

Publications

August 11, 2026 • Updates

CMS, FDA Propose RAPID Pathway for Medicare Coverage of Certain Medical Devices

Key Takeaways

- The proposed RAPID pathway would create a new voluntary CMS/FDA process for certain innovative medical devices, with the stated goals of expediting Medicare coverage, improving efficiency and supporting patient access.
- The proposed dual-agency pathway highlights the importance for medical device companies to carefully integrate reimbursement, FDA, intellectual property and compliance planning at the earliest possible stages of product development.
- The public will have 60 days from publication to comment on the procedural notice, and CMS will respond to comments in a subsequent final notice.

On Aug. 7, the Centers for Medicare & Medicaid Services (CMS) and the U.S. Food and Drug Administration (FDA) published a proposed procedural notice for certain innovative medical devices governing a new, voluntary CMS/FDA dual pathway titled the Regulatory Alignment for Predictable and Immediate Device (RAPID) coverage pathway that is designed to expedite Medicare coverage, promote efficiencies and foster patient access to innovative medical devices.

The new RAPID coverage pathway is another reminder of the increasing importance of integrating reimbursement, FDA, intellectual property and compliance strategies from the earliest possible stages of product development. In a growing number of instances, educating political decision-makers is another key element to success for issues involving coverage, coding and reimbursement.

For those interested in submitting written comments, comments will be due 60 days after publication in the Federal Register. The proposed notice can be found [here](#).

Polsinelli's health policy team, including our reimbursement, coding and FDA specialists, will be working closely with our clients to adapt their strategies to account for the new opportunities arising from the evolving regulatory landscape, including but not limited to the RAPID coverage pathway. Please do not hesitate to reach out to Steve Stranne, Michael Gaba, or your preferred Polsinelli attorney with any questions and to learn more

Related People

- Steve Stranne
- Michael M. Gaba

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