



February 23, 2026

The Honorable Robert F. Kennedy Jr.
Secretary of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Assistant Secretary Thomas Keane, M.D.
Assistant Secretary for Technology Policy (ASTP), Office of the National Coordinator for
Health Information Technology (ONC)
U.S. Department of Health and Human Services
330 C Street, SW, Floor 7
Washington, DC 20201

Re: HHS Health Sector AI RFI

Dear Secretary Kennedy and Assistant Secretary Keane:

The Association for Behavioral Health and Wellness (ABHW) appreciates the opportunity to submit our recommendations to the U.S. Department of Health and Human Services (HHS) and the Office of the Assistant Secretary for Technology Policy /National Coordinator for Health Information Technology (ASTP/ONC) Request for Information: Accelerating the Adoption and Use of Artificial Intelligence as Part of Clinical Care.

ABHW is the national voice for payers managing behavioral health insurance benefits. Our member companies provide coverage to 200 million people in both the public and private sectors to treat mental health (MH), substance use disorders (SUDs), and other behaviors that impact health and wellness. Our organization aims to increase access, drive integration, support prevention, raise awareness, reduce stigma, and advance evidence-based treatment and quality outcomes. Furthermore, our policy work aims to ensure that physical and behavioral health care is integrated and coordinated. ABHW is committed to ensuring better outcomes for whole-person care for all individuals and communities. We believe access to comprehensive, evidence-based MH and SUD services is critical to enhancing patients' health and overall well-being.

The rapid evolution of artificial intelligence (AI) in clinical care presents both promising clinical opportunities and complex challenges for patients, providers, and health plans. ABHW's responses to the questions below reflect the distinct clinical and operational considerations relevant to behavioral health care.

1. What are the biggest barriers to private sector innovation in AI for health care and its adoption and use in clinical care?

ABHW has identified several barriers to AI innovation and adoption that underscore the need for regulatory alignment, clear accountability frameworks, provider education, and the creation of policies that reflect the distinct clinical, operational, and privacy considerations in behavioral health care.

First, data limitations remain a foundational barrier. Many AI models are trained on incomplete or non-representative datasets that underrepresent behavioral health conditions and comorbid physical health needs. As a result, tools that perform well in controlled settings often do not translate effectively to real-world behavioral health populations, raising concerns about reliability and safety.

Closely related is the need for clear, transparent communication with patients about AI data. Such communication should be implemented in a manner proportionate to the risk and aligned with existing federal and state laws, as well as established medical practice standards. For higher risk AI, patients must understand, where clinically and operationally appropriate, how and when their data is used, how AI informs care decisions, and what role human clinicians play in the clinical process. Any disclosure obligations should be tailored to the level of risk presented by the AI application and avoid duplicative or conflicting requirements where existing legal frameworks already govern patient communications. Lack of transparency undermines trust and may slow adoption, particularly in behavioral health, where privacy and stigma are especially sensitive.

Additionally, providers, particularly small and independent practices, may lack the resources to independently evaluate AI tools for their use. AI literacy remains uneven, and implementation support is limited, creating a need for federally supported education and technical assistance resources. HHS can play an important role by developing provider-facing best practices and educational tools to help support responsible adoption of AI, while helping providers understand how these technologies can be integrated into their clinical workflows in compliance with existing laws and standards.

While the U.S. Food and Drug Administration's (FDA) and Centers for Medicare and Medicaid Services (CMS) serve distinct and appropriate roles, the absence of clear, coordinated guidance on how AI-enabled tools can be evaluated, implemented, and paid for across different care settings creates challenges for developers, providers, and health plans seeking to responsibly deploy these technologies.

2. What regulatory, payment policy, or programmatic design changes should HHS prioritize to incentivize the effective use of AI in clinical care and why? What HHS regulations, policies, or programs could be revisited to augment your ability to develop or use AI in clinical care? Please provide specific changes and applicable Code of Federal Regulations citations.

ABHW recommends that HHS work with the FDA to create a risk-based framework for AI oversight that distinguishes among applications based on their impact on patient safety and

clinical decision-making. Higher-risk tools, such as those that make treatment recommendations or crisis intervention, should be subject to stronger validation, transparency, and monitoring requirements, while lower-risk tools that support administrative or clinical workflow functions should face more flexible oversight. This distinction is particularly important in behavioral health, where data sensitivity and clinical variability heighten the consequences of AI-related errors.

Clear distinctions are needed between general-purpose AI-enabled mental health applications and clinically validated digital behavioral health technologies, such as Digital Mental Health Therapeutics (DMHTs), that are intended to diagnose and treat conditions and are typically evidence-based, and subject to FDA oversight if they meet the definition of a medical device.

Regulatory clarity should be grounded in intended use, risk level, and clinical claims to ensure appropriate oversight. Some available AI-based digital behavioral health solutions have limited evidence supporting their effectiveness and medical necessity. This could be due to shorter or smaller-scale studies lacking control groups, or control groups that do not demonstrate comparable improvement. Studies may also be subject to selection bias, as participants with specific circumstances that enabled their access to digital therapeutics may contribute to the marked improvements. For MH apps, demonstrating clinical effectiveness is complex because outcomes are subjective and influenced by engagement, which can fluctuate.

