February 27, 2026

Dr. Thomas Keane
Assistant Secretary for Technology Policy
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
330 C St. SW
Washington, DC 20201

Re: Public Comments on the Proposed Rule — Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability; Withdrawal *(RIN: 0955–AA09)*

Dear Assistant Secretary Keane,

The American Medical Informatics Association (AMIA) appreciates the opportunity to comment on the proposed rule, *Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability; Withdrawal* (HTI-5). AMIA's overarching position on this proposed rule is that it is premature, although we do support the ultimate goals of reducing burden on the health IT community and improving data exchange, including through AI-enabled interoperability.

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 plays a leading role in advancing health and wellness by moving basic research findings from bench to bedside, and evaluating interventions, innovations, and public policy across care settings and patient populations.

AMIA aligns with many of ASTP/ONC's current proposals conceptually. Specifically, we support modernization through APIs and interoperability standards, agree that excessive regulatory requirements can impose burden, and support ASTP/ONC's focus on patient access and evolving technology definitions. However, the push to deregulate in 2026 by removing existing infrastructure before another, FHIR-based API infrastructure is available is rushed, unnecessary, and ill-conceived. AMIA has consistently supported the use of HL7 FHIR standards. Research shows that FHIR provides a standards-based, interoperable apps platform that enables medical applications to be written once and run unmodified across different healthcare IT systems.[1] We endorsed FHIR implementation in our response

[1] Mandel, J. C., Kreda, D. A., Mandl, K. D., Kohane, I. S., & Ramoni, R. B. (2016). SMART on FHIR: A standards-based, interoperable apps platform for electronic health records. *Journal of the American Medical Informatics Association, 23*(5), 899–908. https://doi.org/10.1093/jamia/ocv189

to the CMS/ASTP joint RFI on the Health Tech Ecosystem but also considered a phased implementation approach given the complexity of standards adoption.[2] During ONC's 21st Century Cures Act proposed rule, AMIA supported the adoption of FHIR as the proposed API standard.[3]

Scope and Structure of Certification Program Changes

HTI-5 proposes significant removal of criteria (including privacy/security and AI-specific certification) that goes beyond the calibration AMIA suggested in HTI-1/HTI-2 proposed rule comments. In those comments, AMIA detailed operational and feasibility concerns regarding timelines for health IT developers to comply with the new compliance requirements, readiness of developers, health organizations and their staff, and clinician burden.[4,5] HTI-5 proposed rule doubles down on deregulatory action rather than addressing AMIA's suggested incremental refinement.

The HTI-5 proposed rule would remove 34 of the 60 existing certification criteria and raises concern that although certified health IT developers may choose to retain certain functionalities, they would no longer be required to include them as part of their certified capabilities. In practice, this could allow developers to unbundle previously certified features and offer them as optional, fee-based add-ons. While such functionality might technically remain available, pricing or contractual barriers could make access financially prohibitive for providers, particularly smaller or resource-limited organizations, which could have the actual effect of diminishing, rather than enhancing access to proven capabilities. AMIA encourages ASTP/ONC to assess whether removing these criteria unintentionally creates gaps in equitable access to essential functionality and to clarify how patient access, interoperability, and transparency goals will be protected if certified capabilities become optional, separately priced features.

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[2] American Medical Informatics Association. (2025, June 16). *AMIA CMS_ASTP-RFI Health Tech Ecosystem Comment Letter* [Comment letter submitted to the Centers for Medicare & Medicaid Services and ASTP/ONC]. https://brand.amia.org/m/58aba4bb9fde4075/original/AMIA-CMS_ASTP-RFI-Health-Tech-Ecosystem-Comment-Letter.pdf

[3] American Medical Informatics Association. (2019, May 23). *AMIA supports ONC Cures rule, recommends ways to improve data access for patients, clinicians, and researchers* [Comment letter submitted to the Office of the National Coordinator for Health Information Technology]. https://brand.amia.org/m/35f89f90fd562d24/original/AMIA-Supports-ONC-Cures-Rule-Recommends-Ways-to-Improve-Data-Access-for-Patients-Clinicians-and-Researchers.pdf

