ata ACTION

February 20, 2026

Robert F. Kennedy Jr.
US Department of Health and Human Services
H. Humphrey Building
200 Independence Avenue
SW Washington, DC 20201

Re: ATA Action Response to HHS Health Sector AI RFI

ATA Action, the American Telemedicine Association's affiliated trade organization, appreciates the opportunity to provide comments on the adoption and use of artificial intelligence (AI) in clinical care. Our input reflects discussions among key stakeholders in the healthcare and technology sectors, including clinicians, life sciences companies, regulatory experts, and AI developers. Collectively, these stakeholders share a strong interest in ensuring that AI is deployed in ways that are safe, effective, and scalable, and grounded in measurable real-world performance, while enabling continued innovation to improve patient outcomes and access to care.

1. Need for a Federal Framework

We strongly support the development of a federal regulatory framework for AI in clinical care. The current 50-state patchwork of laws, enforcement actions, and private rights of action creates confusion and can stifle innovation. A clear, unified federal framework grounded in validated performance standards and accountability mechanisms must be established to ensure consistent national expectations for patient safety, transparency, and trust. Federal leadership is essential to provide regulatory certainty and prevent fragmentation that impedes responsible innovation and adoption. Without such clarity, developers and providers face unnecessary barriers to innovation, and patients may not fully benefit from AI-enabled tools. A national framework would provide guidance for adoption at scale and ensure that federal preemption supports, not undermines, safe, effective implementation of AI across the healthcare system. Such a framework should align with existing federal authorities—including FDA oversight, HIPAA protections, and ONC transparency requirements—while establishing harmonized standards that allow AI tools to scale responsibly across care settings.

2. Regulatory Clarity
AI regulation should provide clear and actionable guidance to reduce uncertainty for developers, providers, and patients. Specifically, regulations should clarify:

- **Scope of Oversight:** Oversight should be clearly defined based on the intended clinical function and validated performance of an AI system, ensuring clarity about when federal regulatory requirements apply and how those requirements interact with professional standards of care.

- **Risk-Based vs. Outcome-Focused Approaches:** Regulatory policy should prioritize outcome-focused evaluation centered on measurable safety, reliability, and real-world clinical performance. Oversight should scale according to validated evidence and demonstrated impact rather than relying on static categorical distinctions. This approach supports innovation while maintaining rigorous safeguards where patient outcomes are materially affected.

- **Safe Harbor Provisions:** Clinicians and developers should have explicit protections when using FDA-regulated AI devices as intended within clearly defined parameters, reducing liability concerns and encouraging adoption of approved technologies. Safe harbors are particularly important for emerging technologies, such as generative AI or adaptive algorithms, where responsible use could otherwise be discouraged by regulatory uncertainty. HHS should establish clear safe harbor protections for clinicians and developers who deploy AI tools in accordance with FDA authorization, labeling, cybersecurity expectations, and recognized governance frameworks (such as NIST AI Risk Management Framework and FDA Good Machine Learning Practices). Safe harbors such as a right to cure period and rebuttable presumptions for compliance with the aforementioned regulatory frameworks, would incentivize greater AI innovation, adoption and improved safety. These protections will reduce uncertainty and accelerate responsible adoption.

In addition, regulatory clarity should include defined obligations for ongoing quality assurance, post-deployment monitoring, model updating, and mitigation of performance drift or bias. A sustainable regulatory framework must recognize that AI performance can change over time and require structured processes for validation and recalibration.

Clear regulatory guidance in these areas would promote trust, reduce fragmentation, and accelerate safe, scalable adoption of AI in clinical care.

3. FDA Considerations

- **Safe harbor/medical device carveouts:** Clear guidance is needed regarding which AI tools are eligible for FDA-approval, which fall under FDA's enforcement discretion, and the expectations for cybersecurity and labeling. Additional clarity is also needed around Prescription Drug Use Related Software (PDURS) regulatory boundaries, including when AI functionality is treated as a regulated device or SaMD versus non-device clinical decision support. Such guidance should emphasize performance validation, post-market monitoring, and continuous improvement mechanisms that ensure tools remain safe and effective over time.

- **Right to cure:** Mechanisms should exist to allow for the identification and correction of AI errors without penalizing providers unnecessarily. This is also an appropriate area for illustrative examples, such as reduced or mitigated HIPAA penalties, where timely remediation, transparency, and corrective action demonstrably reduce patient risk.

- **Liability:** Providers remain ultimately responsible for clinical decisions; however, guidance is needed on the responsibilities of developers and deploying entities (e.g., hospital systems), particularly where AI systems operate with varying degrees of autonomy or integration into clinical workflows. Federal guidance should clearly delineate responsibilities across developers, deployers, and clinicians based on control, capability, and validated system performance.

