INFORMATICS PROFESSIONALS. LEADING THE WAY.

Micky Tripathi, PhD, MPP
National Coordinator
Assistant Secretary for Technology Policy
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C Street, SW, 7th Floor
Washington, DC 20024

Re: RIN 0955-AA06 HTI-2 NPRM

Dear Dr. Tripathi:

Thank you for the opportunity to comment on the Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) Proposed Rule. We look forward continuing to support the Assistant Secretary for Technology Policy Office of the National Coordinator for Health Information Technology's (ASTP/ONC) efforts to advance health IT infrastructure, enhance interoperability, improve equity, and support patient empowerment. AMIA applauds the enormous effort ASTP/ONC undertook to create the HTI-2 Proposed Rule.

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 limited our comments in this letter to the following sections:

- Information Blocking Definition Enhancements and Exceptions
- Public Health
- TEFCA
- Health IT Certification Program Updates
- Real-Time Prescription Benefit

Information Blocking Definition Enhancements and Exceptions

Definition Enhancements

"Health Care Provider"

AMIA supports the language proposed to update the "Health Care Provider" definition to include laboratories and pharmacies for information blocking regulation purposes, but requests further regulatory guidance for clarity from ASTP/ONC. Clarifying "Actors", defined in § 171.102, covered under "Health Care Provider" is helpful to potentially reduce burden and liability to physicians.

"Interfere with" or "Interference"

AMIA supports the proposed language but requests further regulatory guidance for clarity from ASTP/ONC. AMIA agrees this definition enhancement could provide confidence and some clarification to actors that certain practices would be considered interference and appreciates allowing room for case-by-case assessment. AMIA seeks further clarity on the "Non-standard implementation" practice that constitutes interference for information blocking definition purposes and the codified list of interferences.

Along with the HIMSS Electronic Health Record Association, AMIA recommends that ASTP/ONC not finalize a specific list of likely interferences for § 171.103. We believe that codifying a list of interferences could detract from the effective evaluation of other potential interferences and assign excessive priority on the list examples, limiting potential flexibility in addressing various situations.

We ask for clarification because there is ambiguity of what is non-standard implementation practices as they differ within the industry. For example, an EHI export for health systems transitioning health IT systems is not standardized. Implementation versus client configuration for health IT developers is difficult to navigate because exports are often based on the health system's needs and is unclear to how far health IT developers control

the implementation process of health IT systems versus the deployment decisions client to client.

Information Blocking Exceptions

AMIA has concerns that the added information blocking exceptions could shift the burden placed on health care providers rather than eliminate.

"Protecting Care Access Exception"

Overall, AMIA views the "Protecting Care Access Exception" as a positive exception for actors and individuals. AMIA agrees that the exception offers actors greater clarity that these practices are an exception and enforces patients' own access to and sharing of EHI.

AMIA Recommends that ASTP/ONC add explicit language that that simplifies the conditions under the exception so that it would allow practices by actors who, in good faith, would then be potentially considered information blocking limit the unnecessary burden and risk of potential exposure to legal actions. As currently constructed, actors must work through a range of conditions in order to satisfy the exception's requirements, creating uncertainty and documentation burden. We urge ASTP/ONC to issue guidance resources and educational sessions to help actors navigate this evolving and often confusing landscape.

"Requestor Preferences Exception"

AMIA recommends that ASTP/ONC provide clear guidance to prevent health care providers or IT developers from unintentionally steering requestors towards easier or more convenient options for sharing EHI, ensuring that requestors can make fully informed choices without undue influence.

HTI-2 and Public Health

ASTP/ONC's proposals and approach to updating public health IT infrastructure and data exchange is laudable but AMIA has readiness and feasibility concerns.

According to the Trust for America's Health, the United States spent $4.5 trillion on health in 2022, but only 4.7 percent of that spending funded public health and prevention initiatives to promote health and prevent illness. ASTP/ONC suggests that to certify each health IT system will cost between $447,000 – $1.82 million USD. With these statistics in mind, We have concerns of the readiness of public health systems to meet the certification criterion transition dates without efforts to ensure the appropriate health IT infrastructure is implemented to transfer data and train/educate the workforce, particularly with the consideration of transitioning to FHIR-based exchange

We propose delaying the transitions dates for implementation to ease the burden on public health systems and allow time for education. During this delay, it is incumbent upon the ASTP/ONC to collaborate with other government agencies responsible for public health to organize and evaluate the health care IT infrastructure of public health systems to identify opportunities to assess funding needs to modernize public health IT, particularly in underfunded, under-resourced, and smaller public health systems. While the major focus of ASTP/ONC in HTI-2 and Public Health is improving the infrastructure, the proposed interventions are not possible without a focus on federal funding needed to make these suggestions actionable. ASTP/ONC must leverage its technical expertise to provide direction to about the importance and estimates of financial resources required to bring these proposals to fruition.

As highlighted by the COVID-19 pandemic, public health systems exposed the gaps and limits in data sharing and constant funding mechanisms to prepare for the next pandemic will allow for more complete and readily available health data to better respond to and potentially detect an emerging threat.

TEFCA

AMIA supports the proposed language from ASTP/ONC and will monitor the TEFCA's progress.

New Real-Time Prescription Benefit

"New Real-Time Prescription Benefit Tools Criterion"

In principle, the prescription benefit information to the health care professions should mirror the same out-of-pocket cost that the pharmacy views. There should be transparency and provide accurate, patient-specific cost based on that person's prescription benefits and not be a representative value. AMIA seeks to ensure technical standards are not only addressed in the HTI-2 Proposed Rule but also the real-world healthcare needs of individual patients, promoting transparency, reducing administrative burden, and informed decision-making in prescription care.

Health IT Certification Program Updates

AMIA supports FHIR-enabled APIs and the requirements built into the certification criterion and ASTP/ONC's proposals to enhance API capabilities for interoperability purposes. We do want to raise concerns regarding the heavy lift on health IT developers for compliance and the impact for healthcare providers to educate and train a workforce that is overburdened.

AMIA supports the adoption USCDI v4 and would enable more accurate and complete patient data, but issues arise for health care systems lagging in implementing reporting previous USCDI versions.

"Payer-to-Payer API"

AMIA supports the proposals for health information to follow the patient when switching insurance plans. This could improve care coordination and continuity of care, supports patient empowerment, and administrative burden.

"Prior Authorization API – Provider and Payer"

We appreciate the potential to reduce administrative burden with prior authorization, streamline the prior authorization process, and patients receive treatment approval/denial sooner. The use of APIs can be helpful in providing

transparency in care management and coordination that result in greater value and cost savings when used properly.

Sincerely,
Carl E. Johnson, MD, EdM, MSc, FAMIA
Chair, AMIA Public Policy Committee
Principal Scientist, GRACS, Global Evidence and Regulatory Policy, Merck & Co. Inc