



Charles N. Kahn III
President and CEO

August 28, 2023

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3421-NC, Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

**Re: Notice with Comment; Transitional Coverage for Emerging Technologies
[CMS-3421-NC]**

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 leading tax-paying hospitals and health systems throughout the United States. The FAH members provide patients and communities with access to high-quality, affordable care in both urban and rural areas across 46 states, plus Washington, DC and Puerto Rico. Our members include teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals and provide a wide range of inpatient, ambulatory, post-acute, emergency, children's, and cancer services. The FAH appreciates the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) regarding its *Notice with Comment; Transitional Coverage for Emerging Technologies* published in the Federal Register (88 *Fed. Reg.* 41,633) on June 27, 2023.

The 21st Century Cures Act¹ established the Breakthrough Devices Program to expedite the development and review of medical devices that meet two criteria: (1) the device provides more effective treatment or diagnosis of life-threatening or irreversibly debilitating disease or conditions and (2) either represents a breakthrough technology; there is no approved or cleared alternative technology; offers significant advantages over existing approved or cleared alternatives; or the availability of the device is in the best interest of patients.

¹ Pub.L. 144-255, December 13, 2016.

To facilitate access to breakthrough technologies, CMS established alternative payment pathways for both the inpatient new technology add-on payment pathway² and the outpatient transitional device pass-through payment pathway³ for devices that receive U.S. Food & Drug Administration (FDA) marketing authorization and breakthrough designation.

CMS now has released a procedural notice with comment outlining a new Medicare coverage pathway. The Transitional Coverage for Emerging Technologies (TCET) pathway for Breakthrough Devices aims to achieve more timely and predictable access to new medical technologies, as well as to provide clear and consistent coverage throughout the process. This will be a voluntary program under which a manufacturer will notify CMS of its interest in participation approximately twelve months prior to the anticipated FDA approval/clearance decision. The TCET pathway will provide coverage for as long as needed to facilitate evidence generation with an additional year upon study completion for analysis and publication. The Agency anticipates the average coverage period will last from three to five years, after which an updated evidence review will be conducted through a third-party contractor. Based on this assessment, CMS will either propose: (1) an NCD without evidence development requirements, (2) an NCD with continued evidence development requirements, (3) a non-coverage NCD, or (4) rescind the NCD.

The FAH commends the Agency's ongoing commitment to ensure Medicare beneficiaries have access to critical life-saving technologies and supports CMS's coverage for these devices through the TCET pathway. The FAH underscores that ensuring the feasibility of the evidence development plan and its' criteria within the TCET pathway is critical to the success of this program. We urge CMS to establish clear guidelines and mechanisms to ensure that the criteria for evidence generation is not overly burdensome for health care providers and manufacturers.

In CMS' Medicare Coverage of Innovative Technology program, a similar coverage pathway that was later repealed, the Agency acknowledged that operational concerns were left unaddressed.⁴ These operational concerns primarily included benefit category determination, coding, and payment issues and the FAH urges CMS to acknowledge and address these concerns in this notice or other guidance. The FAH urges CMS to ensure that established coding and payment processes for breakthrough devices are addressed as coverage is determined. Coverage through the new TCET pathway will not ensure access if appropriate coding and adequate reimbursement are also not achieved.

CMS has indicated that it will allow up to five breakthrough technologies to benefit from the program each year. The FAH urges CMS to be flexible in its review and approval of applicable technologies that might receive TCET coverage in any given year. Setting an artificial cap may preclude patient access to new technology offering important improvements in care and treatment. The cap also ignores the uncertainty in timing and approval/clearance of a product by the FDA. Delay or early approval of a product approved by CMS for inclusion in the

² 84 FR 42292-42297

³ 84 FR 61295-61296

⁴ 86 FR 62944-62958

program could necessitate the need for more technologies needing TCET proposal in a year. CMS should provide flexibility for this uncertainty.

The FAH also recommends that CMS exercise flexibility when evaluating similar devices nominated for the TCET pathway. Similar FDA-designated Breakthrough Devices could lead to comparable CED requirements and redundant efforts through the TCET process for both CMS and manufacturers. To prevent delays in access to these devices and minimize duplicative evaluation efforts, the FAH's recommendation is to allow these similar devices to be covered under the same NCD. Considering the resource constraints that are expected to limit the number of candidates approved through the TCET pathway, this flexibility could not only enhance efficiency but also widen the scope of technologies benefitting from the pathway each year. Through the CED inclusion of devices similar to the original device, CMS would align with its overarching goal of granting timely access to emerging technologies for Medicare beneficiaries while upholding safety and quality standards.

Thank you for the opportunity to comment on this Notice with Comment. If you have any questions, please contact me or a member of my staff at 202-624-1534.

Sincerely,

