February 28, 2022

Re: Office of Science and Technology Policy (OSTP) Request for Information (RFI) on Strengthening Community Health Through Technology (*via email submission*)

Dear OSTP Team,

The Community Connected Health Initiative's mission, as presented through this RFI, closely aligns with our own mission. We are both focused on ways to use digital health technologies – specifically digital therapeutics (DTx) in our case – to lower the barriers to quality healthcare, while improving community health, patient outcomes, and health equity. As such, we hope the Digital Therapeutics Alliance (DTA) can play a more integral role in this Initiative.

When appropriate product access is provided to patients, digital therapeutics can address critical gaps in care for underserved populations regardless of patient age, language, culture, income, disease state, or geography.

DTA members – including 80+ companies across major healthcare industries and geographic regions – are therefore working to provide patients, caregivers, clinicians, community health workers, payors, and policymakers with access to resources that enable them to assess, utilize, and scale DTx products in everyday settings and improve clinical and health economic outcomes.

What is a DTx?

DTx products, a new category of medicine, deliver therapeutic interventions directly to patients using scientifically developed, clinically evaluated software to treat, manage, and prevent a disease or disorder. As demonstrated through DTA's Product Library, digital therapeutics address a wide array of health conditions, with products developed for ADHD, anxiety, asthma, cancer side effect management, diabetes, depression, insomnia, migraine, muscle/movement disorders, opioid and substance use disorders, and PTSD — to name a few. DTx products are used independently, alongside medications, and/or in tandem with clinician-delivered therapy.

Ensuring DTx Trustworthiness

Since digital therapeutics deliver clinical-grade medical interventions directly to patients, these products are subject to greater clinical, security, and regulatory scrutiny than general digital wellness and fitness apps. Therefore, all DTx products should adhere to these foundational industry principles:

1. Prevent, manage, or treat a medical disorder or disease
2. Produce a medical intervention that is driven by software
3. Incorporate design, manufacture, and quality best practices
4. Engage end users in product development and usability processes
5. Incorporate patient privacy and security protections
6. Apply product deployment, management, and maintenance best practices

7. Publish trial results inclusive of clinically meaningful outcomes in peer-reviewed journals
8. Be reviewed and cleared or certified by regulatory bodies as required to support product claims of risk, efficacy, and intended use
9. Make claims appropriate to clinical evaluation and regulatory status
10. Collect, analyze, and apply real world evidence and/or product performance data

Providing Care to Underserved & Undertreated Populations

DTx products can easily reach high-risk, rural, underserved, and undertreated populations who often lack access to healthcare services even during the best of times. This includes digital therapeutics' ability to:

- Be accessible through patient-owned devices, such as a smartphone or tablet
- Enable flexibility in how, when, and where patients access clinical therapies
- Offer therapy independent of a patient's work, education, or childcare schedule
- Transform how patients understand, manage, and engage in their healthcare
- Create safe and discreet spaces for patients to share insights initially deemed too personal or sensitive by using AI-based personalized therapies
- Remove stigma of seeking and receiving help by discretely delivering therapy to patients
- Provide therapies in a variety of languages
- Directly impact life and disease state outcomes, validated through clinical studies and real-world data
- Provide meaningful results and insights on personalized treatments, goals, and outcomes
- Leverage a variety of internet connection types, including intermittent Wi-Fi access, sustained basic internet access, and broadband internet access
- Extend clinicians' and community health workers' ability to care for patients
- Support healthcare teams in settings with varying degrees of health care infrastructure

Improving Health Equity: Therapy Accessibility and Scalability

Payors and policymakers are now able to deliver care to entire populations that have previously been outside the reach of traditional care – either due to geographic limitations, cultural and language boundaries, well-documented disparities, or health condition severity. Compared to traditional medications which rely on physical distribution and dispensing processes, digital therapeutic products are software-based and able to be hosted on multi-purpose platforms (i.e., patient-owned smartphone, tablet). This introduces an entirely new degree of product scalability and patient access opportunities. Instead of having a geographic-dependent delivery model, it is possible to deploy a needs-based delivery model.

Community Health Worker Access to Real-World Outcomes

In another departure from traditional medications, digital therapeutics generate a wide variety of real-world data (RWD) outcomes related to patient use and clinical impact. This includes patient-specific measures (i.e., actionable clinical outcomes, standardized patient assessments, physiologic data via associated sensors), patient and clinician utilization (i.e., patient utilization and

engagement, product onboarding metrics, clinician prescribing parameters), and product functionality (i.e., product performance, analytics, quality measures).

Real-world insights generated by digital therapeutics may be used to optimize outcomes at the individual patient and population levels. At the individual patient level, digital therapeutic products provide clinicians with meaningful, actionable clinical reports. At the population level, data generated by DTx products may be aggregated to track progress or compare aggregate outcomes based upon patient disease state, level of acuity, geographic location, age, gender, etc.

Necessary Legislative & Regulatory Changes

While numerous patients who receive their insurance coverage through private payors and employers in the United States have access to DTx products, low income and aging populations covered by Medicare, Medicaid, and other publicly funded programs generally do not have access to DTx therapies. Until Medicare and Medicaid begin providing patients with access to remotely delivered therapies and enable formal funding pathways for DTx products, there will continue to be an unbalanced ecosystem in the U.S.

First, we therefore encourage the U.S. Food and Drug Administration (FDA) to officially recognize and define digital therapeutics in formal guidance. Although the Agency reviews and clears DTx products through various medical device regulatory pathways, by formally defining and recognizing digital therapeutics in this capacity, the Agency will provide clarity for *patients* (i.e., transparency regarding DTx product attributes, quality standards, and claims), *clinicians* (i.e., evidence, safety, and prescription requirements to provide patient access), and *government agencies* (i.e., Federal Communications Commission and Federal Trade Commission enforcement of product claims).

Second, we need legislative action to direct CMS to expand access to DTx products by:

- *Formally recognizing DTx products*: Officially define and recognize DTx products in legislation so that Medicare and Medicaid patients can have access to these critical therapies.
- *Codifying DTx product coverage*: Require CMS to assure that Medicare and Medicaid cover technologies that meet the definition of a digital therapeutic.
- *Expanding clinician coding and payment*: Direct CMS to ensure adequate payment mechanisms exist to pay primary care providers and clinicians engaged in the authorization and clinical use of DTx products.

Covid-19 provided a heightened awareness of how digital therapeutics can help patients manage their chronic conditions within home settings, improve the efficiency and impact of mental health services, and extend effective treatment to the millions of individuals who are otherwise unable to access treatment. We look forward to working with you and your team on this crucial effort!

Sincerely,
Megan Coder, PharmD, MBA
Chief Policy Officer