800 17th St., NW, Washington, DC 20006

DHEH

Transforming the future of healthcare through digital inclusion.

August 28, 2023

Ms. 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]

Dear Administrator Brooks-LaSure:

The Digital Health Equitable Health (DHEH) Alliance is pleased to provide the Centers for Medicare & Medicaid Services (CMS) with the following recommendations regarding the Transitional Coverage for Emerging Technologies, or TCET Notice, with a comment period.

DHEH is a multi-stakeholder coalition aimed at creating a more digitally inclusive society that facilitates improved health and well-being for underserved populations. It is out of DHEH's commitment to addressing the substantial equity gap in our healthcare system that we share our comments.

As proposed, the Transitional Coverage for Emerging Technologies (TCET) pathway applies to devices that have Breakthrough Designation from the Food and Drug Administration (FDA) and is designed to facilitate Medicare coverage for new treatments that usually need time to develop data proving their value. DHEH applauds efforts to create an alternative, expedited pathway to coverage and payment for emerging devices that are designed to mitigate existing and potential barriers to high-quality care. The proposed TCET pathway is a beneficial first step to overcome regulatory gaps that continually impede streamlined Medicare coverage of—and beneficiary access to—breakthrough devices.

Unfortunately, the notice prohibits breakthrough-designated devices (despite securing FDA clearances) without an existing Medicare Part A or Part B benefit category, such as prescription digital therapeutics (PDTs), that did not exist or were not considered when Medicare was first created from receiving coverage. Thus, as proposed, the TCET pathway will continue to widen the gap between FDA marketing authorizations and CMS coverage policies and will not deliver on the intended promise to bring innovations to patients sooner.

The Breakthrough Devices program provides patients and healthcare providers timely access to certain medical devices and device-led combination projects that provide more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. It speeds development, assessment, and review for premarket approval, 510(k) clearance, and De Novo marketing authorization. To date, there are a limited number of FDA-approved PDT applications on the market. As such, we are at an inflection point regarding the industry's growth, which is dependent mainly on reliable coverage.

Notably, PDTs have emerged as an essential element in addressing healthcare disparities and bring new methods of safe and effective treatment to underserved populations, including individuals who are economically disadvantaged, seniors, racially and ethnically minoritized communities, people with disabilities, and rural communities. PDTs can be particularly valuable for patients in underserved populations as these mechanisms bind patients with their care teams through frequent communication, on-demand education, remote monitoring, coaching, digital assistance, care coordination, and procurement of medical supplies. PDTs are FDA authorized through the 510(k), premarket notification or *de novo* processes, having demonstrated clinical safety and efficacy. Many PDTs qualify for breakthrough status because, as noted above, they address effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. Despite their classification, PDTs have undergone robust evidence generation.

However, like many facets of healthcare, there are perennial challenges keeping reimbursement mechanisms like coding and payment systems as well as insurance coverage determinations for PDTs on pace with innovation. As a result, the PDTs industry lacks the uniformity and efficiency needed to expedite beneficiaries' access to high-quality modalities that can address the prevention, management, and treatment of chronic diseases and mental health disorders through non-invasive technology solutions.

A recent study by the Stanford Byers Center for Biodesign found it takes an average of five years for medical technologies to achieve nationwide coding, coverage, and payment. The future of digital therapeutics hinges on these components with coverage at the center. Continued coverage challenges impede innovation, hinder progress within the industry, and can prevent patients living with a wide variety of unmet medical needs from accessing the care they need. As the landscape for these digital treatments develops across multiple therapeutic areas, challenges related to coverage, reimbursement, and access must be solved to advance broader adoption and utilization.

Transitional coverage for these technologies would bolster the innovation ecosystem and provide Medicare patients swift access to new technologies that existing therapies may be unable to address. CMS has made several recent statements about the Agency's interest in promoting health equity. Coverage for new PDTs will advance that goal.

Medicare coverage for these novel treatments can hopefully prompt faster adoption by insurers and the health care system. **Accordingly, we encourage CMS to revise the notice and remove the requirement under eligibility criteria that a device be determined to be within an existing Medicare benefit category.** Failure to do so will impede efforts to improve care for traditionally underserved populations.

We look forward to working with CMS to ensure that evidence-based treatments get into the hands of those who need them most. We greatly appreciate this opportunity to provide our input. If you have any questions, please contact Miranda Franco at miranda.franco@hklaw.com or 202-469-5259.