investigating the regulation, use, evidence, and cost of prescription drugs, medical devices, and other interventions. Our research program is independent of the pharmaceutical and medical device industries.

We share CMS' commitment to facilitating timely access to safe and effective medical devices for Medicare beneficiaries. Our key comments on the proposed RAPID pathway include:

1. **Requirements for rigorous, patient-centered clinical evidence that is representative and relevant for Medicare beneficiaries;**
2. **Clarifying eligibility of 510(k)-cleared devices for the pathway; and**
3. **Transparency on RAPID selected devices and agreed qualifying outcomes.**

These comments are described in greater detail below.

1. CMS should require rigorous, patient-centered clinical evidence that is representative and relevant for Medicare beneficiaries.

Specific Recommendations:

1.1. CMS should retain the notice's definition of clinical outcomes as direct measures of how a patient feels, functions, or survives; and

1.2. The final notice should specify that a qualifying outcome must meet all of the following conditions:

- It is a prespecified primary endpoint, or a key secondary endpoint tested only after the primary endpoint succeeds, under a prespecified, hierarchical testing procedure fixed in the statistical analysis plan before unmasking;
- It is analyzed in Medicare beneficiaries enrolled in the study, ideally under an analysis plan agreed in advance with CMS;
- It is not a technical, procedural, or device-success composite, presented as clinical benefit. A composite endpoint qualifies only if (a) every component of the composite is a clinical outcome or the results are reported by component, (b) the clinical components support the claimed benefit, and (c) none of the components show meaningful harm; and
- It is not a surrogate measure, unless the surrogate is validated for the device's indication, the manufacturer documents the evidence for that validation, and the manufacturer provides a plan to continue to collect further clinical evidence post-approval.

Commentary:

We support CMS' decision to define clinical outcomes as "direct measures of how a patient feels, functions or survives" (pp. 51710, 51717). This definition directs coverage toward outcomes that matter to patients, rather than measures of device performance. However, the notice does not specify how this definition applies to trial endpoints, including whether a qualifying outcome must be prespecified or primary, whether composites combining clinical and technical components qualify, or whether surrogate measures may be used. The final notice should clearly state that a qualifying outcome must be a clinical or patient-reported outcome, and that technical, procedural, or device-success composites presented as clinical success do not satisfy this requirement, nor do surrogate measures that have not been validated for the device's indication.

A device that does not meet its primary endpoint but improves a single secondary measure should not qualify for national coverage that remains in effect until reconsidered. Because qualifying outcomes will be agreed upon through the RAPID kickoff process, recording them as outcome performance commitments and reporting them publicly would make the standard verifiable and consistent as the program expands. Agreed outcomes should be reported and published as described in Section 4 of this public comment.

2. RAPID eligibility should not include 510(k)-cleared devices that do not have direct clinical evidence of improvement for Medicare beneficiaries.

Specific Recommendations:

2.1. CMS should strike the eligibility loophole in footnote 18 (p. 51714), which would allow "510(k) cleared devices where the primary predicate was authorized via the De Novo classification pathway no earlier than 18 months prior to acceptance into the RAPID coverage pathway," and limit class II eligibility to De Novo-granted devices.

Commentary:

Although class III devices eligible for RAPID should by definition be approved through premarket approval, which requires reasonable assurance of safety and effectiveness supported by valid scientific evidence concerning the device itself, most class II devices subject to premarket review enter the US market based on substantial equivalence to one or more legally-marketed predicates.

CMS' objective of ensuring that the RAPID pathway prioritizes devices with clinical evidence that is directly relevant to the Medicare population is undermined by footnote 18. First, RAPID depends on a prospective investigational device exemption (IDE) study, but 510(k) devices often do not have any prospective clinical data, let alone an IDE study. A class II device might satisfy an eligibility criterion that an IDE study exists and enrolls Medicare beneficiaries without the data from that study having been submitted to the FDA as part of the premarket notification or having been relied upon by the FDA in reaching that regulatory clearance. The FDA's Total Product Life Cycle Advisory Program (TAP) is intended to improve timeliness and quality of premarket interactions but does not currently ensure that participating class II devices have relevant clinical evidence for Medicare beneficiaries.

Second, the proposed notice does not give a reason for the 18-month window, and we are not aware of any empirical evidence to support this extension. The predicate's De Novo record supports the predicate, not the later device that references it. How recently the predicate was authorized does not answer the question of whether the follow-on device has been studied adequately in Medicare beneficiaries and otherwise meets the criteria for RAPID.

