August 24, 2017

The Honorable Donald Rucker, MD,
National Coordinator for Health Information Technology,
US Department of Health and Human Services
200 Independence Ave. SW
Washington, DC, 20201

Comments submitted at:
https://oncprojectracking.healthit.gov/wiki/display/INTEROP/Common+Agreement+and+Exchange+Framework

Re: 21st Century Cures Act Trusted Exchange Framework and Common Agreement Public Comments

Dr. Rucker:

AMIA supports development of this Trusted Exchange Framework and Common Agreement. The ONC event hosted July 22, 2017, revealed a scattered landscape of governance policies, technical standards, and stakeholders engaged in varying forms of health information exchange. The meeting included a description of existing networks and an environmental scan detailing that specific networks have specific policies designed around specific use cases for specific stakeholders.

While we acknowledge the important work undertaken in the last several years with the emergence of several exchange networks, AMIA recommends ONC use the TEF/CA to encourage coordination and harmonization among those existing private sector networks, as well as provide opportunities for new networks to emerge.

To do this, the TEF/CA should provide a floor upon which existing networks – and new networks – can build. This floor could focus on functionality, such as ability to query or transmit data, or it could focus on use cases, such as "closing the referral loop." Regardless, harmonization along the key dimensions of (1) data availability and (2) permitted purposes for which data can be exchanged are needed.

Variances related to permitted participants and identity proofing, could reasonably remain, so long as these policies are well documented and communicated. As for technical infrastructure, we point to our comments regarding the importance of standards. We do not see a need to have alignment on architecture, but use of standards will be critical.

We see important work undertaken in the last several years with the emergence of several exchange networks. However, ONC must continue look to foster a system of exchange that will be operating

August 24, 2017

fifty years from now. Coordination among existing networks will be critical, but progress in cross-EHR exchange is needed.

Finally, an unstated assumption of any exchange value case is that patients will be matched correctly with their data, and not confused with or linked to data from others. We see development of a national patient identification system as foundational and would encourage ONC to consider how the TEF/CA could improve patient matching.

Below are comments related to select Comment Areas. Should you have any questions or require additional information, please contact AMIA Vice President for Public Policy Jeffery Smith at jsmith@amia.org or (301) 657-1291 ext. 113. We, again, thank ONC for the opportunity to comment and look forward to continued dialogue.

Sincerely,

Douglas B. Fridsma, MD, PhD, FACP, FACMI
President and CEO
AMIA

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4720 Montgomery Lane, Suite 500 | Bethesda, Maryland 20814

Comment Area 1: Standardization	**Adhere to industry and federally recognized technical standards, policies, best practices, and procedures.**
	AMIA Comment: AMIA recommends that ONC ensure alignment between the policies of the Trusted Exchange Framework and Common Agreement (TEF/CA) and the standards referenced in Interoperability Standards Advisory (ISA). At a minimum, the TEF/CA and ISA should be mutually reinforcing documents. We emphasize the importance of comparable and consistent information in all exchange infrastructures. Increasingly, Accountable Care Organizations and other value-based payment reforms will require that healthcare organizations examine the outcomes and consequences of care pathways that occur inside and outside their four walls. The TEF/CA must support this kind of cross-organizational analytics. Further, making sure that technical standards are part of the TEF/CA will improve the capacity to perform practice improvement across organizations and locations. And given updates to the Common Rule, this kind of inquiry will more readily result in point-of-care learning – a hallmark of a learning health system. Finally, adherence to standards will facilitate public health goals by enabling queries of reportable conditions across regions, and nationally. We cannot understate the imperative of robust, semantically congruent, and consistent information. The TEF/CA must further this important area.
Comment Area 2: Transparency	Conduct all exchange openly and transparently.
	AMIA Comment: While we assume many stakeholders will promote, rightly, the concepts of open governance and process, AMIA seeks to add to this conversation a need to provide transparency on standards. To ensure the consistency and comparability of biomedical and clinical data, HIT standards must have coordinated development, open participation, and transparent governance. We also support the development and management of HIT standards as a public good, operated in a non-profit, non-proprietary basis, with low barriers to review, reference, or use.
Comment Area 3: Cooperation and Non-Discrimination	Collaborate with stakeholders across the continuum of care to exchange electronic health information, even when a stakeholder may be a business competitor.
	AMIA Comment: AMIA recommends ONC conceptualize the TEF/CA as a pre-competitive public good. This enables an environment where businesses can compete on services, not infrastructure. The TEF/CA

	should encourage the default expectation is one of sharing, using standard protocols and uniform data reuse policies.
Comment Area 4: Security and Patient Safety	Exchange electronic health information securely and in a manner that promotes patient safety and ensures data integrity.
	AMIA Comment: The TEF/CA has an obligation to patients to minimize risk of breach and improper use of data. We would encourage review of the All of Us Research Trust Principles[1] / Data Security Policy Principles and Framework[2] as a starting point for this framework. While not every aspect of the Trust Principles will apply, it provides a foundation for more tailored concepts, and should be leveraged.
Comment Area 5: Access	Ensure that patients and their caregivers have easy access to their electronic health information.
	AMIA Comment: AMIA strongly recommends that the TEF/CA be leveraged to improve access for patients' data. A core use case this framework could demonstration is the patient's right to access provided by HIPAA. A patient should be able to request a digital copy of their data maintained by all stakeholders within the TEF/CA. In past comments to ONC, we have called for a "digital, print-all" functionality to be developed for CEHRT. The TEF/CA could be leveraged to produce such functionality, and ensure that would-be participants can deliver on such a request in order to be part of the TEF/CA.
Comment Area 6: Data-Driven Choice	Exchange multiple records at one time to enable identification and trending of data to lower the cost of care, improve the health of the population, and enable consumer choice.
	AMIA Comment: n/a
General Comments	Stakeholders may submit additional comments in this section that do not fit in the above categories. Alternatively, commenters may submit their comments in their entirety in this category if they choose. We note that while we encourage use of the above comment areas, it is not required.

[1] https://allofus.nih.gov/sites/default/files/privacy-trust-principles.pdf
[2] https://allofus.nih.gov/sites/default/files/security-principles-framework.pdf

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