FDA Perspective: Generative Artificial Intelligence-Enabled (GenAI) Digital Mental Health Medical Devices

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Improving Mental Health by Advancing Access to Safe and Effective Medical Devices

- Mental health diagnoses are increasing.
- Mental health treatment needs are increasing
- Timely access to mental healthcare is decreasing
- Development of and technological advances in digital mental health technologies are accelerating
- We have an opportunity to help facilitate innovative, safe and effective technologies for patients struggling with mental health conditions

Source: Substance Abuse and Mental Health Services Administration. Key substance use and mental health indicators in the United States: Results from the 2021 National Survey on Drug Use and Health, 2022 (https://www.samhsa.gov/data/report/2021-nsduh-annual-national-report)

Accelerate the Delivery of Safe and Effective Medical Device Software to Market by Supporting Consistency and Predictability in Development and Review

FDA's Risk-based Approach to Device Software Regulation

Not a Device

Example – an app that provides daily motivational tips to reduce stress and promote a positive mental outlook to support an individual's general wellness

Intention to Exercise Enforcement Discretion

Example – an app that helps patients diagnosed with anxiety maintain their behavioral coping skills by providing a "Skill of the Day" behavioral technique that a user can access when experiencing increased anxiety

Focus of FDA's Regulatory Oversight

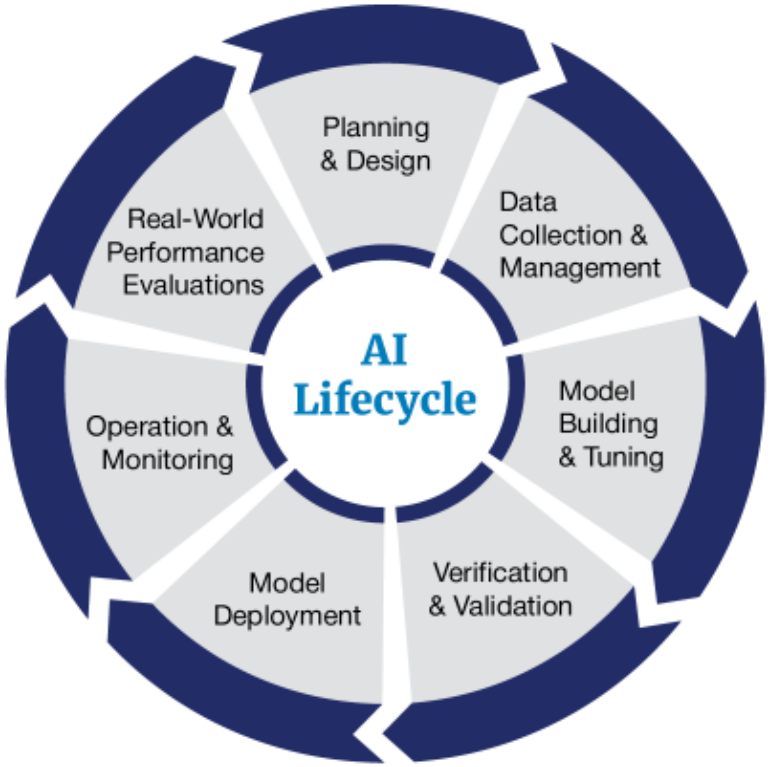
Example – an app that provides computerized behavioral therapy for psychiatric disorders as an adjunct to clinician supervised outpatient treatment (21 CFR 882.5801)

Increasing Risk

Draft Guidance: Lifecycle Management and Marketing Submissions for AI-Enabled Devices

- Proposes recommendations on the premarket expectations for AI-enabled devices based on FDA's experience with these devices

- Proposes a total product life cycle approach, including recommendations for the design, development, deployment, and maintenance of AI-enabled devices, including performance monitoring



Source: Draft Guidance: Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations, 2025 (www.fda.gov/regulatory-information/search-fda-guidance-documents/artificial-intelligence-enabled-device-software-functions-lifecycle-management-and-marketing)

Draft Guidance: Recommendations for Lifecycle Management

- AI-enabled devices are sensitive to changes in input data, which may lead to changes in performance that create a risk to patients over time but can be difficult to identify.
- Manufacturers should have a postmarket performance monitoring plan to help identify and respond to changes in performance in a postmarket setting as part of the quality system.
- The inclusion of a performance monitoring plan in the marketing submission may help to reduce uncertainty and support FDA's evaluation of risk controls.