[4] American Medical Informatics Association. (2023, June 20). *AMIA comments on ONC Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1)* [Public comment letter submitted to the Office of the National Coordinator for Health IT]. https://brand.amia.org/m/ffd5f878a58babb/original/AMIA-ONC-HTI-1-Comments.pdf

[5] American Medical Informatics Association. (2024, October 4). *AMIA HTI-2 comment letter final* [Public comment letter submitted to the Office of the National Coordinator for Health Information Technology]. https://brand.amia.org/m/26505498d5951f15/original/AMIA-HTI-2-Comment-Letter-Final.pdf

Additionally, in the proposed revision of the Decision Support Interventions (DSI) certification criterion, ASTP/ONC proposes removing the AI model card requirements, first introduced in HTI-1, and only just implemented in 2025, providing less than one year of implementation experience and data. The transparency requirements for AI-enabled clinical DSI, including provisions such as model cards, represent emerging regulatory standards within the health IT marketplace.

For clinical users, transparency is generally intended to support health system–level evaluation through AI governance processes, rather than point-of-care decision-making by individual clinicians. In this context, transparency can also inform how health systems provide guidance and education to clinicians and staff on appropriate use. Transparency about AI systems is essential to health systems as part of their evaluation processes. Health systems request and review information such as AI model cards from current and prospective vendors, including EHR vendors and other developers, when considering AI adoption. Increased accessibility and standardization of this information, such as through centralized or public repositories, could support more efficient review and comparison, rather than information located across multiple sources. Several AI-specific requirements related to source transparency, risk management, and intervention enablement would be eliminated. Blocking appropriate health information requests from AI-enabled technologies is explicitly identified as potential information blocking.

Model cards can enable patient engagement by providing transparent, accessible information about the AI tools used in their care. This transparency could allow patients to understand how AI models are trained and validated, ask informed questions about AI-generated recommendations, and participate meaningfully in shared decision-making about treatment options influenced by algorithm-based tools, ultimately fostering trust and supporting patients' rights to informed consent in AI-assisted healthcare delivery.

Given this limited implementation timeframe and the evolving nature of these requirements, there is insufficient empirical evidence to determine the degree of efficacy of these transparency mechanisms in advancing the safe and appropriate deployment of clinical decision support tools. **As such, it is AMIA's position that HTI-5's proposed elimination of the entire DSI AI transparency framework is premature, as it would remove these standards before adequate data and stakeholder experience have been gathered to evaluate their utility and impact on patient safety, clinician trust, and care quality outcomes.**

Insights and Maintenance of Certification

The proposed rule substantially narrows Insights and Maintenance reporting obligations. Health IT developers would only be required to report one measure – the use of FHIR in applications through certified health IT – while multiple existing access, exchange, immunization, and bulk data measures would be removed, despite the fact that many

existing non-FHIR mechanisms have been widely and effectively adopted. For example, electronic laboratory reporting (ELR) coverage in most jurisdictions exceeds 95% using HL7 v2.5.1 and is meeting public health data needs. At this level of adoption, transitioning to another process would itself become a burden and should not be prioritized over addressing systems that genuinely need improvement.

AMIA supports the proposed rule's goal of advancing interoperability through FHIR-based APIs but urges ASTP/ONC to strengthen transparency around measuring progress and adoption across all care settings to avoid widening gaps in interoperability. Specifically, the final rule should require clear, outcome-oriented metrics to track the spread, scale, and real-world use of FHIR APIs not only in hospitals and ambulatory care, but also in under-resourced and rural settings, post-acute and long-term care, behavioral health, and emerging models such as at home care. Without such visibility, gaps in interoperability may persist or widen across the healthcare ecosystem.

In addition, AMIA recommends ASTP/ONC further shift certification emphasis away from broad EHR functionality and toward certifying standardized data models and APIs. Prioritizing conformance to FHIR profiles, USCDI data classes, and consistent API behavior will better advance the intent of the 21st Century Cures Act than recertifying functionality that does not directly enable exchange. Finally, the rule should continue to reinforce a person-centered, "no special effort"[6] API ecosystem, ensuring that patients and authorized applications can access and exchange electronic health information seamlessly and consistently, regardless of vendor or care setting, while balancing deregulatory goals with accountability for nationwide interoperability progress.

