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August 28, 2023

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–3421–NC, P.O. Box 8013
Baltimore, MD 21244–8013

RE: Medicare Program; Transitional Coverage for Emerging Technologies
File code: CMS–3421–NC, Via Docket Submission

Dear CMS Review Team:

The Digital Medicine Society (DiMe) is a global non-profit dedicated to advancing the ethical, effective, equitable, and safe use of digital technologies to redefine healthcare and improve lives. DiMe appreciates the opportunity to respond to Centers for Medicare & Medicaid Services' (CMS) Transitional Coverage for Emerging Technologies (TCET) procedural notice, and encourages CMS to further expand the scope of this pathway to more fully benefit patients. DiMe's comment focuses exclusively on the opportunity for TCET to provide patients with critical access to digital health technologies (DHT) to improve lives across the United States.

Overall Support
DiMe recently conducted a digital health industry needs assessment to identify 1) the drivers of successful DHT development and adoption, and 2) the regulatory policy needed to facilitate these drivers. This effort focused on advancing the development of regulatory science, strategy, and policy that supports patient access in the U.S. to high-quality, safe, and effective medical devices.

In the *Digital Health Industry Regulatory Needs Assessment* released this week, industry experts identified their top need as regulatory agency alignment with downstream payer decision makers, followed by the necessity of clear alternate pathways to market for truly novel DHTs. TCET, with its mission to create a Medicare coverage pathway that achieves more timely and predictable patient access to new medical technologies, aligns with these two top industry needs.

Increasing Efficiencies
DiMe supports CMS' aims to: (1) facilitate early, predictable, and safe beneficiary access to new technologies; (2) reduce manufacturers' and innovators' uncertainty about coverage by evaluating early the potential benefits and harms of technologies;

and (3) encourage evidence development if evidence gaps exist. Closer partnerships between CMS and product developers will lead to streamlined DHT product development and evaluation timelines and will ideally remove unnecessary steps and time between product ideation and patient use.

Common DHT Evidence Standards
TCET's vision to improve patient care and innovation by providing clear, transparent, and consistent coverage processes and evidence-generation frameworks will provide benefits to a wide variety of stakeholders. Clearer DHT evidence standards will create much-needed alignment on what levels of evidence are considered as "good" and "sufficient," particularly as Medicare beneficiaries, their caregivers, clinicians, and program administrators determine which medical devices are most appropriate for use in real-world patient settings.

Updating Medicare Pathways
Since Medicare's initial benefit category system was designed in the 1960s, CMS is responsible for continually reassessing existing coverage pathways to ensure that innovative and effective technologies have viable pathways into patient care settings. Through TCET, CMS is establishing a novel pathway for clinically validated DHTs that are otherwise not yet eligible for Medicare coverage and market access. Given the diversity of patient needs and the emergence of personalized technologies to address these needs, it is the ideal time for CMS to provide beneficiary access to these innovative medical device technologies.

Opportunities for Increased Impact on Patient Outcomes
To optimize TCET's impact on CMS' strategic aims to advance equity, expand access, engage partners, drive innovation, protect programs, and foster excellence across each of its programs, DiMe proposes the following adjustments to the program.

Broaden TCET's Scope to Meet Patient Needs
Patient medical needs are not limited to the subset of devices that are cleared through FDA's Breakthrough Device program. Therefore, TCET should not focus only on devices achieving market access through this single regulatory pathway.

TCET states, "Given the unique FDA criteria for Breakthrough designation status, the TCET pathway will apply to certain eligible FDA-designated Breakthrough Devices *because this is the area with the most immediate need for a pathway like TCET*" (emphasis added).

Instead of designing the TCET pathway to address the needs of FDA-designated Breakthrough Devices, TCET should be focused on the most critical needs of patients

and design all program pathways based on those needs. CMS should identify the most important problems that Medicare patients face, identify categories of medical devices that appropriately address those problems, and apply TCET's methodology to those products.

Provide Holistic Patient Care

If CMS does focus only on Breakthrough Devices, further clarity is required to identify which specific subsets of devices will qualify for coverage, and which subsets do not. Medicare beneficiaries and clinicians need to understand what gaps in access to care may be created as a result of TCET's allowances.

For example, if TCET only covers Software in a Medical Device (SiMD) products and leaves out Software as a Medical Device (SaMD) products, then patients will not have access to this robust category of product types that demonstrate strong clinical outcomes and work alongside pharmaceuticals, clinician-delivered care, and SiMD devices to deliver holistic care. When patients lack access to a full stack of products due to CMS' reimbursement requirements, they face a Swiss cheese-like model, where they only have access to a portion of cross-functioning technologies.

