

June 16, 2025

Dr. Mehmet Oz  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-0042-NC  
2500 Security Boulevard  
Baltimore, MD 21244

Dr. Thomas Keane  
Assistant Secretary for Technology Policy (ASTP)  
National Coordinator for Health IT (ONC)  
Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

**Re: Request for Information; Health Technology Ecosystem (CMS-0042-NC)**

Dear Administrator Oz and Assistant Secretary Keane:

On behalf of the American Medical Informatics Association (AMIA), we are pleased to submit these comments in response to the Request for Information (RFI) on the Health Technology Ecosystem. AMIA represents more than 5,500 informatics professionals from over 65 countries, serving as the professional home for biomedical and health informatics. We are dedicated to the development and application of informatics in support of patient care, public health, teaching, research, administration, and related policy.

AMIA appreciates CMS and ASTP/ONC's continued leadership in advancing interoperability and patient access to health information. We strongly support your vision of empowering Medicare beneficiaries through greater access to innovative health technologies that enable informed health decisions, improved chronic disease management, and more efficient care access. As the leading voice for health informatics professionals, AMIA offers the following recommendations to help realize this vision.

While we appreciate the opportunity to provide input on this important initiative, we must note that the 30-day comment period for this comprehensive RFI was insufficient given the breadth and complexity of the topics addressed. The RFI spans critical areas including patient access, provider workflows, technical standards, value-based care, security considerations, and the entire health technology ecosystem. A longer timeline of at least 60-90 days would have allowed AMIA to conduct more thorough member surveys, convene expert workgroups, and provide more detailed technical recommendations based on our members' extensive experience implementing and evaluating health IT systems. We

encourage CMS and ASTP/ONC to consider extended comment periods for future RFIs of this scope to ensure all stakeholders can provide the comprehensive feedback necessary to inform such transformative policy initiatives.

In developing this response, AMIA has drawn upon our previous comments on related rules and initiatives. We have identified and prioritized overlapping themes across these initiatives, particularly in the areas of patient data access, digital identity, and reducing barriers to information sharing, to provide cohesive and consistent recommendations that build upon our established policy positions.

## **Patient and Caregiver Considerations**

### **Digital Health Product Adoption**

AMIA recognizes that effective digital health tools must be designed with Medicare beneficiaries' unique needs in mind. Based on our members' expertise, we recommend:

1. **User-Centered Design:** Digital health products should prioritize usability for older adults, including larger text options, simplified navigation, voice controls, and multimodal interfaces that accommodate varying levels of digital literacy and physical abilities. Our members have emphasized that current health management applications face significant usability challenges across care settings, particularly with complex appointment scheduling systems and fragmented access to health information.
2. **Care Coordination Features:** Applications should facilitate seamless communication between patients, caregivers, and multiple providers, particularly for beneficiaries managing multiple chronic conditions. This aligns with AMIA's longstanding advocacy for patient-centered care and coordination.<sup>1</sup> AMIA members have highlighted the critical need for a consolidated calendar system that integrates appointments across multiple providers and health systems, reducing the burden on patients who currently must navigate multiple patient portals. We recommend bold solutions, including the use of artificial intelligence to create a comprehensive calendar system that would serve as a single source of truth for patients' appointments and care gaps, integrating all appointments and locations across different healthcare systems.
3. **Integrated Personal Health Records:** CMS should encourage development of comprehensive personal health record applications that aggregate data from

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<sup>1</sup> Brennan PF, Valdez R, Alexander G, et al. Patient-centered care, collaboration, communication, and coordination: a report from AMIA's 2013 Policy Meeting. *J Am Med Inform Assoc* 2015;22(e1):e2–6.

multiple sources, including claims, clinical records, patient-generated health data, and social determinants of health information. Research shows that patient portal adoption can improve health outcomes, but significant disparities exist in access and use among vulnerable populations.<sup>2</sup>

4. **Educational Components:** Digital tools should include built-in educational resources to help beneficiaries understand their health conditions, medications, and care plans, with particular attention to health literacy considerations.
5. **Proxy Access Improvements:** CMS should address the complexities in defining and managing proxy access for "loved ones." Current systems often fail to accommodate the diverse caregiving relationships that exist in real-world scenarios, creating barriers for family members and other caregivers who need to assist beneficiaries with their healthcare management.
6. **Comprehensive Access to Longitudinal Health Information:** AMIA strongly supports patient and caregiver access to complete, computable health records in a single location. Today, easy access to all relevant health information—such as notes, labs, images, and personal data—remains elusive. Barriers include:
  - Limited API scope restricted to USCDI elements, excluding broader EHI;
  - Manual, non-computable EHI exports;
  - Fragmented login systems for multiple patient portals;
  - Inaccessibility of diagnostic imaging through patient-facing APIs.

