August 25, 2017

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

Dear Dr. Rucker:

Health Level Seven (HL7) International welcomes the opportunity to submit comments to the Office of the National Coordinator’s (ONC) Request for Public Comment on the organization’s implementation of the 21st Century Cures Act (Cures Act) trusted exchange framework and comment agreement provisions.

HL7 is a global authority and driver of interoperability standards in healthcare. The products of our organization – including the rapidly evolving FHIR standards - provide the underpinnings for connected, patient-centered health care and an information highway for precision medicine.

We would like to offer the following general observations to be considered as a framework and common agreement is developed across participating networks:

HL7 believes that a trusted exchange framework and common agreement are very timely topics, even apart from the legislative requirement. The use of standards is foundational in achieving and implementing these aims. It is therefore critical for exchange participants to:

• Adhere to industry and federally recognized technical standards, policies, best practices, and procedures;
• Conduct all exchange openly and transparently.

Important progress has been made through many stakeholders including networks, exchange frameworks, vendors, providers, and payers. ONC’s work and Cures Act implementation must build upon and not disrupt this work and investment. Some critical HL7 work that should be consulted and addressed in ONC’s implementation of the Cures Act trusted exchange framework and comment agreement provision includes:

**HL7 Privacy, Provenance, and Security Standards** - Achieving a trusted exchange framework and common agreement seems unlikely unless such an agreement addresses issues related to preserving the originating discloser’s privacy policy governance over information about their patients as this travels through various health information exchange nodes. We recognize that there are also variances in policies as information travels provider-provider, provider-payer, provider-patient or other flows.

In addition, policy guidance and technical mechanisms to support the persistence and enforcement of the originator’s privacy policy need to be specified. HL7 Privacy, Provenance, and Security standards are being used to effectively ensure this capability, including behavioral health HIEs such as ONC Funded Colorado Regional Health Information Organization (CORHIO) and Prince George’s County Health Department Consent2Share implementation. HL7 Security Labeling related standards are in the process of being implemented in the Veteran's Administration as well. These should be leveraged by a trusted exchange framework and common agreement.
HL7 Trust Framework for Federated Authorization - Support for maintaining data provenance is critical for improving clinical decision making and patient safety in a trusted exchange. While data provenance is essential now, it will become foundational as healthcare evolves from monolithic and static trust frameworks to dynamic, run time trust frameworks as specified in the HL7 Trust Framework for Federated Authorization, on to the emerging trustless exchange environment that are making headway in other industries. ONC and HL7 have jointly developed Data Provenance standards. HL7 Data Provenance standards support V2, C-CDA and FHIR, and can be evolved to work in a trustless exchange environment using digital ledger technologies and smart contracts. ONC Data Provenance project is conducting pilots that use HL7 Data Provenance standards, and the majority are developing solutions for trustless exchange. The ONC trust framework should be designed to be flexible enough to grow and adapt to changing technology evolution in this area without prematurely forcing adoption of specific emerging technologies.

HL7 Security Labeling and Consent Directive Standards - A Learning Health System is not achievable if health information is siloed due to concerns related to ensuring privacy protection of patient deemed or policy prescribed restrictions on the collection, access, use, and disclosure of sensitive protected health information. If the trusted exchange framework and common agreement supports use of security labels to persist privacy protections assigned by the originating discloser, then we could move closer to a paradigm of sharing with protections rather than just protecting from sharing. This requires use of HL7 security labeling and consent directive standards in combination with data provenance to convey the privacy, security, and patient consent directive policies with which an end user must comply. Applicable security labels are derived from computable privacy, security and consent directive policies, which use the same HL7 Healthcare Privacy and Security Classification system vocabulary.

Finally, operationalizing a trusted framework will require relevant (meta)data to be part of the access/exchange. HL7 is fully committed to further enhance the V2, V3 C-CDA and FHIR specifications as necessary to provide practical long-term solutions to support such metadata where not already present, and to develop the relevant implementation guidance to achieve consistent deployments. Examples are the efforts on the FHIR Consent resource, the expanded use of the V2 ARV segment and inclusion of further provenance and consent through C-CDA.

Thank you for the opportunity to comment. Should you have any questions about our attached comments, please contact Charles Jaffe, MD, PhD, Chief Executive Officer of Health Level Seven International at cjaffe@HL7.org or 734-677-7777. Our HL7 Security Workgroup also stands ready to answer specific privacy and security related inquires. We look forward to continuing this discussion and offer our assistance to ONC.

Sincerely,

Charles Jaffe, MD, PhD
Chief Executive Officer
Health Level Seven International

Patricia Van Dyke
Board of Directors, Chair
Health Level Seven International