Removing this extension of eligibility would not leave 510(k) devices without a route to coverage: their manufacturers may request National Coverage Determinations (NCDs) under the agency's existing procedures or request reconsideration of existing NCDs that might be extended to cover the follow-on device.

3. RAPID should require a prespecified analysis of outcomes in Medicare-eligible participants.

Specific Recommendations:

3.1. The IDE protocol for each RAPID device should prespecify an analysis of the qualifying outcome among Medicare-eligible participants;
3.2. For each RAPID-qualifying device, CMS should report the number and proportion of participants aged 65 years or older, and, when feasible, those eligible for Medicare through disability or end-stage renal disease, in the RAPID proposed NCD; and
3.3. CMS should set minimum enrollment criteria for Medicare-eligible participants in RAPID IDE studies.

Commentary:

We agree that a RAPID device should demonstrate that it achieves its outcomes in the Medicare beneficiary population. As CMS notes, Medicare beneficiaries are often older, have multiple

comorbidities, and are underrepresented in clinical studies. However, the notice does not establish a minimum enrollment of Medicare-eligible participants and does not require an analysis of outcomes in this subgroup.

Few Breakthrough-designated devices authorized by the FDA have clinical outcomes analyses that are include substantial patients in the Medicare population. Initial results from our ongoing study of Breakthrough-designated devices show that only 22% of premarket approved high-risk devices and 9% of 510(k) cleared devices reported a median age over 65 years in their outcome analyses.

Examining inclusion and exclusion criteria will only demonstrate that Medicare-eligible adults *could* enroll, for example if the study is open to enrollment by adults aged18 years or older. But this is not sufficient to understand the number of Medicare-eligible adults who did enroll or whether the device was effective in the Medicare population. Inadequate and inconsistent age reporting in regulatory documents, trial registries, and peer-reviewed publications further limit this assessment. FDA decision documents and trial records generally reported age, when reported at all, as a mean or median, and rarely reported the proportion of participants aged 65 years or older. Age is also an incomplete proxy, as the Medicare population includes individuals eligible through disability or end-stage renal disease.

We therefore recommend that CMS require a minimum enrollment of Medicare-eligible participants, reporting of their number and proportion, and a prespecified subgroup analysis of the qualifying outcome. This public reporting should be required, even if the agency allows "more concise evidence summaries" (p. 51716) than conventional NCD decisions. Together, these evidentiary standards would allow CMS to assess both the extent to which Medicare beneficiaries were represented and whether the results are representative of them.

4. CMS should provide more transparency about the RAPID pathway, including publishing each device's agreed qualifying outcomes when it enters the program.

Specific Recommendations:

4.1. CMS should finalize its proposal to publicly identify the manufacturers and devices accepted into RAPID;
4.2. At the time of acceptance, CMS should also make public the qualifying outcomes that FDA and CMS have agreed are appropriate for the device, the analysis population, and any planned Medicare subgroup analysis, with a link to the study's ClinicalTrials.gov registration; and
4.3. CMS should make public any subsequent change to the agreed outcomes, along with the reason for the change.

Commentary:

We support CMS' proposal to make public the identity of devices accepted into the RAPID coverage pathway, consistent with its stated commitment to "maximum transparency" (p. 51718). To achieve this aim, CMS should go further than the identity of a device alone, which does not allow the public to evaluate whether the evidence supporting a RAPID national coverage determination meets the pathway's own standard.

First, RAPID moves the substantive coverage judgment earlier in the process and out of public view. Under the conventional NCD process, CMS explains which outcomes it considered and whether the evidence in the Medicare population was sufficient in a proposed decision memorandum that is open to public comment. Under RAPID, those judgments are made during the IDE pre-submission and review stages, in confidential exchanges among FDA, CMS, and the manufacturer. By the time a proposed NCD is posted, the questions of which outcomes qualify and what evidence is sufficient have largely been settled. Publishing the agreed outcomes at entry would promote public visibility into the decisions that determine coverage.

Second, without a public record of the outcomes agreed in advance, commenters cannot determine whether the reported results correspond to those outcomes, whether endpoints changed during the study, or whether the planned Medicare analysis was performed.

Third, a public record of agreed outcomes would allow CMS, manufacturers, and the public to assess whether comparable devices are being held to comparable standards. This serves CMS' own goal of a predictable pathway, as manufacturers considering RAPID could see the outcomes accepted for similar devices before designing their studies.

* * *

CONCLUSION

We thank CMS for the opportunity to provide comment on the proposed RAPID pathway, and our team is available to discuss these proposals in further depth.

These comments were prepared by Thomas Hwang, M.D., and Shria Bucha, B.A. Please contact our team at PORTAL@bwh.harvard.edu with any questions.