To address these issues, AMIA recommends:

- Mandating API-accessible, computable full EHI export aligned with industry specifications;
- Requiring certified self-service portals that allow electronic patient requests for EHI access;
- Ensuring automated access to diagnostic medical images through APIs;
- Creating a TEFCA Patient-Developer Credential to support direct, secure, and comprehensive patient access across systems;
- Supporting federated digital identity solutions (e.g. unique patient identifier) that reduce login burdens and facilitate secure, remote account provisioning.<sup>3</sup>

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<sup>2</sup> Grossman LV, Masterson Creber RM, Benda NC, et al. Interventions to increase patient portal use in vulnerable populations: a systematic review. *J Am Med Inform Assoc.* 2019;26(8-9):855-870.

<sup>3</sup> [What is Patient ID? – PATIENT ID NOW](#)

Additionally, AMIA urges CMS and ASTP/ONC to recognize the role of patients not just as beneficiaries, but as data stewards, contributors, and innovators. HL7, ASTP/ONC, and SDOs must systematically include patient voices by lowering participation barriers, supporting education, and acknowledging patients' lived experience with fragmented systems and data errors. As articulated by ASTP/ONC's own patient-centered care framework, patients are both users and generators of critical health data, including those related to behavioral, environmental, and social determinants of health. Their engagement is foundational to both interoperability and the success of value-based care models.<sup>4</sup>

### **Encouraging Digital Health Engagement and Tools for Patients and Caregivers**

AMIA believes CMS's primary role is enabling access and preserving rights, not approving individual apps. Digital health engagement can be accelerated by:

- Mandating comprehensive API-based EHI export;
- Maintaining current SMART App Launch and Backend Services Specifications for APIs;
- Establishing TEFCA Patient-Developer Credentials to promote equitable tool development;
- Mandating electronic pathways for data correction that patients can initiate through apps or portals;
- Ensuring transparency and control over TEFCA data sharing through audit logs and user-directed privacy controls.

### **Technical Standards and Interoperability**

#### **Patient-Centered Standards Development**

AMIA encourages CMS and ASTP/ONC to support the HL7 standards development process and ASTP/ONC's standards recognition process by ensuring patient participation is systematic and impactful. Patients bring unique insight as firsthand observers of interoperability gaps and as data contributors (e.g., family history, symptoms, device data). Their inclusion will improve the usability and relevance of data standards and help fulfill mandates from the 21st Century Cures Act. AMIA supports reduced barriers to participation in standards work, such as cost, travel, and technical

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<sup>4</sup> Office of the National Coordinator for Health IT. Component 25: Patient-Centered Care, Health IT Workforce Curriculum Version 4.0. Spring 2016. Available at: [https://files.healthit.gov/Component\\_25/Comp25\\_Component\\_Guide%20\(1\)/Comp25\\_Component\\_Guide%20\(1\).docx](https://files.healthit.gov/Component_25/Comp25_Component_Guide%20(1)/Comp25_Component_Guide%20(1).docx)

communication gaps, in alignment with our long-standing policy commitments to Patient Empowerment and Inclusive Innovation.<sup>5</sup>

## **Security and Privacy Considerations**

### **High-Assurance Digital Identity and Authorization Credentials**

AMIA supports broad adoption of NIST IAL2/AAL2-compliant digital identity credentialing, which can reduce login fatigue and strengthen account security. However, identity alone is insufficient. Systems must support bound authorization credentials that define and limit access in a trustworthy and accountable architecture, particularly within TEFCA's Individual Access Services (IAS).

AMIA recommends:

- CMS mandate CEHRT support for high-assurance remote portal account provisioning;
- CMS and ASTP/ONC ensure these credentials enable secure access, not just identification;
- Payers and providers offer federated identity login options;
- Developers integrate IAL2-compliant credentials in app design.