C-CDA

HTI-5 further advances a transition away from C-CDA standards toward FHIR-based APIs for data exchange, particularly for transitions of care and public health reporting. While AMIA supports the transition to FHIR-based APIs, AMIA urges a longer runway to make this transition.

AMIA supports this transition because our members are aware that C-CDA is not a perfectly effective way for clinicians to exchange data. Our members have even reported having notes and data they input being reported back to them, making the exchange ineffective. However, removing the C-CDA requirements before FHIR-based APIs are available removes the infrastructure without having anything to replace it, akin to removing the stairs before providing an escalator, elevator, or other mode of transition between

[6] Adler-Milstein, J., Aggarwal, N., Ahmed, M., Castner, J., Evans, B. J., Gonzalez, A. A., James, C. A., Lin, S., Mandl, K. D., Matheny, M. E., Sendak, M. P., Shachar, C., & Williams, A. (2022). *Meeting the moment: Addressing barriers and facilitating clinical adoption of artificial intelligence in medical diagnosis*. NAM Perspectives. Advance online publication. https://doi.org/10.31478/202209c

levels. Additionally, without the C-CDA, there are no requirements for EHRs to accept information from elsewhere, which would only stymie interoperability and create data quality issues. EHRs will be forced to rely on state requirements for information exchange, which obviously varies between jurisdictions and could exacerbate barriers to data exchange across jurisdictions.

Existing public health systems still dependent on C-CDA may face data quality or compatibility challenges without a viable alternative. Moreover, the deregulation of C-CDA for public health reporting will effectively shift responsibility for interoperability from federal certification to local implementation, creating greater variability in how (and whether) providers report certain public health data. And without Insights Condition Reporting measures to monitor public health reporting activities, public health authorities may have less visibility into the real-world performance of EHR-based reporting, potentially reducing the ability to identify underperforming systems and interoperability failures.

AMIA encourages ASTP/ONC to ensure FHIR-based APIs are available and required under TEFCA before removing C-CDA requirements, January 1, 2027, is entirely premature.

Clinical Decision Support and AI

HTI-5 proposes removing certification requirements for predictive clinical decision support and revising DSI criteria. In the proposed rule, ASTP/ONC states "While this approach would directly and rapidly reduce compliance burdens for health IT developers that participate in the Certification Program, more broadly, it enables ASTP/ONC to reset the Certification Program's regulatory scope and establish a new foundation on which to build FHIR-based API requirements in the future." This statement nails the prematurity issue on the head. AMIA is concerned with building the FHIR-based API requirements for the future while dropping the existing AI transparency requirements immediately will, yet again, remove infrastructure without providing an alternative support structure. In addition to the infrastructure concerns, AMIA does not understand why ASTP/ONC would propose rolling back the AI transparency requirements now. These requirements are new and have not matured enough to even know if they are ineffective and burdensome. The rule was effective March 11, 2024, for developers to update their certified technology to the new DSI criterion by December 31, 2024, to allow just 2025 to determine its efficacy. Additionally, all the work and investment to meet the requirements has already been met. The current burden and cost are associated with maintenance of AI tools. If maintaining the tools' accuracy and efficacy is up for debate, AMIA would be interested in discussing how ASTP/ONC foresees those AI tools working and their use by clinicians and health systems.

Our physician members have repeatedly stated that they would not trust an AI CDS tool without at least the opportunity to assess how the model is trained. Physicians may not

always access the information, but they would be more likely to distrust the advice if such information was not provided.

AMIA encourages ASTP/ONC to maintain the AI transparency requirements until both the AI tools and requirements are mature enough to understand their true efficacy.

In healthcare and life sciences, the regulation of AI is warranted due to the significant unknowns associated with these technologies and the potential for unintended consequences in a high-risk, patient-facing environment. The HTI-5 proposed rule proposes eliminating certain AI transparency and accountability requirements on the basis that ASTP/ONC found "no publicly available evidence" that existing transparency provisions improved patient care outcomes, such as identifying deficient algorithms or prompting local validation.

If such evidence is lacking, AMIA strongly encourages ASTP/ONC to clarify what literature review or evaluation methods were used to reach this conclusion. Additionally, what monitoring mechanisms were used to determine that current requirements were ineffective? Absent a clear evaluation framework, it is difficult to assess whether the requirements failed or whether implementation and measurement approaches were insufficient.