4. Scope of AI Autonomy

Policy should emphasize appropriate oversight, accountability, governance, and measurable performance standards for AI-enabled clinical functions. The role of AI in clinical care should scale based on evidence, validation, regulatory authorization, and real-world performance data.

A performance-based framework can support innovation while maintaining safeguards, recognizing that:

- AI systems may appropriately perform functions commensurate with their demonstrated safety, effectiveness, and regulatory status.

- Governance expectations should align with validated system capability, regulatory authorization, and real-world performance data. As AI systems demonstrate reliability and effectiveness within defined parameters, policy should permit appropriate integrated clinical deployment consistent with applicable standards.

- Clear accountability, transparency, and governance structures are essential for AI-enabled clinical decision-making, regardless of the level of autonomy.

This approach preserves patient protections while allowing flexibility for future models that may prove safe, effective, and well-regulated as technology continues to evolve.

5. Implementation and Adoption

Successful implementation and broader adoption of AI in clinical care depend on demonstrating clear value in real-world settings. Pilot programs that show measurable improvements in outcomes and effective workflow integration are essential to building provider confidence and scaling adoption. AI tools are unlikely to gain traction if they do not meaningfully improve efficiency, quality, or patient outcomes. Radiology has emerged as a leading example of successful integration, and expansion into additional specialties should be guided by evidence-based best practices and ongoing performance evaluation.

Federal agencies should support standardized performance evaluation frameworks that enable benchmarking, interoperability, and reproducibility across care settings. These frameworks should facilitate access to high-quality, longitudinal, multi-source data, helping AI tools integrate evidence safely and effectively. Transparent performance reporting, continuous monitoring, and AI-assisted pharmacovigilance mechanisms will further strengthen provider and patient trust by ensuring ongoing safety, early detection of treatment-emergent risks, and reliable clinical outcomes.

Robust data collection and evaluation frameworks are equally important to support provider trust, enable benchmarking, and promote continuous improvement. Establishing mechanisms for performance monitoring and outcome measurement will help ensure that AI tools are used effectively, responsibly, and in ways that deliver sustained clinical value.

6. Reimbursement and Market Incentives

Reimbursement models should recognize the value of AI in chronic disease management and other high-value care areas. CMS programs, such as the CMMI ACCESS Model, could serve as a blueprint for incentivizing AI adoption beyond chronic conditions.

Reimbursement policies should reflect the full scope of effort, resources, and risk involved in developing AI tools, particularly those subject to FDA regulation. Each AI device or software platform varies significantly in terms of:

- Development time and complexity: Some AI tools require years of algorithm training, clinical validation, and iterative testing.
- Resource intensity: Investment in data acquisition, annotation, cybersecurity safeguards, and integration into existing workflows can be substantial.
- Regulatory requirements: FDA clearance or approval, ongoing monitoring, and compliance with labeling, cybersecurity, and quality standards entail additional costs and operational effort.
- Research and validation: Evidence generation, clinical trials, and real-world performance studies are essential to ensure safety and effectiveness, and these processes vary widely by device or application.

CMS should take all of these factors into consideration when establishing reimbursement levels, recognizing that AI adoption is contingent on viable economic models. We also encourage consideration of new reimbursement approaches and coding frameworks that better capture the value of AI-enabled care, including models that move beyond time-based methodologies and instead reflect clinical impact, automation, and outcomes. Appropriate reimbursement not only rewards innovation but also ensures that AI tools can be safely and effectively integrated into clinical practice, supporting better patient outcomes while sustaining developer investment and innovation.

7. ATA Action Recommendations

- Convene a stakeholder advisory group to define AI evaluation standards, real-world performance benchmarks, governance best practices, and safe harbor criteria grounded in validated evidence.
- Provide clear regulatory frameworks and guidance on labeling, cybersecurity, and compliance expectations.
- Ensure transparency in the allocation of responsibility and liability among providers, developers, and deploying organizations.
- Support pilot programs that demonstrate outcomes and facilitate scalable adoption.
- Develop reimbursement strategies that take into consideration clinical value, workflow efficiency and patient outcomes enabled by AI.
- Establish a national performance-based framework that aligns oversight with validated outcomes and harmonizes standards across federal agencies to provide regulatory certainty and scalability.
- Clarify FDA's device approval process, scope and requirements for AI tools used in healthcare settings.

ata**ACTION**

We appreciate HHS's leadership in advancing a thoughtful and coordinated approach to AI policy. Establishing clear, consistent performance-driven federal standards will be critical to ensure that AI enhances patient safety, strengthens provider confidence, and accelerates innovation across the healthcare system. ATA Action stands ready to serve as a resource and partner in this effort and looks forward to continued collaboration to ensure AI is deployed responsibly, effectively, and at scale to improve care for all patients.

Sincerely,

Alexis Apple
Deputy Executive Director
ATA Action