## **Addressing Barriers to Adoption**

AMIA identifies several key barriers that must be addressed:

- **Digital Divide:** Many Medicare beneficiaries lack reliable internet access or appropriate devices. CMS should consider partnerships to provide device lending programs and subsidized internet access. A study found that 26% of Medicare beneficiaries lack access to a desktop, laptop, or smartphone at home, and smartphone-only internet access is associated with lower patient portal use.<sup>6,7</sup>
- **Training and Support:** Device provision alone is insufficient without comprehensive training. As noted by our members' experiences with state initiatives, such as New York State's device distribution program, the lack of patient training creates significant barriers to adoption and places additional burden on healthcare

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<sup>5</sup> Office of the National Coordinator for Health IT. Component 25: Patient-Centered Care, Health IT Workforce Curriculum Version 4.0. Spring 2016. Available at: [https://files.healthit.gov/Component\\_25/Comp25\\_Component\\_Guide%20\(1\)/Comp25\\_Component\\_Guide%20\(1\).docx](https://files.healthit.gov/Component_25/Comp25_Component_Guide%20(1)/Comp25_Component_Guide%20(1).docx)

<sup>6</sup> Sachs JW, Graven P, Gold JA, Kassakian SZ. Disparities in telephone and video telehealth engagement during the COVID-19 pandemic. JAMIA Open. 2021;4(3):ooab056.

<sup>7</sup> Perzynski AT, Roach MJ, Shick S, et al. Use of Electronic Health Record Patient Portal Accounts Among Patients With Smartphone-Only Internet Access. J Am Med Inform Assoc. 2017;24(5):927-932.

providers who must adapt to supporting patients with varying levels of technological literacy.

- **Privacy Concerns:** Clear, understandable privacy policies and robust security measures are essential to build trust.
- **Technical Support:** Dedicated support services should be available to help beneficiaries navigate digital health tools.
- **Language and Accessibility:** Tools must be available in multiple languages and comply with accessibility standards for beneficiaries with disabilities.

### Strategic Approach to Product Development

AMIA recommends that CMS adopt a focused approach to digital health product development rather than supporting multiple fragmented solutions. We suggest:

1. **Identify and Scale Success:** Rather than developing numerous new products, CMS should identify existing successful digital health tools that have demonstrated effectiveness and work to scale these solutions across the Medicare population.
2. **Industry Partnership Council:** Leverage developers to gather systematic insights from major vendors regarding their tools, client feedback, and implementation experiences. This collaborative approach can help identify best practices and common challenges.
3. **Cross-Industry Collaboration:** Foster collaboration across industry partners to address shared challenges in healthcare technology, ensuring that solutions are interoperable and reduce rather than increase fragmentation in the digital health ecosystem.

### Provider Perspectives

#### Reducing Documentation Burden

AMIA has long advocated for reducing clinical documentation burden as a critical component of improving care quality and provider well-being through our 25x5 Initiative, which aims to reduce documentation burden to 25% of current levels by 2026.<sup>8,9</sup> We recommend:

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<sup>8</sup> AMIA 25x5 Initiative. American Medical Informatics Association. Available at: <https://amia.org/about-amia/amia-25x5>

<sup>9</sup> Rossetti SC, et al. 25x5 Symposium Drives Ongoing Efforts to Reduce Documentation Burden on U.S. Clinicians: Final Summary Report. December 2021.

1. **Leveraging Passive Data Collection:** Support development of technologies that capture clinical data "behind the scenes," including natural language processing, voice recognition, ambient clinical intelligence, and automated medical device data integration. As noted in our 2018 comments to CMS, there is "great promise" in the use of passive data collection facilitated through EHRs and other health IT.<sup>10</sup>
2. **Streamlined Prior Authorization:** Build upon the recent CMS Interoperability and Prior Authorization final rule by ensuring digital health products can seamlessly integrate prior authorization workflows, reducing administrative burden on providers. AMIA recently applauded CMS for these improvements that support streamlined processes and increase transparency around denials.<sup>11</sup>
3. **Interoperable Clinical Decision Support:** Promote standards-based clinical decision support tools that can be shared across health systems and integrated into existing workflows.

## Technical Standards and Interoperability

### FHIR Implementation

AMIA strongly supports the continued evolution and implementation of HL7 FHIR standards, as demonstrated through our partnership with HL7 and annual FHIR Application Competitions.<sup>12,13</sup> Research has shown 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.<sup>14</sup> However, we recommend:

1. **Phased Implementation:** Given the complexity of standards adoption, CMS should implement requirements in phases that align with industry readiness and certified health IT capabilities. In our 2019 comments, AMIA recommended a phased approach for API requirements, noting that government timelines were too aggressive given the state of standards development.<sup>15</sup>

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<sup>10</sup> AMIA Supports CMS Efforts to Reduce Documentation Burden, Streamline MIPS and Advance Patient Data Access. American Medical Informatics Association. 2018.

