HEALTH IT
End Users Alliance

February 20, 2026

Jim O'Neill
Deputy Secretary
US Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Dr. Thomas Keane
Assistant Secretary and National Coordinator
Assistant Secretary for Technology Policy / Office of the National Coordinator for Health Information Technology
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Submitted electronically to www.regulations.gov

RE: HHS Health Sector AI RFI

Dear Deputy Secretary O'Neill and Dr. Keane:

The Health IT End-Users Alliance (the Alliance) appreciates the opportunity to provide input on the Office of the Deputy Secretary and Assistant Secretary for Technology Policy / Office of the National Coordinator for Health Information Technology (ASTP/ONC) Request for Information: Accelerating the Adoption and Use of Artificial Intelligence as Part of Clinical Care, or HHS Health Sector AI RFI, as published in the December 23, 2025, *Federal Register* (RIN 0955-AA13).

The Alliance brings together health information professionals, physicians, hospitals, and other front-line healthcare providers and organizations that use health information technology (IT) to ensure that policy and standards development activities reflect the complex web of clinical and operational challenges facing those who use such technologies today. By working collaboratively, the Alliance is focused on priorities for how technology can best support clinical care and operations.

The Alliance appreciates HHS' interest in creating a policy and regulatory environment that is optimal to realizing the benefits of AI. AI is rapidly transforming healthcare, with developments and innovations producing promising non-clinical and clinical benefits in various settings and specialties. Concerns remain related to how AI models are developed, trained, used, and monitored, and the significant impact AI has on healthcare operations, patient care delivery, and health outcomes. Due to those concerns, widespread

adoption of AI in healthcare requires thoughtful oversight and governance frameworks to minimize risks and ensure the appropriate, safe, and ethical use of AI. Health IT end-users are at the forefront of AI use in healthcare and are well-equipped to collaborate on common principles to ensure the proper balance between innovation and use of AI with appropriate guardrails.

The Alliance published a [consensus statement](#) in April 2025 reflecting the current state of AI in healthcare including principles intended to guide policymakers as they work to ensure appropriate oversight of AI tools without hampering innovation. As end-users are often brought into the development cycle for technology during implementation, the Alliance's consensus statement highlights the need for end-users to be engaged throughout the entire AI development lifecycle. **The Alliance recommends HHS prioritize policymaking activities that bring developers, policymakers, and end-users to the table from a project's outset to ensure AI tools are built in ways that fit organizations' unique needs, integrate with existing workflows, promote trust and confidence in the use of such tools, and inform organization-specific governance frameworks for end-users.**

As HHS pursues policies and regulations to determine the appropriate methods and areas for governance and oversight of AI in clinical care, the Alliance urges HHS to consider implementing policies that assist the industry in fostering innovation in AI while maintaining the protection of health data, lowering administrative burden, and improving health outcomes. Recommendations on specific areas of policy and regulatory oversight include:

Regulation and oversight of AI. AI tools should augment, not replace, end-users' expertise, and policy must ensure these tools supplement cognitive and administrative tasks while preserving human judgment. AI tools in healthcare require a risk-based approach to oversight where the level of scrutiny and validation should be proportionally accounted for in policymaking to minimize the disparate harm and consequences the tool might introduce. The Alliance urges HHS to leverage ASTP/ONC's statutory coordinating role and its component agencies, including the Office for Civil Rights (OCR), Centers for Medicare and Medicaid Services (CMS), and other relevant agencies to ensure policies are aligned across the federal government to avoid competing and confusing standards that could lead to non-compliance and increased burden. This includes ensuring HIPAA regulatory frameworks incorporate data handling practices by AI tools to protect patient privacy and prohibit data/information exchange beyond minimum necessary, secondary use of data without consent, or data handling practices that may enable unintended or unauthorized data reidentification.

Safety and transparency. Transparency in the development of AI tools and what data are used in decision-making, governance, and ongoing testing and maintenance plans is critical. AI developers should provide clear, understandable information describing how the AI solution makes predictions, tailored in a way to best suit the needs of end-users. Such transparency requirements should provide a conceptual model on the importance of data used for AI tool inferences and how data is used. That transparency includes ensuring patients and healthcare organizations can confidently trust companies will maintain

confidentiality of data. For trust to be maintained, AI developers should disclose how data from patients and end-users is collected, stored, used, and shared.

Liability. The Alliance encourages HHS to ensure AI companies dealing with health data are held to the same standards HIPAA-covered entities are held to today. HHS should determine the appropriate balance of accountability that considers the role of AI developers in the creation, maintenance, and use of clinical and non-clinical tools and the role of end-users in the use of these tools. HHS should also partner with the Federal Trade Commission to ensure AI developer oversight includes unfair and deceptive trade practices. Providers should not be held liable for an AI tool's performance if they have completed good faith evaluations and taken steps to mitigate quality or safety concerns. Policies must reflect that developers are often best positioned to prevent harm due to their knowledge of the development, function, and intended use of these tools.

Cybersecurity. As AI systems become deeply integrated into clinical and operational environments, their exposure to sophisticated cyber threats presents an escalating risk to patient safety and organizational integrity. End-users depend on AI tools that are secure by design, yet they often lack visibility into the system's vulnerabilities or control over its defenses. AI developers, not end-users, are best positioned to mitigate and respond to cyberattacks given their direct access to system architecture, code, and infrastructure. The Alliance recommends HHS strengthen regulatory guardrails to ensure that developers bear primary responsibility for securing AI systems against intrusions, data exfiltration, and model manipulation. Holding end-users liable for breaches or system failures they cannot control would undermine trust and deter adoption. Robust, enforceable cybersecurity requirements for developers, aligned with federal health data protections, are essential to protect patients, sustain trust in AI, and accelerate responsible innovation in healthcare.

Real-world testing. Consistent with the Alliance's [Real-world Testing Consensus Statement](#), it is critical to conduct real-world testing of AI tools across a variety of clinical settings to confirm these technologies are operating as expected without adverse patient consequences. Real-world testing and documentation of identified issues, including implicit biases, are of critical importance to end-users to advance AI adoption in healthcare. End-users are often included at the end of the policymaking and technology development process, not the beginning, which leads to technologies and policies that do not meet their intended goals. It is crucial for HHS to prioritize policies that include end-users throughout the policymaking and technology development processes to ensure regulatory and technology innovation goals, as well as the needs of end-users, are met.

The Alliance is actively working with the National Institute of Standards and Technology (NIST) on its [AI Standards Zero Drafts Pilot Project](#), an initiative seeking to broaden stakeholder participation in the creation of AI standards. We applaud NIST's commitment to working with stakeholders on this effort to implement directives within the Trump Administration's [AI Action Plan](#). Thus far, the Alliance has provided feedback on the four initial topic areas identified by NIST for draft standards documents and the first

outline on testing, evaluation, verification, and validation. We have also held a listening session with NIST to provide more detailed feedback. We encourage HHS to coordinate with NIST to advance nationwide AI standards and ensure any AI policy frameworks are harmonized with such standards.

The Health IT End-Users Alliance thanks HHS for the opportunity to provide input on this request for information. We are committed to being a partner in identifying unnecessary barriers to AI innovation, development, and implementation while ensuring patient safety and improving the healthcare experience for all stakeholders involved. To discuss our feedback further or if you have any questions, please contact Tara O'Donnell, Manager, Regulatory Affairs at Tara.ODonnell@ahima.org.