Office of Science and Technology Policy
Eisenhower Executive Office Building
1650 Pennsylvania Avenue NW
Washington, DC 20504

Attn: RFI Response - Regulatory Reform on Artificial Intelligence (OSTP-TECH-2025-0067)

Dear OSTP Leadership:

The American Medical Informatics Association (AMIA) appreciates the opportunity to respond to the Office of Science and Technology Policy's Request for Information (RFI) on regulatory reform for Artificial Intelligence (AI). As the professional home for over 5,500 informaticians and the leading organization advancing biomedical and health informatics, AMIA brings unique expertise regarding AI implementation in healthcare settings.

AMIA acknowledges the Administration's dedication to maintaining the United States' position at the forefront of healthcare innovation, consistently exemplified through institutions such as the Assistant Secretary for Technology Policy (ASTP), the Agency for Healthcare and Research Quality (AHRQ), and National Institutes of Health (NIH) National Library of Medicine (NLM), among other agencies[1,2]. We support the continuation of this leadership role in the realm of AI, while emphasizing the critical importance of implementing robust safeguards to optimize healthcare delivery and patient outcomes. Our members, including clinicians, researchers, educators, and industry professionals, have decades of experience developing, implementing, and evaluating AI systems in healthcare. This response reflects AMIA's expertise and established policy positions on responsible AI development and careful consideration for reforming federal regulations[3,4].

Documentation Burden and AI

Clinical documentation represents an area where AI tools offer significant potential to support healthcare providers while maintaining necessary patient privacy protections. AMIA's 25x5 Task Force has identified documentation burden as a key challenge, and we support collaborative efforts between regulators and healthcare organizations to establish clear frameworks that enable AI deployment while preserving the strong privacy protections patients rightfully expect. To achieve meaningful documentation reform, AMIA advocates for leveraging technology to eliminate duplicate data entry through enhanced data liquidity and interoperability. The Trusted Exchange Framework and Common Agreement (TEFCA) provides a foundation for building trust between data-sharing entities, enabling secure and efficient information exchange. Supporting Fast Healthcare Interoperability Resources (FHIR®)

[1] AMIA Factsheet - ASTP and NLM
[2] Friends of AHRQ Appropriations Request FY26
[3] AMIA Public Policy Principles
[4] AMIA Policy Brief: AI in Healthcare - Touchstones for Responsible Use

as the standardized approach for healthcare information exchange further streamlines these processes, allowing AI tools to access and process data without requiring repetitive manual input from providers.[5]

Prior Authorization (PA) represents a major source of burden for clinicians, health systems, and patients, requiring elimination or substantial reform. AI tools can reduce delays and denials while identifying and eliminating excessive or inappropriate care delivery. To achieve this potential, several requirements must be met:

- payors must provide transparency on AI tool function and use in PA processes, including medical necessity determinations, allowing third-party auditors to review algorithms and implement feedback mechanisms;
- AI tools alone cannot be used to deny PA requests, ensuring AI-generated denials don't override point-of-care clinical decision-making and that tools create personalized rather than generalized care plans;
- and interoperability standards must be improved for integrating AI tools with EHRs for PA requests, working with the ASTP to enhance integration.[6]

Regulatory Frameworks Adapting to Emerging Technologies

The evolution of regulatory frameworks to accommodate AI's unique characteristics demonstrates the healthcare system's commitment to both innovation and safety. Continuous learning systems present an opportunity for regulators and stakeholders to collaborate on new approaches. Current medical device regulations, which have ensured product safety for decades, can be supplemented with pathways that accommodate AI's iterative nature. We recommend working with the Food and Drug Administration (FDA) to develop complementary regulatory mechanisms that maintain rigorous safety standards while enabling real-time performance monitoring, algorithmic auditing, appropriate rollback procedures, and transparent patient communication about system updates.