ABHW also encourages HHS to collaborate with the FDA to strengthen post-market surveillance of AI-enabled clinical tools. Ongoing, real-world evaluation is essential to assess effectiveness over time, particularly given common patient dropout, nonadherence, and frequent software updates that are not systematically reviewed post-authorization but may raise safety and performance concerns.

3. For non-medical devices, we understand that use of AI in clinical care may raise novel legal and implementation issues that challenge existing governance and accountability structures (e.g., relating to liability, indemnification, privacy, and security). What novel legal and implementation issues exist and what role, if any, should HHS play to help address them?

ABHW supports the implementation of accredited, consensus-driven standards that promote broad stakeholder engagement and alignment with policy objectives, including the NIST Artificial Intelligence Risk Management Framework (AI RMF) and standards developed through ANSI-accredited standards development organizations (SDOs). Additionally, while the NIST AI Risk Management Framework provides a strong qualitative foundation, organizations need practical, automated tools to implement and monitor the framework in real time.

4. For non-medical devices, what are the most promising AI evaluation methods (pre- and post-deployment), metrics, robustness testing, and other workflow and human-centered evaluation methods for clinical care? Should HHS further support these processes? If so, which mechanisms would be most impactful (e.g., contracts, grants, cooperative agreements, and/or prize competitions)?

Mental health (MH) care is highly nuanced and influenced by tone, context, and the therapeutic relationship is not consistently captured by existing evaluation frameworks. Evaluation tools need to be able to capture the complexity of clinical judgment and the wide variability in patient presentation. ABHW recognizes the need for clear, clinically grounded evaluation methods to assess non-medical AI-enabled chatbots and large language models (LLMs) used to support MH care. As a result, robust clinical oversight, meaningful human-in-the-loop requirements, and additional validation are necessary before such tools can be appropriately relied upon in practice.

ABHW encourages HHS to support the development of consensus-based standards, led by accredited standards organizations, to ensure alignment with best practices as technologies evolve. Any framework should be supported by peer-reviewed, published evidence demonstrating reliability and safety across diverse populations and use cases.

For high-risk MH use cases, pre-deployment evaluation should include clinical simulation testing, bias and robustness testing across diverse behavioral health populations, and assessment of guardrails for high-risk scenarios such as suicide risk, SUD treatment, and crisis escalation. Post-deployment evaluation should focus on real-world monitoring for safety signals, response accuracy and consistency, appropriate escalation to human care, and patient experience over time. Human-centered evaluation should also examine integration into clinical workflows and transparency around a chatbot's role and limitations.

HHS could further support these efforts through targeted grants and applied research partnerships to develop shared evaluation metrics, testing protocols, and best practices for MH chatbots, enabling responsible innovation while protecting patient privacy and safety.

5. Where have AI tools deployed in clinical care met or exceeded performance and cost expectations and where have they fallen short? What kinds of novel AI tools would have the greatest potential to improve health care outcomes, give new insights on quality, and help reduce costs?

One of our member health plans has leveraged AI-enabled tools to increase its inbound correspondence processing capacity by 400 percent, while achieving 96 percent accuracy. As a result, communications that previously required up to six days to be appropriately routed are now directed to the correct team within hours. This improvement has enhanced operational efficiency and significantly improved the experience of members, providers, and internal staff alike.

6. Are there specific areas of AI research that HHS should prioritize to accelerate the adoption of AI as part of clinical care?

HHS should prioritize research into how AI-enabled tools can support greater efficiency, consistency, and clinical appropriateness while helping manage costs across the health care system.

In behavioral health, where timely access to treatment is critical, AI has the potential to assist with documentation review and summaries, identification of requests that meet established

criteria, and prioritization of cases for expedited review, under appropriate human oversight. When thoughtfully designed and governed, such tools could help reduce administrative burden and clinician burnout while promoting more consistent application of evidence-based standards. Any high-risk use of AI should complement clinician judgment, as well as established laws, frameworks, and consumer protections safeguards.

Conclusions

Accelerating the responsible adoption of AI in behavioral health clinical care will require a balanced approach that promotes innovation while maintaining strong patient protection. HHS should rely on existing safeguards, such as privacy protections under HIPAA and 42 CFR Part 2 (Part 2), established clinical standards of care, and existing FDA oversight rather than layering on duplicative or unnecessary requirements.

ABHW is committed to engaging with ASTP/ONC and other partners to identify innovative opportunities to improve behavioral health access for all individuals. If you have questions, please contact Kathryn Cohen, Senior Director of Regulatory Affairs, at cohen@abhw.org.

Sincerely,

A handwritten signature in black ink that reads "Deborah H. Withey". The signature is written in a cursive, flowing style.

Debbie Withey, MHA
President and CEO