The proposed removal of key oversight mechanisms, EHR certification requirements, Safety-Enhanced Design criteria, and Real-World Testing, raises particular concern. While these programs are imperfect, they represent the only nationally scaled infrastructure for baseline safety, functionality, and accountability standards. Eliminating them without a clearly articulated alternative risks weakening minimum safety and efficacy safeguards at a time when AI tools are rapidly evolving.

AMIA's Biomedical Informatics–Driven Quality Measurement Public Policy Principle supports AI's promise in CDS and quality measurement but emphasizes that evolving AI tools must uphold human-centered values, especially transparency.[7] Under HTI-5, reducing transparency requirements risks weakening trust, oversight, and accountability at a time when clear insight into AI performance and data is essential to understand AI's future role in provision of healthcare and increasing efficiency.

Further, national policy direction from Sec. Kennedy Jr. has emphasized radical transparency in health care. The HTI-5 proposal appears to move in the opposite direction without identifying a replacement accountability structure. What mechanisms does

[7] American Medical Informatics Association. (2025). *AMIA Public Policy Principles 2025*. https://brand.amia.org/m/7094a39156542fdf/original/AMIA-Public-Policy-Principles-2025.pdf

ASTP/ONC envision to ensure ongoing monitoring of AI performance, model evolution, and real-world impact?

In February 2025, the American Medical Association released the "AMA Augmented Intelligence Research Physician sentiments around the use of AI in health care: motivations, opportunities, risks, and use cases Shifts from 2023 to 2024" survey results and found that physicians overwhelmingly want detailed, transparent information about AI tools in order to understand their capabilities and make informed choices about their use in practice. According to the survey, 78% of physicians rated information about how an AI's performance is monitored as useful, while 78% also rated clear explanations and references that help explain how AI decisions are made as useful. Performance metrics/validation data was considered useful by 72% of respondents and use case examples with expected outputs were useful to 70%.[8]

Additionally, recent FDA guidance on Clinical Decision Support narrows the agency's oversight in certain areas pushing software as a medical device out of its purview in criterion 3, increasing the importance of transparency and certification guardrails within the ASTP/ONC framework.[9]

For these reasons, maintaining meaningful transparency and accountability requirements within the HTI-5 rule is essential to patient safety, clinician trust, and responsible AI adoption.

Information Blocking Definitions of "Access" and "Use"

AMIA recognizes ASTP/ONC's foresight in explicitly recognizing automated and agentic systems in HTI-5's revised definitions of 'Access' and 'Use' for electronic health information. This regulatory clarity advances multiple AMIA Public Policy Principles. It directly supports *Patient Empowerment* principle, which calls for enabling individuals to 'access and transmit all electronic data contained in their electronic health record, rather than a limited or pre-defined set of data', rights increasingly exercised through automated systems and applications. The clarification also advances *HIT Data Standards & Interoperability* principle which supports 'HIT standards that are modular and substitutable, having extensible, expandable boundaries for use and application, with specifications for automated access, use, and integration with relevant data.' However, expanded access rights must be accompanied by proportional governance frameworks. Consistent with AMIA's *HIT Safety* principle supporting 'regulatory and

[8] American Medical Association. (2025). *Physician sentiments around the use of AI in health care: Motivations, opportunities, risks, and use cases* (Physician AI sentiment report). https://www.ama-assn.org/system/files/physician-ai-sentiment-report.pdf

[9] U.S. Food and Drug Administration. (2026). *Clinical decision support software: Guidance for industry and Food and Drug Administration staff* (GUI01400062). U.S. Department of Health and Human Services. https://www.fda.gov/media/109618/download

oversight frameworks that are designed to be proportional to the risk of the activity,' and our *AI Principles in Healthcare* principle on accountability requiring that 'AI harm and unintended consequences must be reported, assessed, monitored, measured, and mitigated'.[10] **AMIA urges ASTP/ONC to clarify how safety oversight, audit requirements, and information blocking boundaries apply when autonomous systems retrieve or act upon EHI without human intervention.**