CMS should refocus TCET on positively impacting the health and outcomes of patients. A first step can be applying the TCET methodology and principles to a full technology stack (i.e., SiMD, SaMD, and affiliated components) that holistically addresses a set of high priority patient needs. From there, CMS can increasingly broaden TCET's areas of clinical focus and product coverage to continue meeting the needs of Medicare beneficiaries.

Clear and Consistent Evidence Requirements

Fit-for-purpose evidence requirements are important to DHT evaluation, and product developers are dedicated to ensuring that all appropriate evidence criteria are met. Therefore, to ensure the methodology behind CMS' Evidence Development Plans (EDP) and Evidence Preview plans are clear, consistent, and fair, DiMe encourages CMS to conduct regular audits on product EDP and Evidence Preview plans.

Additionally, CMS needs to clarify whether fit-for-purpose evidence requirements will be established at the product category level or if they are determined on a product case-by-case basis. Unnecessary or inappropriate evidence requirements will delay product time to market, inhibit scalability, and prevent timely patient access.

Benefit Category Limitations

Products that address critical Medicare beneficiary needs and meet all other program criteria should not be disqualified from TCET on the sole grounds that they do not

have a clearly defined benefit category. Administrative problems should not hinder patient access to clinically validated medical devices.

DiMe recommends CMS introduce a threshold for products that are reasonably likely to fall within a Medicare benefit category, or closely related to or supportive of a covered item or service to qualify for a benefit category review with CMS. Additionally, CMS should create a plan that enables the appropriate coverage of qualified medical devices regardless of an existing benefit category.

Federal Agency Workforce Upskilling
Building a specialized workforce within CMS for evidence evaluation and/or hiring a neutral, expert body to create EDPs and conduct evidence reviews is critical. In a fit-for-purpose study design environment, it is critical for CMS representatives to work with developers in designing study protocols that meet the greatest number of objectives with the most efficient study designs possible. This includes the use of controlled trials, real-world data and evidence, implementation studies, etc.

Long-term Implementation
Lastly, CMS needs to create a clear plan on how to support the long-term implementation and impact of TCET. One example to consider is the parallel review program: a joint FDA-CMS pathway that allows agencies to review devices and hand down coverage decisions, at the same time to streamline the evidence-generation process. The parallel review program started with a lot of excitement. However, only two devices have successfully gone through it. Therefore, given the importance of the TCET pathway and its potential impact on patient care, we want to ensure that CMS is sufficiently resourced to support this program.

Supporting Work and Resources
DiMe's Evidence DEFINED publication provides healthcare stakeholders with a framework to define 'what good looks like' when it comes to evidence evaluation. The Framework builds on existing evaluation approaches but differs in its inclusion of unique elements that are designed to increase evaluation rigor, efficiency, and speed.

Building on the Evidence DEFINED framework, this fall DiMe will launch a project to advance the use of integrated evidence plans (IEPs) to better position DHTs for broad adoption, commercial success, and improved health and economics outcomes across U.S. patient care settings. CMS' existing pathways will form a core part of this analysis.

To support the necessary workforce upskilling to maintain trust, safety, equity, and effectiveness in the digital era of healthcare, DiMe also offers professional education

via the Digital Medicine Academy. Current offerings included courses on medical product development, applied digital health ethics, and regulatory considerations.

Conclusion

Patient needs are diverse, as are the environments they receive care. Digital solutions — whether artificial intelligence (AI) products, monitoring products, digital diagnostics, digital therapeutics, artificial pancreases, or the generative AI decision support products that will be on the market in two to three years — need to have a clear line of sight on the evidence and coverage pathways they should take in order to deliver high quality, evidence-based care to the incredibly diverse spectrum of Medicare patients across the United States.

TCET provides CMS with an opportunity to design more efficient and effective coverage pathways. It also has the potential of enabling product developers to generate fit-for-purpose evidence packages that directly lead to market access opportunities and widespread patient benefit. This program's success is critical for the future of patient care delivery in the U.S., and program delays or missed opportunities will inhibit the broad adoption of DHTs, substantially increase the costs of evidence generation, and delay patient use of technologies that can directly improve clinical and economic outcomes.

This procedural notice represents a strong first step and DiMe encourages CMS to further expand the scope of this pathway to benefit patients more fully. Thank you for taking patient care seriously and we look forward to partnering with CMS to further develop this critical pathway.

Sincerely,

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