U.S. Food and Drug Administration (FDA)
Center for Devices and Radiological Health (CDRH)
Digital Health Advisory Committee (DHAC) Meeting

Meeting Topic: *"Generative Artificial Intelligence-Enabled Digital Mental Health Medical Devices"*

FDA DISCUSSION QUESTIONS

November 06, 2025

There is a mental health crisis in the US and insufficient access to mental health care providers. New devices may be one way to help address this gap in care for people, potentially improving outcomes and access. FDA has long promoted a total product life cycle (TPLC) approach to the oversight of medical devices, including artificial intelligence (AI)-enabled devices, and has committed to advancing regulatory approaches for these devices.

Along with the rise of widely accessible generative AI products for general purposes, we are seeing an increase in the development and demand for a new kind of digital mental health medical device: "AI therapists" and other AI-based medical devices offering to provide a wide range of mental health therapies and interactions (some even being diagnostic) with therapist/healthcare provider-like chatbots. These chatbots may engage with users in individualized ways with, or without, the oversight of a health care provider (HCP), which pose novel risks for use. As digital mental health medical devices continue to evolve in complexity, regulatory approaches will need to accommodate these challenges and opportunities to provide a reasonable assurance of their safety and effectiveness while promoting innovation to support public health.

The questions below are designed to address the information and practices needed for a comprehensive approach to the assessment of performance and management of risk throughout the TPLC for digital mental health medical devices. Consider the following initial scenario, subsequent modifications to this scenario, and related questions:

Scenario	A patient diagnosed with major depressive disorder (MDD) by their healthcare provider is experiencing intermittent tearfulness due to increasing life stressors. Although the patient has consistently refused recommendations for therapy from their healthcare provider, the patient is willing to try a software device that provides therapy.

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Device Description	This prescription therapy device is built on a large language model (LLM) that utilizes contextual understanding and language generation with unique outputs that mimic a conversation with a human therapist.
Device Indications for Use	This product is a standalone prescription digital therapy device indicated to treat MDD for adult patients (aged 22 years and older) who are not currently engaged in therapy.

1. First, consider that a healthcare provider prescribes the digital mental health medical device to the patient to use independently at home.
    a. Briefly discuss the probable benefits of this type of device that provides automated therapy in an ongoing manner.
    b. What probable risks are presented by this type of device that provides automated therapy?
    c. What risk mitigations should be considered for this type of device (e.g., alerts for self-harm ideations)?
    d. What premarket evidence would you want to see to determine whether the benefits outweigh the risks to health?
        i. What are the key aspects of clinical evidence and trial design such as clinically meaning endpoints (e,g., measurable reduction in symptomatology), follow-up time, study eligibility criteria) ?
        ii. What alternative approaches could be used to demonstrate clinically meaningful benefits and risks (e.g., benchmarking, model-based evaluation)?
    e. What specific postmarket monitoring capabilities should be considered to ensure continued safety and effectiveness of this medical device in real-world use (e.g., methods, metrics, tools)?
    f. What labeling would be important for users of this type of device?

2. The manufacturer of the aforementioned, generative AI-enabled mental health medical device has decided to expand their labeled indications for use. They are contemplating the following changes.
    a. Making the device available over-the-counter (OTC) for people diagnosed with MDD.
    b. Modifying the OTC device to autonomously diagnose and treat MDD in an ongoing manner without the involvement of an HCP. They intend for the device to be used by people who have not been diagnosed with MDD by an HCP but have been experiencing symptoms of depression.
    c. Modifying the OTC, autonomous diagnosis and treatment device to be used for multiple mental health conditions (e.g., multi-use indications), meaning that it can

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provide both diagnosis and treatment for multiple mental health conditions related to sadness (in contrast to a device that is specifically indicated for MDD). The user of the device may not be clinically diagnosed with any mental health condition but has been feeling sad and has not met with an HCP.

3. Expanding the population to include a child or adolescent (i.e., 21 years and younger).

    a. As you consider the manufacturer's proposed changes, please discuss whether your prior responses to question 1 would change if the population were children or adolescents.
    b. If so, how would the responses change?

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