Additionally, we propose standardized package labeling for AI-based digital health technologies. Similar to nutrition labeling standards, labeling would increase transparency and help address the black box problem in AI medical devices. The labeling framework could encompass key elements that would be required on AI tool packaging:

- First, the type of evidence basis would describe the primary benefit or utility of the tool, specifying whether it was validated through randomized controlled trials, real-world evidence, or other methods.
- Second, an ethical framework section would outline population benefit-risk considerations, including inclusion and exclusion criteria as well as the tool's interpretability and explainability.
- Third, reproducibility information would provide statistically quantified and qualified claims about specific indications, efficacy, data lineage, and model versioning.

[5] AMIA 25x5 Policy Reforms
[6] AMIA 25x5 Taskforce Recommendations to Reform Prior Authorization

- Fourth, the training data description would detail the applicability and specificity to various populations, explaining the rationale for included and excluded populations and how training and testing data were split.
- Fifth, a disclosure of bias section would clearly state limitations of use and contraindications, including potential issues with phenotypic traits such as skin tone.
- Sixth, a risk management framework component would address product integrity concerns, covering cybersecurity resilience, prevention of AI poisoning, and measures for protecting user data through methods like differential privacy.
- Finally, performance metrics would present the primary benefit or utility through standard measures including sensitivity, specificity, negative predictive value, and positive predictive value.

This standardization would create consistency across different types of manufacturers and ensuring users understand the capabilities, limitations, and evidence basis for AI medical tools.[7]

Additional Recommendations

Several areas would benefit from additional regulatory guidance to support responsible AI deployment while maintaining robust patient protections. Building on the successful ASTP HTI-1 rule's Decision Support Interventions requirements, we support the development of comprehensive standards for algorithmic transparency. This collaborative approach should establish risk-appropriate explainability requirements, robust documentation standards for AI development processes, and comprehensive performance monitoring frameworks. Clear regulatory expectations will help developers create safer, more effective AI systems while ensuring consistent patient protections across the healthcare ecosystem.

AMIA recognizes the value of ASTP's algorithmic transparency requirements in the HTI-1 rule as an important step in establishing comprehensive federal AI governance. These requirements for predictive decision support interventions demonstrate how transparency standards can work in harmony with technological advancement. The framework effectively integrates explainability requirements with implementation realities, offering a foundation for consistent standards across federal healthcare programs.

Effective AI deployment in healthcare benefits from robust data exchange standards, and AMIA appreciates the role of FHIR-based interoperability standards in creating a structured foundation for health information exchange. Federal regulations can support a measured approach that enables data sharing within appropriate frameworks while systematically building toward comprehensive interoperability standards. This approach allows for responsible development within established guardrails while regulatory frameworks continue to evolve and mature.

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[7] Perakslis E, Nolen K, Fricklas E, Tubb T. Striking a Balance: Innovation, Equity, and Consistency in AI Health Technologies. JMIR AI. 2025;4:e57421. doi: 10.2196/57421
The article is available at: https://ai.jmir.org/2025/1/e57421

AI systems have significant implications for health equity, making regulatory oversight crucial for ensuring fair and equitable outcomes. Federal AI regulations appropriately require comprehensive safeguards including representative training data encompassing all patient populations, systematic bias testing across demographic categories (including race, gender, ethnicity, geographic location, and age), continuous monitoring for differential outcomes, and structured community engagement in development and deployment processes. These regulatory requirements help ensure that AI technologies serve all Americans equitably while protecting vulnerable populations from potential adverse impacts.

Conclusion

Integration of AI tools in healthcare brings great opportunities as well as challenges. AI use promises improved quality, safety, and care equity by enabling real-time data analysis to support clinical decision-making and personalized treatment. At the same time, risks of biases and lack of transparency pose safety and accessibility threats if deployed without appropriate safeguards. AMIA's members, who work at the intersection of healthcare, technology, and policy, offer unique expertise in navigating these complex challenges and welcome collaboration.

For questions or additional information, please contact Tayler Williams, AMIA's Senior Manager of Public Policy, at twilliams@amia.org.

Sincerely,

Eileen Koski

Chair, AMIA Public Policy Committee