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OPINION: CMS Can Make RAPID A Win For Patients And American Medtech Innovation



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RAPID could speed Medicare access to breakthrough medtech, but CMS and FDA should add firm milestones, adequate staffing and flexible eligibility, including for Class II devices. Those refinements would give start-ups the predictability they need and get proven technologies to patients sooner.

For a healthier future for America, proven medical technologies should reach patients before preventable illness becomes irreversible, hospital care becomes unavoidable, or small businesses developing innovative treatment solutions run out of time. The administration has put forward a potentially valuable proposal to help achieve that goal for Medicare beneficiaries, but the details are critical to success.

The Regulatory Alignment for Predictable and Immediate Device (RAPID) coverage pathway from the Centers for Medicare & Medicaid Services and the US Food and Drug Administration aims to expedite Medicare beneficiary access to certain FDA-designated breakthrough medtech. Appropriately pointed at one of the most significant barriers to medtech innovation today, RAPID requires targeted refinements to ensure the program delivers fully for patients and avoids the fate of parallel review, a similarly well-intentioned program held back by structural barriers and limited manufacturer participation.

Small medtech companies spend years bringing innovative products from idea to market. They invent and refine both the product and procedure, conduct bench testing, complete preclinical studies and clinical trials, meet rigorous FDA requirements, and prepare to manufacture at scale. These steps require years' worth of substantial investment, often at significant operating losses. Yet even after FDA authorization, patients may still wait several more years for Medicare coverage of the procedures or services that use these technologies.

That uncertainty can be devastating. When Medicare access is unclear, investors hesitate, companies conserve cash, and patients wait even when the clinical need is well established. Roughly three out of four medtech start-ups never achieve commercial success, underscoring why reimbursement uncertainty can be existential. Given that 80% of all medtech companies are start-ups or small businesses, the prospect of valuable technologies never reaching patients because of unpredictable reimbursement is sobering.

The administration deserves credit for recognizing this problem and working to fix it. RAPID is aimed at the right challenges: aligning agencies and their standards for approval and coverage earlier, reducing duplicative review, and helping Medicare beneficiaries gain timely access to technologies that address serious unmet medical needs.

Now that public comments have closed, CMS and the FDA have an opportunity to build on RAPID's foundation by:

- **Making RAPID more predictable.** Issuing a proposed Medicare national coverage determination on the same day as FDA market authorization is a worthy ambition, but specific milestones would make that objective more actionable for patients, clinicians, companies and investors. CMS could strengthen the process by setting key milestones, formally committing to its own version of the FDA's principle of least burdensome approach to requirements, explaining what happens if deadlines slip, identifying who is accountable, and clarifying how RAPID will fit with existing coverage pathways, including Transitional Coverage for Emerging Technologies (TCET), parallel review, and traditional national coverage determinations. Small companies and investors can plan around predictable rules, not uncertainty.

- **Keeping eligibility flexible.** The proposal's focus is correct: on eligible FDA-designated breakthrough medical devices that address unmet medical needs among Medicare beneficiaries and generate evidence on relevant clinical outcomes. These breakthrough designations should be awarded consistently and with rigorous standards for those innovations responsive to otherwise unmet medical needs. The final RAPID framework can preserve that focus while ensuring high-value technologies are not excluded for procedural reasons. We should all want such innovations, validated by robust clinical evidence and authorized by FDA under the highest regulatory standards globally, to be accessible to patients in need as soon as possible. Eligibility should turn on clinical need, evidence quality and Medicare relevance, not whether a company's medical device is designated as a class II versus III product. That flexibility is especially important for Class II devices, which may reach FDA authorization through different pathways and timelines. CMS can ensure that participation in FDA's Total Product Life Cycle Advisory Program (TAP) helps select Class II technologies reach Medicare beneficiaries but does not need to serve as a requirement that creates a procedural barrier for all Class II devices to participate in RAPID.

- **Devoting the resources needed for success.** Earlier FDA-CMS coordination will require significant staff time, clinical expertise and disciplined program management. Many are skeptical that CMS has the bandwidth and resources to meet the scale of demand by Medicare beneficiaries and the supply of innovations that FDA authorizes annually. Providing that capacity is essential to make RAPID a dependable framework while protecting other important existing workstreams. Equally, Medicare beneficiaries deserve access to Class II devices that are also supported by robust clinical evidence without delay. The FDA's resources beyond TAP may require expansion to ensure we can meet the needs of patients for these products, too.

CMS also can support technologies already moving through existing coverage processes. As CMS focuses on implementing RAPID and pauses TCET for new candidates, defined bridge provisions would give companies that pursued TCET a practical road ahead.

RAPID is not, and should never be, a way for companies to bypass evidence. Instead, it can define CMS's evidence needs early, communicate agency expectations clearly, lead to timely decisions, and avoid duplicative processes that do not improve patient care. By creating a clearer pathway from FDA approval to Medicare coverage, RAPID also can encourage innovators to invest in high-quality clinical evidence that benefits patients, physicians, taxpayers, companies and the broader healthcare system.

The US has been the world leader in medtech innovation, but that leadership is not guaranteed. If set up for success, RAPID can strengthen it, accelerate patient access to valuable healthcare solutions, and offer a model for other insurers. Most important, it can help more American patients benefit from American ingenuity.

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