Privacy and Security Certification Criteria

The HTI-5 proposed rule plans to eliminate all privacy and security certification requirements and the associated certification framework, based on the rationale that these criteria impose administrative burden and largely overlap with Health Insurance Portability and Accountability Act (HIPAA) obligations or widely adopted market practices.[11] AMIA's Public Policy Principles assert our position that Health Data Privacy and Health IT Safety as core pillars of informatics policy, emphasizing the importance of robust privacy and security safeguards to protect patient information and uphold ethical use of health IT.[12] Removing stand-alone privacy and security certification requirements could weaken baseline assurances of secure functionality, such as authentication, access control, audit logging, and encryption, that support patient safety and data integrity and that are not always directly enforced through HIPAA, particularly in the context of emerging AI capabilities. **Given the continuing evolution of health data technologies, AMIA urges that any deregulatory action from HTI-5 proposed rule should be paired with clear, risk-based mechanisms to ensure privacy and security protections keep pace with innovation. We ask if ASTP/ONC plan to potentially update Safety Assurance Factors for EHR Resilience (SAFER) Guides, annual review as condition of participation requirements, and guidance to explicitly address AI-enabled tools and interoperability use cases.[13]** By aligning certification expectations with AMIA's Principles for informatics policy of dependability, auditability, and human-centered transparency, ASTP/ONC can better safeguard trust while fostering responsible innovation.

Public Health Reporting

HTI-5 proposes removing or revising several public health reporting certification criteria, particularly those dependent on C-CDA standards. The proposal emphasizes a future transition to FHIR-based public health reporting and greater flexibility in meeting functional reporting requirements, a potentially transformative moment for public health informatics.

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[10] American Medical Informatics Association. (2025). *AMIA Public Policy Principles 2025*. https://brand.amia.org/m/7094a39156542fdf/original/AMIA-Public-Policy-Principles-2025.pdf

[11] ONC certification criteria for Health IT, 45 C.F.R. § 170.315 (2025). https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-170/subpart-C/section-170.315

[12] American Medical Informatics Association. (2025). *AMIA Public Policy Principles 2025*. https://brand.amia.org/m/7094a39156542fdf/original/AMIA-Public-Policy-Principles-2025.pdf

[13] Office of the National Coordinator for Health Information Technology. (2025). *SAFER guides: 2025 edition*. HealthIT.gov. https://healthit.gov/clinical-quality-and-safety/safer-guides/

Its emphasis on reducing regulatory burden, modernizing interoperability standards, and preparing for automation and artificial intelligence reframes certification not as a compliance exercise but as a lever for re-architecting national data exchange.
One of the proposal's most promising elements is the move toward FHIR-based exchange. Aligning public health reporting with the same API-driven ecosystem being advanced through standards bodies such as HL7 could finally reduce the fragmentation that has forced agencies to maintain separate pipelines for surveillance, quality reporting, and clinical interoperability. Over time, this convergence could lower integration costs, shorten onboarding timelines for new reporters, and enable more nimble responses to emerging threats. Advancing API-centric architectures and automated analytics would push training programs to modernize curricula around cloud platforms, interoperability frameworks, and AI stewardship. In the long run, HTI-5 could help reposition public health informaticians as system architects and strategic data leaders rather than custodians of legacy message feeds.

HTI-5's explicit recognition of automation and AI further expands this opportunity space. With standardized, near-real-time FHIR feeds, health departments could deploy machine-learning tools for outbreak anomaly detection, automated case identification prioritization, or monitoring climate-related health signals. For public health informatics as a discipline, the rule implicitly elevates public health data science to a core public-sector competency rather than an experimental side project.

Yet alongside these opportunities, HTI-5 raises significant concerns for the public health informatics community. A central risk is that certification reform may outpace the modernization capacity of many state, local, tribal, and territorial health departments. While vendors may rapidly pivot toward FHIR, agencies that are in the initial stages of data modernization and or have limited legacy surveillance platforms could face mounting pressure to develop and/or integrate new functionality and infrastructures, developing and/or maintaining C-CDA ingestion while building new APIs, without commensurate funding or technical assistance.