<sup>11</sup> AMIA Comments on CMS Interoperability and Prior Authorization Final Rule. American Medical Informatics Association. March 2024.

<sup>12</sup> AMIA and HL7 Announce Partnership to Advance Interoperability in the Healthcare Community. American Medical Informatics Association. May 2022.

<sup>13</sup> AMIA/HL7 FHIR Applications Competition. American Medical Informatics Association. Annual Symposium 2022-2024.

<sup>14</sup> Mandel JC, Kreda DA, Mandl KD, Kohane IS, Ramoni RB. SMART on FHIR: a standards-based, interoperable apps platform for electronic health records. *J Am Med Inform Assoc.* 2016;23(5):899-908.

<sup>15</sup> AMIA Recommends 'Phased Approach' to Payer API Requirements. American Medical Informatics Association. June 2019.

2. **Implementation Guide Harmonization:** Work with standards development organizations to ensure consistency across implementation guides and reduce conflicting requirements. As we noted in comments on ASTP/ONC's HTI-1 rule, we support enhanced harmonization of policies among agencies.<sup>16</sup>
3. **Real-World Testing:** Support pilot programs that test FHIR implementations in diverse clinical settings before mandating widespread adoption. A recent assessment of real-world FHIR applications found significant heterogeneity in implementation characteristics across healthcare settings, highlighting the need for careful testing and evaluation.<sup>17</sup>

## Data Standards Evolution

1. **USCDI Expansion:** Continue thoughtful expansion of the United States Core Data for Interoperability (USCDI) with adequate lead time for implementation and clear value propositions for each addition. AMIA has provided detailed feedback on USCDI versions, recommending specific data classes and elements.<sup>18</sup>
2. **Vocabulary Standards:** Maintain support for updated vocabulary standards including SNOMED CT, LOINC, and CDC race and ethnicity standards, ensuring version control and backward compatibility. AMIA strongly supports the use of these updated vocabulary standards.<sup>13</sup>
3. **Quality Measurement:** Develop digital quality measures that leverage existing data flows rather than creating new documentation requirements. AMIA has long advocated for informatics-driven quality measurement.<sup>19</sup>
4. **TEFCA Implementation Assessment:** While TEFCA represents an important step forward in nationwide health information exchange with its six exchange purposes, implementation challenges must be addressed, particularly for Individual Access Services. The limited transparency around actual data exchange volumes and patterns through TEFCA networks makes it difficult to assess its effectiveness. Current barriers include concerns about patient matching accuracy, potential HIPAA liability for incorrect matches, and the need for federated identity solutions. CMS should establish clear reporting requirements for QHINs to provide data on

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<sup>16</sup> AMIA Comments on ONC Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing. American Medical Informatics Association. 2023.

<sup>17</sup> Griffin AC, He L, Sunjaya AP, et al. Clinical, technical, and implementation characteristics of real-world health applications using FHIR. JAMIA Open. 2022;5(4):ooac077.

<sup>18</sup> AMIA Comments on the ONC USCDI v6 Draft. American Medical Informatics Association. 2025.

<sup>19</sup> AMIA Public Policy Principles. American Medical Informatics Association. 2024-2029.



exchange volumes by use case, adoption rates, implementation barriers, and specifically track IAS utilization to enable evidence-based policy improvements.

## **Value-Based Care Integration**

AMIA recognizes the critical role of health IT in supporting value-based care models. We recommend:

1. **Real-Time Quality Data:** Develop infrastructure for real-time access to quality metrics that inform clinical care, not just retrospective reporting. Studies have shown that improving clinical data sharing through interoperability can significantly enhance the accuracy of quality measurements and patient safety.<sup>20</sup>
2. **Risk Stratification Tools:** Support development of standardized risk stratification algorithms that can be transparently shared across organizations.
3. **Care Coordination Platforms:** Encourage platforms that facilitate data sharing among all members of a care team, including community-based organizations addressing social determinants of health. While TEFCA supports six core exchange purposes (Treatment, Individual Access Services, Payment, Health Care Operations, Public Health, and Government Benefits Determination), AMIA members have identified significant practical challenges in implementation, particularly with Individual Access Services (IAS). Despite IAS being one of the core use cases committed to by QHINs, and demonstrations of functionality such as Epic's patient app showcased at the National Academy of Medicine, there remains limited transparency about actual data exchange volumes and patterns. We recommend that CMS work with stakeholders to establish clear metrics and reporting requirements to assess TEFCA's real-world impact on patient data access, addressing concerns about patient matching accuracy and potential HIPAA liability that may be deterring broader IAS implementation.

