



August 28, 2023

The Honorable Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
Attention: CMS-3421-NC  
7500 Security Boulevard  
P.O. Box 8013, Baltimore, MD 21244  
Mail Stop: C4-26-05

**RE: Medicare Program; Transitional Coverage for Emerging Technologies**

Dear Administrator Brooks-LaSure:

The Healthcare Leadership Council (HLC) appreciates the opportunity to provide comments on the Centers for Medicare & Medicaid Services' (CMS) proposed pathway to provide transitional coverage for emerging technologies (TCET).

HLC is a coalition of chief executives from all disciplines within American healthcare. It is the exclusive forum for the nation's healthcare leaders to jointly develop policies, plans, and programs to achieve their vision of a 21st century healthcare system that makes affordable high-quality care accessible to all Americans. Members of HLC – hospitals, academic health centers, health plans, pharmaceutical companies, medical device manufacturers, laboratories, biotech firms, health product distributors, post-acute care providers, homecare providers, group purchasing organizations, and information technology companies – advocate for measures to increase the quality and efficiency of healthcare through a patient-centered approach. Innovation leading to improved patient outcomes is at the core of HLC's work.

HLC applauds CMS for recognizing the immense value new innovative medical technologies bring to Medicare beneficiaries and for proposing the TCET pathway to provide access to certain medical devices that have already been designated as Breakthrough Devices by the Food and Drug Administration. HLC wholeheartedly shares CMS' goal of "providing a clear, transparent, and consistent coverage process while maintaining robust safeguards for the Medicare population."<sup>1</sup>

HLC thanks CMS for engaging stakeholders in this process, and, as CMS considers the proposed TCET pathway and issues additional guidance documents, we strongly urge the agency continue to closely collaborate with stakeholders to ensure the coverage process is truly transparent, predictable, and centers on patient clinical outcomes and safety in a manner that is not overly burdensome for stakeholders or beneficiaries. We appreciate that the proposed TCET pathway is voluntary for manufacturers, prioritizes safeguards for beneficiaries, and

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<sup>1</sup>Fact Sheet: Notice with Comment - Transitional Coverage for Emerging Technologies, Centers for Medicare & Medicaid Services, (June 22, 2023), <https://www.cms.gov/newsroom/fact-sheets/notice-comment-transitional-coverage-emerging-technologies-cms-3421-nc>.

allows fit-for-purpose studies to appropriately address evidentiary gaps in a manner that aligns the study design with the aim of the study.

Thank you for the opportunity to provide feedback on the proposed TCET pathway, an important step in providing expedited access to potentially transformative breakthrough devices for seniors and those living with disabilities. HLC looks forward to continuing to engage with CMS on this important issue. If you have any questions, please do not hesitate to contact Debbie Witchey at [dwitchey@hlc.org](mailto:dwitchey@hlc.org) or 202-449-3435.

Sincerely,

A handwritten signature in black ink, reading "Mary R. Greal". The signature is written in a cursive style with a large, prominent initial "M".

Mary R. Greal  
President