AMERICAN PSYCHIATRIC ASSOCIATION

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October 17, 2025

Division of Dockets Management (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Comments on Docket No. FDA–2025–N–2338
Digital Health Advisory Committee; Establishment of a Public Docket; Request for Comments—Generative Artificial Intelligence-Enabled Digital Mental Health Medical Devices

Dear Deputy Commissioner Graham and Members of the Digital Health Advisory Committee:

The American Psychiatric Association (APA) appreciates the opportunity to submit comments to the Food and Drug Administration (FDA) regarding the upcoming meeting on Generative Artificial Intelligence (AI)-Enabled Digital Mental Health Medical Devices. As the national medical specialty society representing more than 39,200 psychiatrists, APA is deeply invested in ensuring that the integration of AI into mental health care advances patient and physician well-being, maintains scientific rigor, and upholds ethical and privacy standards.

APA puts forth the following recommendations to this committee for consideration:

- **The FDA should establish a clear framework for evaluating the safety and effectiveness of generative AI-enabled mental health devices, including the use of validated psychiatric assessment tools and ongoing post-market surveillance to monitor evolving model behavior.**
- **That the FDA requires evidence demonstrating that AI-enabled systems function fairly across demographic, cultural, and diagnostic subgroups**.
- **The adoption of standardized labeling framework for AI-enabled devices that discloses the data sources used for training and validation, the model's intended scope, capabilities, and limitations, and known uncertainty levels or confidence intervals for outputs.**
- **Regulatory standards specifying whether patient data are processed locally or via cloud services. Secondary data use, such as for marketing or retraining, should be prohibited without explicit, informed consent.**
- **The FDA shift liability to developers from clinicians and health systems to better balance the risks and duty of care of a tool that is being implemented in clinical care.**

Safety and Effectiveness

The integration of generative AI into mental health care presents both remarkable opportunities and significant concerns. While these technologies may help expand access to providers by reducing administrative burdens and augment clinical decision-making, their rapid evolution requires thoughtful and evidence-based regulatory oversight. While these technologies may help expand access to providers by reducing administrative burdens and augmenting clinical decision-making, their rapid evolution requires thoughtful and evidence-based regulatory oversight. **A clear framework for evaluating AI-enabled mental health devices is therefore crucial to safeguard patients and uphold standards of care, especially since many AI-models are being implemented outside of the therapeutic relationship.**

Generative AI models must be trained and evaluated using established and standardized psychiatric assessment instruments such as the PHQ-9 (Patient Health Questionnaire-9), MADRS (Montgomery-Asberg Depression Rating Scale), AUDIT (Alcohol Use Disorders Identification Test), and GAD-7 (Generalized Anxiety Disorder-7), rather than relying solely on generic natural language processing benchmarks. Given the dynamic nature of AI models that evolve through retraining, ongoing post-market surveillance should be a requirement to monitor shifts in model behavior over time.

Bias and Equity

Beyond safety and performance, equity must be a foundational consideration in the regulation of AI-enabled mental health tools. Generative AI systems trained on limited or unrepresentative data risk amplifying existing disparities in mental health diagnosis and treatment. FDA's framework should therefore embed fairness and inclusivity as core evaluation criteria from the outset. Ensuring equitable performance across diverse populations is essential. **APA urges the FDA to require evidence demonstrating that AI-enabled systems function fairly across demographic, cultural, and diagnostic subgroups**. Independent third-party bias audits, in addition to developer-reported metrics, would help strengthen public trust and promote fair access to emerging technologies.

Transparency

For clinicians to rely on AI-assisted models in mental health care, they must understand how these technologies work and where their limitations lie. Transparency not only supports accountability but also strengthens clinical decision-making by clarifying the evidence base behind algorithmic recommendations. Clinicians and patients alike need clear, actionable information to make informed decisions. **APA supports a standardized labeling framework for AI-enabled devices that discloses the data sources used for training and validation, the model's intended scope, capabilities, and limitations, and known uncertainty levels or confidence intervals for outputs.** Additionally, version control and update disclosures should be mandatory, allowing users and regulators to track model changes that could affect clinical performance and patient safety.

Privacy and Data Use

Transparency alone is not enough to safeguard patient trust. The responsible use of psychiatric data demands equally rigorous privacy protections that address how information is collected, stored, and shared throughout the AI system's lifecycle. As digital tools become more integrated into care delivery, data governance must evolve accordingly to preserve confidentiality and prevent

misuse. Because psychiatric data are among the most sensitive forms of health information, **APA strongly recommends regulatory standards specifying whether patient data are processed locally or via cloud services. Secondary data use, such as for marketing or retraining, should be prohibited without explicit, informed consent.** Uniform de-identification and re-identification risk assessment standards applicable to mental health datasets should also be established.

Accountability

Clear delineation of responsibility and liability is essential when implementing AI-enabled decision tools. **APA recommends that FDA shift liability to developers from clinicians and health systems to better balance the risks and duty of care of a tool that is being implemented in clinical care.** Transparent audit trails of model outputs and user interactions should be required to support clinical review and legal oversight. There must also be a robust post-market surveillance for these models for unintended consequences, similar to how the FDA monitors drugs for side effects.

Conclusion

APA appreciates FDA's leadership in convening this important discussion and welcomes continued collaboration to develop thoughtful, evidence-based frameworks for AI in mental health care. We look forward to participating in ongoing dialogue to ensure these technologies enhance, rather than compromise, patient safety, equity, and clinical effectiveness. If you have any questions or would like any further discussion regarding these comments, please contact Zuhal Haidari (zhaidari@psych.org), Associate Director, Digital Health.

Sincerely,

Marketa Wills, MD, MBA, FAPA
CEO and Medical Director
American Psychiatric Association