The proposal's embrace of functional flexibility also cuts both ways. Although it encourages innovation, it may dilute the leverage public health authorities have historically used to secure consistent vendor implementations and data sharing. If certification requirements become too permissive, jurisdictions could again be forced into bespoke negotiations with each EHR supplier, re-creating the patchwork of interfaces that national interoperability efforts were designed to eliminate.

HTI-5 further appears thin on transitional strategy. Publication in the Federal Register establishes regulatory seriousness, but the absence of a clearly articulated migration roadmap, complete with timelines, federally supported tooling, or shared services, creates uncertainty for informatics leaders planning multi-year system investments. Without such guardrails, agencies may divert scarce resources to infrastructure churn rather than to analytics, preparedness, and community engagement.

The rule's enthusiasm for AI-enabled futures also invites caution. While standardized feeds enable advanced modeling, HTI-5 offers little guidance on explainability, audit trails, bias mitigation, or accountability once automated systems inform public-health actions. Many of the historical criteria that have ensured accountability are removed in the proposed rule. For agencies operating in sensitive and/or public health environments, weak governance frameworks for algorithmic outputs could expose them to legal and reputational risks.

Moreover, smaller and rural jurisdictions often lack the informatics workforce or cloud infrastructure assumed by FHIR-first strategies. Without explicit incentives to support transitions for low-resource agencies, or federal investment in shared reporting hub, HTI-5 could inadvertently widen gaps in surveillance capacity nationwide, resulting in decreased early sentinel awareness and timely case investigation.

Finally, the proposal underestimates the legal and organizational inertia embedded in public health reporting. Surveillance workflows are tightly bound to statutes and regulations that reference historical standards and timelines. Technical certification reform alone cannot modernize public health data exchange unless accompanied by coordinated updates to reporting laws, funding mechanisms, and interagency governance structures.

The proposed revision or elimination of certification criteria that affect the public health system should be accompanied by an evaluation of the potential impact on both public health systems and the public's health. These proposed criteria include family health history. transmission to cancer registries; transmission to public health agencies-electronic case reporting; transmission to public health agencies- antimicrobial use and resistance reporting; transmission to public health agencies-health care surveys.

Taken together, HTI-5 offers a compelling vision for a leaner, AI-ready, FHIR-based public health informatics ecosystem, but one that depends heavily on synchronized investment, clear migration pathways, equity safeguards, in depth evaluation on public health and consumers, and governance frameworks. If these elements are strengthened in the final rule, HTI-5 could mark a genuine inflection point for population health intelligence. Without them, the risk remains that modernization will proceed unevenly, benefiting well-resourced

systems while leaving others to struggle at the margins of a rapidly evolving interoperability landscape.

TEFCA Manner Exception

The proposal would remove the TEFCA Manner Exception, citing limited incentive value and confusion regarding its application. The removal is intended to reduce misinterpretation that participation in TEFCA could be used to justify denying other lawful access to electronic health information.

AMIA urges ASTP/ONC to clarify the relationship between TEFCA and the Centers of Medicare & Medicaid Services Health Tech Ecosystem (CMS HTE). The CMS HTE was the result of the 2025 joint RFI between the two agencies.[14] The CMS HTE will not have verification requirements and if the deregulation in this proposed rule are finalized, what will be the oversight to standardize data and data exchange? What is the relationship between ASTP/ONC and the CMS HTE?

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HTI-5's proposals aim to reduce developer burden and create space for innovation, which are both goals AMIA strongly supports. In that endeavor, ASTP/ONC has created holes in the existing health data ecosystem infrastructure. It is clear that additional proposals are needed in a follow up policy to build a new, advanced infrastructure that supports quality data, interoperability, and AI adoption in clinical care. AMIA urges ASTP/ONC to release those proposals in a follow-up HTI-6.

Thank you for your attention to these comments. For questions or additional information, please contact Tayler Williams, AMIA's Senior Manager of Public Policy, at twilliams@amia.org.

Sincerely,

Eileen Koski

Eileen Koski
Public Policy Committee Chair

[14] Centers for Medicare & Medicaid Services & Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology. (2025, May 16). Request for information; Health technology ecosystem. *Federal Register*, *90*(94), 21034–21041. https://www.federalregister.gov/documents/2025/05/16/2025-08701/request-for-information-health-technology-ecosystem