



August 24, 2017

Don Rucker, MD
National Coordinator
Office of the National Coordinator for Health Information Technology (ONC)
Department of Health and Human Services
Hubert H. Humphrey Building, Suite 729
200 Independence Avenue SW
Washington, DC 20201

Dear Dr. Rucker:

eHealth Initiative (eHI) appreciates the opportunity to respond to the request for public comment on ONC's implementation of the *21st Century Cures Act* (Cures Act) trusted exchange framework and common agreement provisions, as outlined in Section 4003 of the law.

eHI is in a unique position to comment and offer insight on the trusted exchange framework and common agreement. Our viewpoints are broad and consensus-based. We are the only independent non-profit, multi-stakeholder coalition dedicated to improving the quality, safety, and efficiency of healthcare through the use of technology and health information. Moreover, eHI's work and its membership have built needed coalitions and moved the health IT field forward at critical junctures. We look forward to continuing this progression and working with key federal government players for better patient care, particularly in the case of *21st Century Cures Act* implementation, a law that involves so many critical healthcare touch points.

Through Section 4003 (b) of the Cures Act, under the *Support for Interoperable Network Exchange* provisions state that, the ONC "National Coordinator shall, in collaboration with NIST and other relevant agencies within HHS, for the purpose of ensuring to convene public-private and public-public partnerships to build consensus and develop or support a trusted exchange framework, including a common agreement among health information networks nationally". Overall, eHI believes that ONC's implementation of the Cures Act and development or support of exchange framework and common agreement provisions provides an important opportunity to: build a solid foundation on existing, rapidly accelerating exchange/trust frameworks efforts, identify critical successes and further foster both innovation and interoperability.

In general, we believe that ONC should focus on identifying and facilitating a sufficient set of private sector trust agreements and foster coordination where needed, rather than on specifying a single overarching framework and eliminating variations across existing agreements. The resulting framework from ONC should also be voluntary in nature, but with a high degree of transparency regarding participation. In addition, it is essential that ONC's work on this framework build on existing public and private sector investments in standards, trust frameworks, and connectivity arrangements and not inadvertently diminish the value of investments or otherwise divert from existing progress, where it has been realized.

Below are eHI's observations and recommendations on the trusted exchange framework and common agreement in areas relevant under the requested categories of standardization, transparency, cooperation and non-discrimination, security and patient safety, access and data-driven choice. We also outline: (1) considerations; (2) concerns; and (3) success stories for the exchange of data across health networks.

eHI looks forward to providing additional clarifications and input. If you have any questions, please contact me at jennifer.covich@ehidc.org

Sincerely,



Jennifer Covich Bordenick
Chief Executive Officer
eHealth Initiative

eHI Responses on Specific Issues

Considerations and Concerns

Importance of Current Initiatives

- eHI believes that important work, investment and progress have been made by developers, health information exchanges (HIEs), exchange consortia, providers, payers and other stakeholders regarding technical standards and technology approaches for interoperability. We encourage future work to build upon this foundation, particularly given the significant scope of investments in relevant standards and associated technology and related healthcare provider initiatives in HIT purchase and upgrade, workflow alignment and refined data capture.
- The rapidly accelerating work and successes of existing exchange/trust frameworks such as CommonWell, Carequality, the CARIN Alliance and DirectTrust should be taken into account.
- Taken collectively, current stakeholder investment in HIE is pointed in the right direction and is advancing cross-organizational interoperability (including patient access) and intra-organizational interoperability. It is critical in the trust framework and other interoperability initiatives, ONC encourages and builds upon this progress rather than seeking to make major mid-course changes. The disruption would be non-productive and would lead to wasted investment in a time of constrained resources. It would also further slow or delay current progress and send a message that industry investments in interoperability are at perennial risk to the changing winds of federal policy priorities.
- Overall, it is important for ONC/HHS to consider the potential negative impact and potential detrimental unintended consequence to current health information exchange of any national trust framework that ONC might create and/or require. A common agreement, even if voluntary in nature, has the ability to negatively affect existing trust

and business agreements within the community. There is no one size fits all solution. It is likely that a network of networks approach will work best.

General

eHI's overarching comments on ONC's implementation of the *21st Century Cures Act* (Cures Act) trusted exchange framework and common agreement provisions, are as follows:

- Do not limit innovation or variation with the exchange ecosystem.
- Work beyond the capabilities of current standards (including piloting new standards) should be encouraged.
- Patient education, patient access and shared decision-making should continue to be a key theme in these endeavors and keep pace with related advances in the federal *All of Us* Research Program.
- ONC should utilize, reference and permit existing trust frameworks and recognize that these may have different elements based on varying use cases, goals and participants.
- ONC should encourage continued dialogue among existing and future trusted framework organizations in order establish areas of collaboration and opportunities for network to network cross communication.
- ONC and OCR should provide guidance for providers, developers and patients using Open APIs to ensure that use of such APIs promotes portability of data for patients, including use of Apps of their choosing, while safeguarding provider system security.
- The areas published by ONC for this public comment call seem to extend beyond what is specifically required by the *21st Century Cures* legislation. It will be important to distinguish between statutory requirements and ONC policy goals.
- Do not require a centralized technical or organizational architecture for interoperability. Enable both centralized and federated models.
- The trust framework should be truly voluntary and failure to adhere should not be considered information blocking.
- A trust agreement should not be equated with specific service agreements or network agreements, nor should they be drafted.

Standardization

- While more information exchange is happening, increased cooperation on interoperability efforts is needed. This is an area for ONC to think through. ONC could play an important role in identifying and facilitating potential areas of increased cooperation among various exchange-focused alliances and organizations.
- ONC must carefully avoid disrupting existing exchange that works and focus instead on accelerating connection across existing platforms.
- Aligned, clear assurances and procedures must exist for health information exchange networks and framework to ensure consistency and that cross-network exchange that is trustworthy, reliable and efficient. A critical area in this regard is a well-defined and

unified understanding of how standards implementation for health information exchange will be addressed.

- eHI supports ONC's efforts related to interoperability standards implementations and specifications. We believe the ONC Interoperability Standards Advisory (ISA) provides valuable guidance to the healthcare industry and supports better patient care. We encourage ONC to continue this work, aligning it with Cures Act implementation efforts. In addition, we encourage ONC to continue work on the 13 consumer facing use cases and the consumer friendly section of the ISA.

Transparency

- There must be common expectations for transparency in the terms and conditions of health information exchange.

Security and Patient Safety

- There must be common processes for how individual entities are being matched and for how notifications will occur in the event of a breach.

Access

- eHI cautions that there could be potential serious repercussions or negative consequences regarding a common agreement for many key stakeholders such as patient, providers, vendors, HIES and exchange frameworks. We urge ONC, through its work in this area, to avoid creating new barriers to connecting within and between systems.

