



February 23, 2026

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U.S. Department of Health and Human Services  
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Dr. Thomas Keane  
Assistant Secretary and National Coordinator  
Assistant Secretary for Technology Policy / Office of the National Coordinator for Health  
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Submitted electronically via Regulations.gov

RE: HHS Health Sector AI Request for Information

Dear Deputy Secretary O'Neill and Assistant Secretary Keane:

The American Medical Informatics Association (AMIA) appreciates the opportunity to respond to the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP/ONC) Request for Information (RFI) regarding policies to accelerate the responsible adoption and use of artificial intelligence (AI) in clinical care.

AMIA is the professional home for more than 6,000 informatics professionals, representing frontline clinicians, researchers, public health experts, and educators who bring meaning to data, manage information, and generate new knowledge across the research and healthcare enterprise. As the voice of the nation's biomedical and health informatics professionals, AMIA advances health and wellness by moving research from bench to bedside and evaluating interventions, innovations, and public policy across care settings and patient populations.

Below, we respond to the numbered questions presented in the RFI.

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

The most significant barriers include limited access to clinically relevant and context-specific data, insufficient implementation infrastructure, unclear return on investment (ROI), and inadequate governance capacity within health systems.

AI developers, particularly startups, often lack local clinical expertise and access to representative datasets necessary to build safe and effective tools. Adoption is further constrained by insufficient interoperability, limited technical infrastructure, and workforce readiness gaps, especially in community-based and under-resourced health systems.

Many health systems also lack clear guidance on how to assess safety, effectiveness, and ROI prior to adoption. Clinicians must understand whether an AI tool improves outcomes, reduces burden, or enhances quality, not merely that it is technologically advanced. Adoption without a defined implementation strategy and measurable value proposition undermines trust and sustainability.

## **2. What regulatory, payment policy, or programmatic design changes should HHS prioritize to incentivize effective AI use in clinical care?**

HHS should prioritize a risk-based regulatory framework that aligns oversight with the potential clinical impact of AI tools:

- Low-risk tools (e.g., workflow optimization) should be subject to streamlined oversight.
- Moderate-risk tools should demonstrate validation and ongoing monitoring.
- High-risk tools should require robust pre- and post-deployment evaluation, algorithmic transparency, and continuous performance monitoring.

When AI is used as a clinical intervention, transparency regarding algorithm function, limitations, and evidence base is essential. Clinicians cannot responsibly rely on “black box” systems without understanding how effectiveness is assessed and how performance is monitored.

From a payment perspective, reimbursement should be rewarded with demonstrated value, not adoption for its own sake. AI should function like a well-designed clinical instrument: improving outcomes, reducing burden, or enhancing quality. HHS should consider pilot programs and regulatory sandboxes to evaluate effectiveness before broad reimbursement.

Programmatic priorities should include:

- Implementation funding support, particularly for under-resourced systems.
- Incentives tied to measurable reductions in administrative burden or improvements in quality metrics.
- Ongoing HHS evaluation to determine whether AI tools merit inclusion in payment schedules.

Payment modernization must balance time savings, complexity reduction, and outcome improvement, rather than relying on a one-size-fits-all reimbursement models.

### **3. For non-medical devices, what novel legal and implementation issues exist, and what role should HHS play?**

Non-medical AI tools used in clinical contexts—including consumer wearables (e.g., Fitbit devices) and general-purpose AI systems—raise novel governance challenges when integrated into care delivery.

Key issues include:

- Liability and indemnification: Reliance on opaque AI outputs may shift liability to clinicians despite limited insight into tool functionality.
- Privacy and secondary data use: Patients express concern about whether identifiable data are incorporated into commercial datasets.
- Lack of professional mediation: Consumer-facing AI may provide health-related information without clinical oversight, increasing the risk of misinformation.

HHS should clarify regulatory boundaries between medical and non-medical AI used in clinical workflows and establish guardrails related to transparency, training data provenance, data monetization practices, and disclosure requirements. Clear accountability frameworks will strengthen public trust.

### **4. How can HHS support private sector activities to promote effective AI use in clinical care?**

HHS can support private sector innovation by:

- Encouraging collaborative development between AI developers and health systems.
- Supporting shared benchmarking datasets and evaluation frameworks.

- Promoting implementation toolkits addressing governance, validation, monitoring, and workforce training.

Accreditation and certification efforts should emphasize transparency, bias testing and mitigation, real-world performance monitoring, and human-centered evaluation. Federal leadership in convening stakeholders to harmonize standards would reduce duplication and accelerate responsible adoption.

## **5. Who influences AI adoption decisions within health care organizations?**

AI adoption decisions are typically influenced by C-suite leadership (e.g., Chief Medical Information Officers, Chief Information Officers, Chief Medical Informatics Officers), IT departments, and executive governance bodies. Nurses, frontline clinicians, and operational staff—despite experiencing the greatest workflow impact—are often underrepresented in decision-making.

Primary administrative hurdles include:

- Unclear liability frameworks
- Absence of formal AI governance structures
- Limited time and resources for workforce training
- Clinicians being responsible for answering patient and caregiver questions about AI use
- Uncertain implementation strategies
- Lack of clear evidence regarding safety and effectiveness

Successful adoption requires inclusive governance models and sufficient time for clinician education and training.

## **6. What challenges do patients and caregivers want AI to address, and what concerns do they have?**

Patients and caregivers hope AI can:

- Improve access to care
- Reduce administrative burdens
- Personalize treatment recommendations

- Enhance care coordination
- Support identification and evaluation of new treatment options

However, concerns include:

- Diminished relationships with clinical providers
- Privacy and protection of personally identifiable information
- Secondary monetization of health data
- Algorithmic bias and inequity
- Lack of transparency in how AI informs clinical decisions
- Use of AI tools without meaningful patient awareness or consent

Patients often prioritize safety, fairness, and transparency over cost efficiency. Historical examples of data use without adequate disclosure continue to shape public trust. HHS should ensure that economic incentives do not outpace ethical safeguards.

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Artificial intelligence holds significant promise to improve clinical care; however, adoption must be purposeful, evidence-driven, and clearly aligned with patient benefit. AMIA encourages HHS to pursue a balanced strategy that aligns regulatory oversight with risk, modernizes payment to reward demonstrated value, and strengthens governance and implementation capacity across care settings. Robust privacy protections, transparency, and ongoing evaluation will be essential to sustaining public trust.

Thank you for your consideration. For questions or additional information, please contact Tayler Williams, Senior Manager of Public Policy, AMIA, at [twilliams@amia.org](mailto:twilliams@amia.org).

Sincerely,



Eileen Koski  
AMIA Public Policy Committee Chair