November 29, 2021

Via Email Submission

Agency for Healthcare Research and Quality
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

Re: Evaluation of Mental Health Mobile Applications

Dear AHRQ Team,

On behalf of the Digital Therapeutics Alliance (DTA), we are pleased to submit these comments related to the Agency for Healthcare Research and Quality's draft technical brief "Evaluation of Mental Health Mobile Applications."

DTA's mission is to help patients, clinicians, payers, and policymakers understand how to identify, assess, and utilize DTx products in everyday settings. As such, DTA works with stakeholders across the healthcare ecosystem to ensure that DTx products are trustworthy and globally accessible care options. Members – including companies across nearly all major healthcare industries and geographic regions – are dedicated to transforming global healthcare by advancing digital therapeutics to improve clinical and health economic outcomes.

One of the projects the Alliance is currently working on is a *DTx Value Assessment & Integration Guide*, which provides healthcare decision makers with a framework to evaluate the value of and enable the implementation of digital therapeutics in clinical practice. This Guide aims to provide consistent pathways that enhance and refine DTx assessment processes within existing health systems, while also providing a foundational template for organizations undertaking the development of new pathways to evaluate and assess DTx products. Therefore, given some of the areas of crossover, we are very interested in the content and approach taken within AHRQ's *Framework to Assist Stakeholders in Technology Evaluation for Recovery (FASTER) to Mental Health and Wellness*.

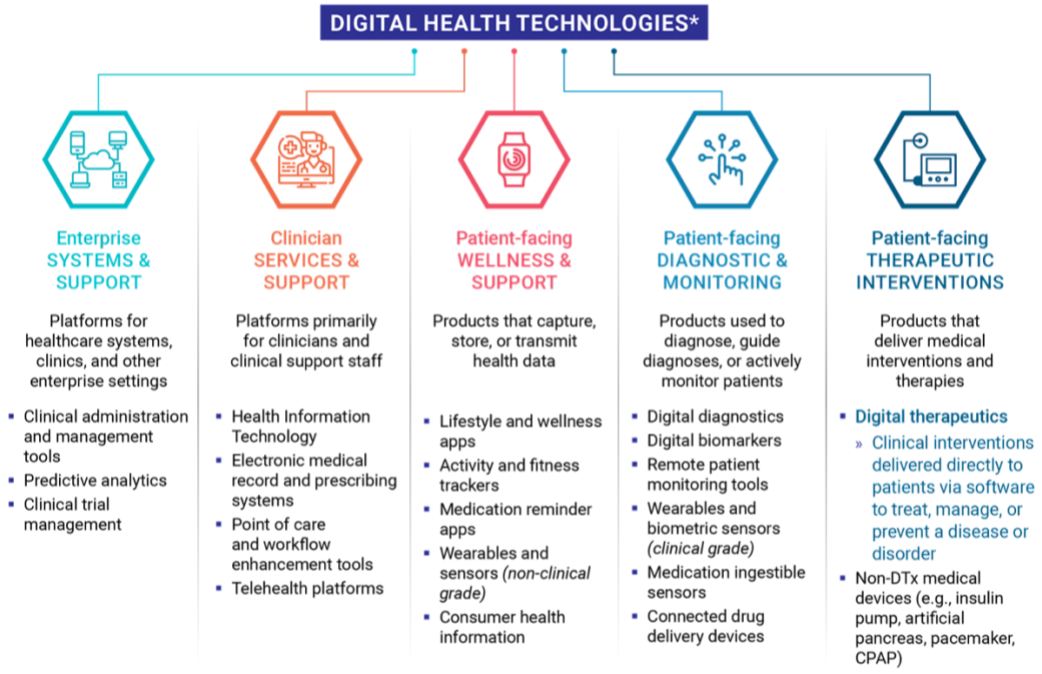
Scope of AHRQ's Evaluation Framework

The approach taken to develop the FASTER framework to evaluate mental health apps is well-planned and executed. In terms of the framework's scope of product applicability, the draft technical brief states, "Mental health apps are being used ***to support*** diagnosis, treatment, and management for mental health illness, as well as to ***provide wellness support*** through meditation and mindfulness. Some mental health apps can provide ***diagnostic*** support or assist in the diagnostic pathway by improving time to diagnosis, for example by offering automated standardized mental health ***assessments***. Apps might also ***facilitate*** treatment for certain mental health conditions and ***provide therapeutic support***." (emphases added)

Since the draft brief defines mental health apps as those intended to support, diagnose, and facilitate medical care, digital therapeutics do not fit into this definition, as DTx products use software to directly treat diseases and disorders.

