August 28, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Medicare Program; Transitional Coverage for Emerging Technologies; CMS-3421-NC

Submitted electronically to regulations.gov

Dear Administrator Brooks-LaSure,

The Health Innovation Alliance (HIA) appreciates the opportunity to comment on the Transitional Coverage for Emerging Technologies (TCET) proposed rule. We believe that the TCET proposed rule should be scrapped and reproposed to return to the original policy goals of:

- Improving access to Breakthrough Devices for Medicare beneficiaries;
- Ensuring the Centers for Medicare and Medicaid Services (CMS) and the Food and Drug Administration (FDA) have clear, transparent, and consistent processes; and
- Improving coordination and mission at HHS to provide Medicare beneficiaries with the best and most innovative care available.

The previous Medicare Coverage of Innovative Technologies rule would have provided a pathway for immediate coverage of breakthrough devices for four years.[1] TCET instead uses the existing national coverage determination (NCD) and coverage with evidence development (CED) processes to "expedite" Medicare coverage of these new devices and therapies through the NCD process.[2] Under this proposal, beneficiaries would have to wait at least nine to 12 months after FDA approval to gain access to novel products.[3] Additionally, CEDs have had a questionable track record, and some devices within the CED process have no consistent data collection or set timelines. Because of these issues with the CED process, Medicare beneficiaries would not gain access to those products through TCET which relies on CED. Effectively, the Biden Administration has repealed a Trump Administration rule granting beneficiaries access to new products, waited two years, and replaced it with a proposal that repackages current practice as something new.

The Memorandum of Understanding (MOU) between the FDA and CMS outlines responsibilities between the two federal partners to establish meetings, increase information sharing, utilize tools available to each federal partner, and promote efficient use of infrastructure and processes to evaluate medical devices.[4] This MOU has been in place since 2017, and it enables the type of coordination between the two agencies required to simultaneously determine the safety and efficacy of novel products and determine they are reasonable and

[1] 86 Fed. Red. 2987.
[2] 88 Fed. Reg. 41633.
[3] *See* https://www.cms.gov/cms-guide-medical-technology-companies-and-other-interested-parties/coverage/national-coverage-determination-process-timeline
[4] *Available at* https://www.fda.gov/about-fda/domestic-mous/mou-225-10-0010.

necessary for care. FDA and CMS should have been working to strengthen parallel review process since at least 2017.

CMS's relationship with the FDA should be focused on bringing all types of care to the market as soon as possible. CMS anticipates receiving eight nominations per year and accepting up to five TCET candidates annually. Companies commit extensive resources to gaining FDA approval for breakthrough devices, and CMS should show a similar commitment to providing seniors with the best care possible. This rulemaking presents an opportunity for CMS and FDA to transcend historical constraints and lay out an actionable framework to expedite access to breakthrough medical devices. To do this, HHS should work to increase approvals of breakthrough devices at FDA and grant access to them for beneficiaries at CMS, all while working together to enhance clarity, predictability, and reliability in coordinated processes across the department. HHS must improve previous efforts to enhance clarity, predictability, and collaboration. We urge the agencies to go further in providing patients with access to these devices and ensuring predictability for industry stakeholders, rather than reconsecrating current policy.

Additionally, TCET leaves diagnostics out of the proposal, claiming that approval diagnostics "should continue to be determined by the MAC through existing pathways."[5] Diagnostics play a pivotal role in patient care, and CMS should reconsider delegating approval of breakthrough diagnostic technologies. HIA also finds it hypocritical that HHS believes diagnostics are too "specialized" for TCET yet simultaneously believes that it should have more direct authority over the review of certain diagnostics through an upcoming proposed rule.[6]

While the TCET rule signifies a positive step to addressing coverage challenges, we believe more can and should be done to give seniors access to the best care. We encourage HHS to reevaluate this proposal and develop new policies that would put new products on the market and in the homes of those who need them faster. We look forward to working with you.

Sincerely,

Brett Meeks
Executive Director

[5] 88 Fed. Reg *at* 41639.
[6] *Id*. and *See* https://www.reginfo.gov/public/do/eoDetails?rrid=325012.