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Publications

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CMS proposes closing optional reimbursement pathways for new innovative medical devices and antimicrobials

Within the annual notice of proposed rulemaking for Medicare's hospital inpatient prospective payment system posted on April 10, 2026, the Centers for Medicare & Medicaid Services (CMS) announced its intent to discontinue some of the optional pathways for new, innovative medical devices and antimicrobial products to qualify for special, favorable Medicare payments under both the New Technology Add-on Payment (NTAP) program for the hospital inpatient setting and the Transitional Pass-Through program. CMS announced the proposed changes within the broader annual notice of proposed rulemaking for the hospital inpatient system, but this proposal also has profound implications for Transitional Pass-Through status in the hospital outpatient and ambulatory surgical center (ASC) settings.

During the first Trump Administration, CMS established alternative pathways for certain medical devices and antimicrobials to bypass the traditional evaluation of clinical evidence to demonstrate a "substantial clinical improvement" over existing clinical alternatives to qualify for favorable payments under NTAP or Transitional Pass-Through. Currently, new medical devices and antimicrobials can avoid Medicare's traditional "substantial clinical improvement" evaluation step if the U.S. Food and Drug Administration (FDA) has designated the technology as a Breakthrough Designated Device, a Qualified Infectious Disease Product (QIDP), or a Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD).

CMS is proposing to repeal the optional pathways and revert to the old policy of requiring all technologies to undergo the traditional, evidence-based evaluation of substantial clinical improvement without regard to these FDA designations. CMS expressed the belief that the proposed changes in policy will enable the Agency to better align spending and value with the needs of Medicare beneficiaries by requiring all such products once again to undergo the traditional evidence-based evaluation process. As proposed, the new policies would apply to submissions presented to CMS after or around September 30, 2026.

Polsinelli's health policy team has extensive experience guiding innovative medical technologies, life sciences companies and health care stakeholders in drafting

Related People

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Related Capabilities

- Public Policy
- Medical Devices
- Life Sciences

applications and advocating for favorable reimbursement under NTAP and Transitional Pass-Through under the traditional requirements. The Polsinelli health policy team will be working to advise clients on whether and how to adjust their clinical research and advocacy strategies to account for the new proposed policies and to integrate these considerations into their evidence development and strategies to pursue favorable coverage, coding, reimbursement and FDA authorization.

We also will be working with companies and stakeholders who wish to provide comments to the CMS on whether to finalize the proposed policy changes described above. Please do not hesitate to reach out to Steve Stranne, Michael Gaba or your favorite Polsinelli health policy contact with any questions.