It is important to note at the industry level that digital health apps are generally recognized as different from digital therapeutics. We therefore welcome further conversations with AHRQ should the above definition eventually be expanded to include DTx products under the umbrella of health apps. The distinction between DTx products and health apps is often made on the grounds that digital therapeutics use software to directly prevent/manage/treat diseases and disorders, are recognized by regulatory agencies as medical devices, are incorporated into formal treatment pathways alongside or in place of medications and in-person therapies, and must adhere to industry principles, including pre- and post-market clinical validation, privacy and security protection requirements, and regulatory oversight according to product claims and risk levels.

In referencing the above definition and figure included below, it appears that certain products in the '*wellness & support'* and '*diagnostic & monitoring'* categories are currently subject to AHRQ's draft evaluation framework (i.e., software that supports or facilitates care), and that products in the '*therapeutic interventions*' category are not subject to this framework (i.e., software that directly treat medical conditions).



*Categorizations of the digital health technology ecosystem will continue to evolve. This is a select representation of a broad, diverse ecosystem.

Importance of Distinguishing Between Product Types

Despite the significant differences between digital health products that are currently on the market, relatively few people are able to differentiate between digital health technologies that serve different purposes. Using traditional pharmaceutical products as an example, most people understand that even if two capsules or tablets look alike, that each medication type can serve a different purpose from the other (i.e., antihypertensive vs. allergy relief). It's common understanding that the active ingredient inside the medication is what dictates a medication's clinical impact, not the packaging or shell it is delivered in.

Nevertheless, patients and clinicians rarely realize that even though software-based products ranging from wellness to therapeutic may be accessed through an online platform such as an app store and downloaded onto their smartphone or tablet – thus appearing externally to be the same – each product type has a very different purpose, indication, and level of clinical impact and risk. Significant education across the healthcare ecosystem is necessary, for example, to convey to end users the different mechanisms of action and clinical impacts that DTx products have from wellness, support, diagnostic, and monitoring products.

Additional education and resources are also necessary for end users as they navigate various app stores. In the case of digital therapeutics, even though the product shell of a DTx product may be available on an app store – thus appearing to be the same as all other wellness and support apps – an authorization code provided by a clinician, insurer, employer, or DTx manufacturer is required to access the full product content. While end users may initially find this confusing, this important process helps ensure that the DTx therapy is being used by the right patient at the right time for the right indication, similar to the requirements established for traditional medications.

While these definitional distinctions may be nuanced, they are important to helping patients, caregivers, policymakers, and payors understand what therapies are available to them and what expectations they should have in terms of the product's clinical impact. An analogy to summarize this section: digital health apps are the likely equivalent of over-the-counter medications, whereas digital therapeutics are the equivalent of behind-the-counter and prescription medications. Every one of these products serves an important role, but the impacts and safety guards vary significantly.

Applicability of the Framework

In the draft technical brief, free versions of apps that did not require permission from an employer, healthcare professional, or insurance agency were chosen for assessment.

Since DTx product content is not available online at no charge, none of these products will have been included in the initial evaluation process. Assuming that DTx products are not included in the final 'mental health app' definition, this is not a problem. If, however digital therapeutics are eventually included in this framework, it will be necessary to include certain DTx products in the initial evaluation of this framework to ensure applicability.

Other Relevant Frameworks

And lastly, since the Appendices of the draft technical brief do not appear to be publicly available, we want to inform you of a highly relevant industry standard that was published earlier this year by International Organization for Standardization (ISO), an independent, non-governmental international organization with a membership of 165 national standards bodies. Through its members, ISO brings together experts to develop voluntary, consensus-based, market relevant International Standards that support innovation and provide solutions to global challenges.

Following years of development, ISO published this framework to assess health and wellness apps earlier this year:

- ISO/TS 82304-2:2021 Health software — Part 2: Health and wellness apps — Quality and reliability

- Provides quality requirements for health apps and defines a health app quality label in order to visualize the quality and reliability of health apps.
- Applicable to health apps, which are a special form of health software. It covers the entire life cycle of health apps.
- Intended for use by app manufacturers as well as app assessment organizations in order to communicate the quality and reliability of a health app. Consumers, patients, carers, health care professionals and their organizations, health authorities, health insurers and the wider public can use the health app quality label and report when recommending or selecting a health app for use, or for adoption in care guidelines, care pathways and care contracts.

In case this standard was not already included in AHRQ's initial research phase, we encourage your team to review this and consider areas of possible overlap and/or applicability.

Thank you again for the opportunity to provide commentary on this process. We look forward to ongoing conversations regarding this and other related efforts.

Sincerely,
Megan Coder, PharmD, MBA

Vice President, Global Policy
Digital Therapeutics Alliance