October 5, 2023

Micky Tripathi, PhD, MPP
National Coordinator
Office of the National Coordinator for Health Information Technology (ONC)
Department of Health and Human Services
Hubert Humphrey Building, Suite 729
200 Independence Avenue SW Washington, DC 20201

Submitted electronically to: https://www.healthit.gov/isa/

Re: ONC's Interoperability Standards Advisory (ISA) Annual Update

Dear Dr. Tripathi:

The American Medical Informatics Association (AMIA) is the professional home for more than 5,500 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 appreciates ONC's efforts to solicit feedback on the 2023 Interoperability Standards Advisory in preparation for the tenth annual reference edition. Overall, AMIA encourages ONC to ensure that all stakeholders are consulted to broaden the of range and address interoperability needs in Health IT. AMIA recognizes and values ONC's thorough approach to collecting recommendations from the public and to stress that the Office consults with health care organizations that are historically underrepresented. We would also add that organizations not using a traditional "big box" EHR system, located in rural regions, and under resourced health care communities, e.g. urban inner-city, sovereign U.S. communities, are also consulted. Data quality is paramount for interoperability and coordinating with these aforementioned organizations will enable ONC to have a more comprehensive understanding of implementation maturity and adoption levels.

Under AMIA's Public Policy Principle for Health IT Data Standards & Interoperability, AMIA believes ensuring the consistency and comparability of biomedical and clinical data, Health IT standards must have coordinated development, open participation, and transparent governance¹. Whether it is the physician, nurse, or administrative staff, the whole care team must be considered when developing a public list of standard and implementation specifications

¹ AMIA Public Policy Principles and Policy Positions | AMIA - American Medical Informatics Association

that could be used to address interoperability needs. AMIA is requesting ONC to collaborate with nursing communities to address implementation maturity and adoption levels of standards because they do play a vital role in transferring data from one health care organization to another. We ask what are the considerations for nurses in this space?

AMIA through multiple initiatives, led by the 25x5 Task Force, are working to find avenues to reduce unnecessary clinical documentation burden for health care professionals. The Task Force's mission is to reduce U.S. health professionals' documentation burden to 25% of current state by the end of 2026. 25x5 will optimize and spread across the U.S. health system impactful solutions that decrease non-value-added documentation and leverage partnerships and advocacy with health systems, professional societies, and public/private sector organizations. Increasing burden on clinical workflow will be a detriment to all stakeholders. The AMIA 25x5 Task Force has developed a toolkit guiding organizations through the process of reducing documentation burden. One section of the toolkit is governance and how with a proper structure can form an organized framework to address documentation requirements and efficiency. For areas of compliance standards, we hope the ONC ISA can provide clarity on standards being utilized in this space and which standards could be consolidated to alleviate that burden.

Lastly, AMIA would like to share the organization's Health IT Data Standards & Interoperability principle from AMIA's Public Policy Principles:

Health IT Data Standards & Interoperability

Technical standards enable disparate systems to communicate and are prerequisite for our health IT ecosystem to interoperate. These Principles and Positions describe the desired characteristics of IT standards for care and research. They also articulate the importance of governance, testing, and multistakeholder standards development.

AMIA Believes:

Clinical, research and health information technology (HIT) systems must be able to exchange biomedical, clinical, and health data consistently and reliably using computable formats while preserving the intended meaning and relationships.

Access to and reliable use of these electronic data at scale requires that established, consistent, well-published, and openly available HIT standards be used to specify the formats and values for biomedical, clinical, and health data.

To ensure the consistency and comparability of biomedical and clinical data, HIT standards must have coordinated development, open participation, and transparent governance.

² AMIA 25x5 | AMIA - American Medical Informatics Association

³ 25x5 Documentation Burden Reduction Toolkit | AMIA - American Medical Informatics Association

Whenever possible, one canonical specification should be designated as the preferred representation for each biomedical, clinical, and health data standard that are required for defined use-cases related to optimizing health and healthcare.

Testing of HIT systems should test both conformance to the standard and interoperability of the standard to ensure data consistency and reliability across implementations.

Based on these Principles, AMIA Supports:

- 1. The development and management of HIT standards as a public good, operated in a nonprofit, non-proprietary basis, with low barriers to review, reference, or use.
- 2. HIT standards that leverage existing information technology stacks, such as the Internet Protocol Suite,⁴ to greatly expand the functionality of existing information systems, and increase the use of HIT standards by disparate systems.
- 3. HIT standards that are modular and substitutable, having clear boundaries for use and application, with specifications for automated access, use, and integration with relevant data.
- 4. HIT standards that are simple, parsimonious, and include documentation that is complete, comprehensible, readily available, and timely.
- 5. HIT standards that are fit for purpose within a declared domain, and clearly recognized and identifiable as the preferred standard.⁵
- 6. HIT standards that leverage prevailing security practices to protect and preserve privacy and confidentiality.
- 7. Efforts to recognize and address stakeholder motivations, aims, activities, business models, and information needs in the specification of HIT standards so as to increase the value of their adoption by users and improve ease of implementation.
- 8. Standards development that incorporates implementation experience and feedback loops from real-world settings to better support an adoption pathway for HIT standards.
- 9. New modalities of biomedical data, use cases, and information technology that can evolve and mature through implementation experience before canonical specifications can be identified as the standard.

⁴ Also known as TCP/IP (https://www.ietf.org/)

⁵ This criterion implies being comprehensive within a declared domain of information, purpose and context, and generating verifiable content, preserving provenance, and computer interpretable.

10. Interoperability testing, which tests both the sending of data using a specific standard(s) as well as receipt of data using such standard(s), and tests adherence to Postel's Principle.⁶

11. Adequate funding for the development, management and maintenance of HIT standards, and the SDOs that create them, due to the enormous positive impact on society HIT interoperability can have.

AMIA would be pleased to serve as a resource to ONC as it continues its important work to advance meaningful data collection. Thank you for your time and consideration of these comments. If you have questions or require additional information, please contact Tayler Williams, AMIA's Senior Manager, Public Policy, at twilliams@amia.org.

Sincerely,

Gretchen Purcell Jackson, MD, PhD, FACS, FACMI, FAMIA

President and Board Chair, AMIA

Gretar P Jackson

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⁶ Also known as Postel's Robustness Principle, stating: Be conservative in what you do, be liberal in what you accept from others (often reworded as "Be conservative in what you send, be liberal in what you accept"). Postel, Jon, ed. (January 1980). Transmission Control Protocol. IETF. RFC 761. Retrieved June, 2017.