Source: Draft Guidance: Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations, 2025 (www.fda.gov/regulatory-information/search-fda-guidance-documents/artificial-intelligence-enabled-device-software-functions-lifecycle-management-and-marketing)

FDA's Digital Health Center of Excellence Seeks Comments on AI Performance in Real-world

Docket name and number:
Measuring and Evaluating Performance of AI-enabled Medical Devices in the Real-World (FDA-2025-N-4203)

Public comment due date:
December 1, 2025

Objective: To obtain comment and feedback on questions related to:

- Real-world evaluation methods and infrastructure
- Performance metrics and indicators
- Postmarket data sources and quality management
- Monitoring triggers and response protocols
- Human-AI interaction and user experience
- Additional considerations and best practices

Source: Request For Public Comment: Measuring and Evaluating Artificial Intelligence-enabled Medical Device Performance in the Real-World, 2025 (www.fda.gov/medical-devices/digital-health-center-excellence/request-public-comment-measuring-and-evaluating-artificial-intelligence-enabled-medical-device)

AI Predetermined Change Control Plan (PCCP)

Description of Modifications	**"What" a manufacturer intends the algorithm to become as it learns** • Identifies specific, planned modifications to AI-enabled device software functions that the manufacturer intends to implement • Includes the specifications for the characteristics and performance of the planned modifications to the AI-enabled device software function
Modification Protocol	**"How" the algorithm will learn/change while remaining safe and effective** • Describes methods that will be followed when developing, validating, and implementing the modifications to ensure the device remains safe and effective • Methods described in Modification Protocol should be consistent with and support the modifications outlined in Description of Modifications
Impact Assessment	**Describes modifications' benefits and risks, and how risks are mitigated** • Assesses benefits and risks of each individual modification, as well as collective impact of modifications, when implementing a PCCP • Discusses how activities proposed within Modification Protocol mitigate identified risks to continue to reasonably ensure the safety and effectiveness of the device

Source: Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions, 2025 (www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-submission-recommendations-predetermined-change-control-plan-artificial-intelligence)

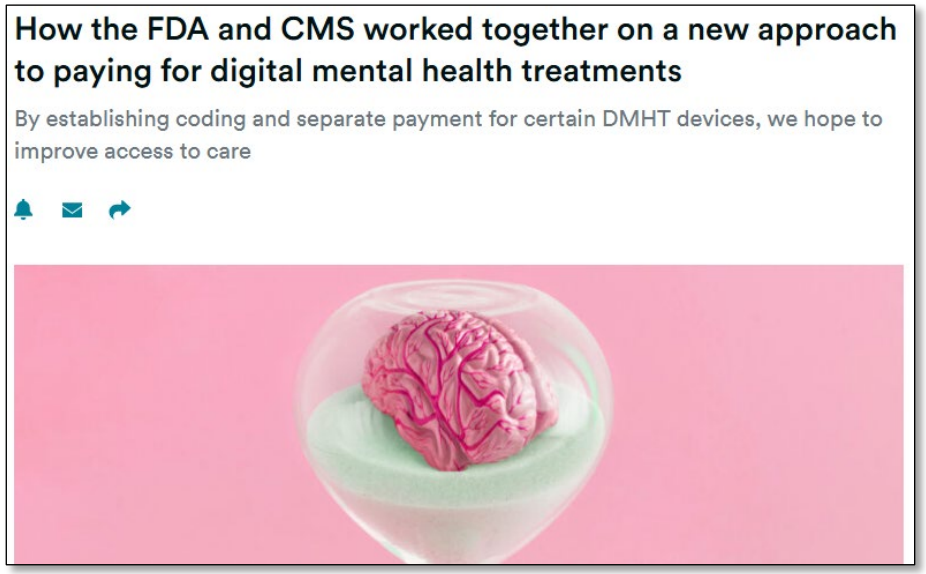
Considerations for PCCPs for Gen AI Enabled Digital Mental Health Medical Devices

- How specific can the modifications be given the nature of the technology?
- What boundaries or guardrails are needed in the PCCP to define the range of automatic updates allowed for a given device?
- How will post-market performance be monitored over time to assure device performance is maintained or improved?
- How will labeling will be updated to inform users when modifications are implemented automatically?
- What are the appropriate notification requirements if the device does not function as intended?

Source: Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions, 2025 (www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-submission-recommendations-predetermined-change-control-plan-artificial-intelligence)

Payer Coverage for Digital Mental Health Care

- FDA collaborated with CMS through HHS on an Administration priority to improve access to affordable and innovative treatments through payment pathways for digital mental health treatment devices
- 2025: CMS issued a rule finalizing changes for Medicare payments under the Physician Fee Schedule for computerized behavioral therapy devices authorized by FDA under 21 CFR 882.5801
- 2026: Proposed expansion for coverage of mental health treatment devices in CY 2026 underway



Sources: Calendar Year 2025 Medicare Physician Fee Schedule Final Rule, 2024 (www.cms.gov/newsroom/fact-sheets/calendar-year-cy-2025-medicare-physician-fee-schedule-final-rule) and https://www.statnews.com/2025/01/17/fda-cms-dmht-code-payments-behavioral-health/

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