



Robert F. Kennedy, Jr.
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
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Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
2500 Security Boulevard
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Dr. Thomas Keane
Assistant Secretary for Technology Policy
National Coordinator for Health IT (ONC)
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Attn: AMIA Response to CMS Health Tech Ecosystem Initiative

Dear Secretary Kennedy, Administrator Oz, and Assistant Secretary Keane:

The American Medical Informatics Association (AMIA) has been at the forefront of health informatics innovation and interoperability efforts for over three decades. Since our founding in 1990 with more than 5,500 members, AMIA has consistently advocated for evidence-based approaches to health information technology that prioritize patient safety, privacy, and equitable access to care. Our organization has played a pivotal role in developing foundational frameworks that guide today's health IT landscape, including contributions to the development of HL7 FHIR standards, participation in the Trusted Exchange Framework and Common Agreement (TEFCA) development process, and leadership in establishing clinical informatics as a medical subspecialty through ACGME-accredited fellowship programs. AMIA's expertise spans the full spectrum of health informatics, from electronic health records and clinical decision support systems to artificial intelligence applications and population health analytics. Our members include physicians, nurses, informaticists, researchers, and technology professionals who have collectively shaped the evolution of health IT policy and implementation. Through our established principles on Health Data Privacy, AI in Healthcare, Population & Public Health, and Quality Measurement, AMIA has provided evidence-based guidance that has informed major federal initiatives and regulatory frameworks.

Given this extensive background and our organization's commitment to advancing health informatics in ways that serve all patients safely and equitably, we respectfully offer our expertise to assist CMS and ASTP in addressing critical questions regarding the CMS Health Tech Ecosystem Initiative. AMIA stands ready to collaborate with your teams to develop comprehensive solutions for the complex challenges this initiative presents. We appreciate your commitment to identify early adopters to achieve the vision of a health ecosystem designed to deliver immediate value to patients through real-world, high-impact tools that are secure, user-centered, and connected.

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Regarding patient safety and privacy protections, we would welcome the opportunity to work with CMS to ensure consistent privacy protections across the 60+ participating companies with varying privacy practices, helping to develop mechanisms that enforce compliance with granular consent requirements. AMIA is prepared to assist in designing specific safeguards that ensure user-centered design and prevent harassment, targeting, bias, and data exploitation as outlined in our Health Data Privacy Principles, particularly for vulnerable populations. We can provide guidance on implementing explicit opt-in consent processes with clear, informed consent mechanisms to ensure patient autonomy. Additionally, AMIA's expertise could prove valuable in establishing comprehensive audit trails across the ecosystem to enable patients to meaningfully control their health information, as well as developing systematic safety monitoring, error reporting mechanisms, and governance frameworks to prevent patient harm.

In the area of AI implementation and algorithmic accountability, AMIA is uniquely positioned to help CMS ensure that AI-driven conversational assistants, symptom checkers, and care navigation tools incorporate the three essential safeguards identified in our AI Principles: auditability for performance tracking, explainability for patient understanding, and special scrutiny to prevent algorithmic bias. We stand ready to collaborate on developing measures that address algorithmic bias to prevent worsening of healthcare inequities, particularly for marginalized communities. Our organization can also assist in ensuring transparency in AI decision-making processes and providing patients with understandable explanations of automated recommendations.

Ensuring equity and access remains a cornerstone of AMIA's mission, and we are committed to helping CMS serve the Medicare beneficiaries lacking digital device access and other vulnerable populations, including elderly patients and those with complex conditions. We can provide guidance on preventing the creation of a two-tiered system where tech-literate populations benefit while vulnerable groups face additional barriers to care. AMIA is prepared to help align this technology-first approach with addressing healthcare's core challenges of access, affordability, and equity as emphasized in our Population & Public Health Principles.

In terms of funding and technical support, AMIA is ready to work with CMS on securing dedicated funding for ACGME-accredited Clinical Informatics fellowships to ensure adequate workforce development. We can assist in developing technical assistance programs for rural providers and other under-resourced healthcare organizations, as well as creating support mechanisms to reduce documentation burden on healthcare workers who may be overwhelmed by additional technological requirements. Without proper informatics expertise guiding implementation, new technologies often increase administrative burden and workflow disruptions rather than improving efficiency, ultimately leading to clinician burnout and potentially compromising patient care quality.

Quality measurement and outcomes represent areas where AMIA's expertise can be particularly valuable to CMS. We are prepared to help incorporate outcome-based measures for improving actual health results, as emphasized in our Quality Measurement Principles. AMIA can assist in developing specific metrics that evaluate whether the initiative achieves its goals of improving patient care

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coordination and health outcomes rather than merely facilitating data exchange, and we can help establish success measures that extend beyond technological implementation metrics.

Finally, regarding governance and professional oversight, AMIA is ready to provide guidance on incorporating board-certified clinical informaticists and other health informatics professionals in the governance and oversight of this initiative. We can assist in developing evidence-based governance frameworks that ensure clinical appropriateness and safety of technology implementations, and we stand ready to help establish mechanisms that ensure informatics expertise guides decision-making throughout the initiative's development and implementation phases.

AMIA appreciates the initiative's ambitious scope and potential to advance healthcare interoperability. As an organization with over 30 years of experience in health informatics, we believe our collaborative approach can help address the complex challenges this initiative presents while ensuring that technological innovation serves all patients safely, equitably, and effectively. We look forward to the opportunity to work closely with CMS and provide our expertise to strengthen this initiative and ensure its success.

Sincerely,

Eileen Koski

Chair of the Public Policy Committee

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