## **Security and Privacy Considerations**

### **Digital Identity**

AMIA supports implementation of robust digital identity solutions but recommends:

1. **Multiple Authentication Options:** Provide various authentication methods to accommodate different comfort levels with technology.

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<sup>20</sup> Clinical Data Sharing Improves Patient Safety. Journal of the American Medical Informatics Association. 2023. Available at: <https://www.smiledigitalhealth.com/our-blog/clinical-data-sharing-improves-patient-care>

2. **Privacy-Preserving Design:** Ensure digital identity systems minimize data collection and provide user control over information sharing.
3. **Interoperability:** Digital identity credentials should work across multiple health systems and applications.

## Data Governance

1. **Transparent Data Use:** Require clear disclosure of how patient data will be used, stored, and shared.
2. **Patient Control:** Ensure patients can easily revoke access to their data and understand the implications of sharing.
3. **Audit Trails:** Maintain comprehensive logs of data access that patients can review.

## Research and Innovation Support

AMIA recommends CMS and ASTP/ONC:

1. **Fund Informatics Research:** Support research into novel applications of informatics for improving Medicare beneficiary outcomes, particularly in underserved populations. AMIA has consistently advocated for ongoing funding for the field, including informatics research.<sup>21</sup>
2. **Clinical Informatics Workforce:** Develop funding mechanisms for ACGME-accredited Clinical Informatics fellowships to ensure adequate workforce to support digital health transformation. In our 2019 comments to CMS, AMIA specifically called on the CMS Innovation Center to develop new models providing structural funding for Clinical Informatics fellowships.<sup>22,23</sup>
3. **Innovation Sandboxes:** Create regulatory sandboxes where innovative digital health solutions can be tested with appropriate safeguards.

## Implementation Timeline and Resources

Given the scope of changes needed to realize the vision outlined in this RFI, AMIA recommends:

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<sup>21</sup> AMIA Public Policy "North Stars." American Medical Informatics Association. Available at: <https://amia.org/public-policy>

<sup>22</sup> AMIA Recommends 'Phased Approach' to Payer API Requirements. American Medical Informatics Association. June 2019.

<sup>23</sup> Bell DS, Baldwin K, Bell EJ III. Characteristics of the National Applicant Pool for Clinical Informatics Fellowships (2018-2020). AMIA Annu Symp Proc. 2022;2022:241-248.

1. **Realistic Timelines:** Provide at least 24-36 months for implementation of major new requirements, with clear milestones and guidance. As we noted in comments on ASTP/ONC's HTI-1 rule, we have concerns about the ability of stakeholders to meet aggressive timelines, especially given resource constraints at hospitals and health systems.<sup>24</sup>
2. **Technical Assistance:** Offer robust technical assistance programs, particularly for safety-net providers and rural health systems.
3. **Funding Support:** Ensure adequate funding mechanisms to support implementation, particularly for resource-constrained providers. AMIA has supported full funding for ASTP/ONC at requested levels to help achieve nationwide, standards-based health information exchange.<sup>25</sup>

## Conclusion

AMIA applauds CMS and ASTP/ONC for your commitment to leveraging technology to empower Medicare beneficiaries. The informatics community stands ready to partner with you in creating a digital health ecosystem that truly serves the needs of all beneficiaries, reduces burden on providers, and advances the quadruple aim of healthcare.

We look forward to continued collaboration as these initiatives move forward. Should you have any questions about our comments, please contact Tayler Williams, Senior Manager, Public Policy at [twilliams@amia.org](mailto:twilliams@amia.org).

Sincerely,



Eileen Koski

Chair of the Public Policy Committee

cc: Robert F. Kennedy, Jr., Secretary, Department of Health and Human Services

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<sup>24</sup> AMIA Comments on ONC Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing. American Medical Informatics Association. 2023.

<sup>25</sup> Multi-Organization ONC FY24 Appropriations Letter of Support. American Medical Informatics Association. May 2023.