Health Level Seven® International

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National Coordinator for Health Information Technology
Department of Health & Human Services

Dear Dr. Mostashari:

Health Level Seven International (HL7) appreciates this opportunity to comment on ONC's Federal Health IT Strategic Plan. HL7 develops standards for interoperability of health information technology in over 55 countries.

General Comments

We appreciate the leadership of ONC in the development of the S&I Framework and would encourage even more ONC participation in standards development activities across the board. We would hope that ONC continues to follow the guidance provided with respect to the development and use of consensus-based standards as described OMB Circular A-119. HL7 and other SDOs have much to offer ONC. This includes mature processes for development and balloting of standards and implementation guides, with balanced representation, established governance, member participation and mechanisms supporting maintenance of the resulting work products.

We refer ONC to our previous comments which we provided on the PCAST report, also relevant to this discussion.

One of the challenges for implementers of Meaningful Use is obtaining access to all of the standards required by the various programs. There is ongoing Federal support for the maintenance and free access to SNOMED-CT® and LOINC®. HL7 would encourage expansion of these programs to include other standards and vocabularies, including those developed by HL7.

Goal I: Achieve Adoption and Information Exchange through Meaningful Use of Health IT

HL7 would like to thank ONC for selecting several of its standards and implementation guides in the Standards and Certification Rule. Many members have noted difficulties in implementation of the Meaningful Use requirements because the regulation names multiple standards in some cases, or provides little implementation guidance in others for the communication of patient information. We would hope that future stages would move towards a common representation of information, and appreciate the opportunities that ONC has provided within the Standards and Interoperability Framework to move in that direction.

ONC should focus more attention on information exchange in subsequent stages of Meaningful Use. The Direct Project certainly addresses one set of use cases, but does not address wider exchange requirements. For example, it is not well-suited for query/response information exchange patterns often needed in clinical care, and which are needed to support public health and research in a learning healthcare environment.

While providers have been incented to exchange information with public health, many barriers remain. More should be done to enable public health to implement standards to accept information exchanges from providers that are called for in the Meaningful Use regulations. Nationwide standardization is also called for, as many of our members have reported challenges addressing exchange requirements in multiple states using conflicting implementation guidance of the ONC selected standards.

Goal II: Improve Care, Improve Population Health, and Reduce Health Care Costs through the Use of Health IT

We would like to see more emphasis on the dependency between quality healthcare, measurement, and clinical decision support on standardized and computable health data. HL7 has developed a number of standards addressing clinical decision support, quality measurement, and structured clinical data that are designed to work together. We would encourage further ONC engagement with HL7 on these topics. Tell us how we can help.

We would further hope that CMS and ONC collaborate on the development of the Claims Attachment regulation, and that CMS take advantage of the Health IT initiatives that ONC has been promoting. HL7 has been engaged in the development of Claims Attachment implementation guides in support of the need for final regulation since 1997. We would hope that CMS and ONC would converge on a common representation of clinical documentation that could be used for clinical care as well as claims attachments.

We also encourage the use of Health IT standards and Health Information Exchange technology developed for Meaningful Use to support the exchange of information needed for claims and quality measurement. The development of separate information exchange infrastructures for treatment, payment and operations can only hinder the adoption of Health IT.

Similarly, in the arena of public health, we believe that ONC should work with CDC to focus on how different initiatives can take advantage of a shared health infrastructure across the public health domain. Greater alignment of other federal agencies, including CDC and NIH, with the standards for health information used in EHR certification and the Meaningful Use program would be beneficial.

Goal III: Inspire Confidence and Trust in Health IT

HL7 recommends that ONC apply risk-based methodologies using existing standards-based approaches and frameworks. Risk analysis should be performed in an open and transparent fashion, engaging with existing standards workgroups responsible for these frameworks, including the HL7 Security Workgroup. HL7 has the following Security and Privacy standards published to be used to mitigate identified risks:

- **HL7 Value Sets using Code System Confidentiality** (2.16.840.1.113883.5.25) -- This vocabulary is used in the confidentialityCode metadata attribute to identify the data object sensitivity and confidentiality classification. This enables both segmentation of especially sensitive topics and also Role-Based-Access-Control that protects objects for both security and privacy.
- **HL7 Version 3 Domain Analysis Model: Medical Records; Composite Privacy Consent Directive, DSTU Release 2** - This document object captures the patient privacy preferences, authorizations, and consents. This document is used as evidence of a patient consent ceremony as well as triggers privacy policy engines to enforce the patient privacy.
- **Role-Based Access Control Permission Catalog (RBAC), Release 2** - This vocabulary enables communication of users permissions in an interoperable way. This vocabulary can be used at a multitude of points in the Privacy and Security system.
- SAIF - Privacy, Access and Security Services (PASS)
    - Access Control Service – This is a service being defined for support of access control decisions and enforcement.
    - Healthcare Audit Services Release 1.0 -- This service specification is available and enables security audit log recording. There are also service endpoints to enable different security and privacy audit analysis use-cases, including the creation of an accounting of disclosure.
- **EHR Functional Model, Release 1** -- The EHR Functional Model includes a comprehensive set of security and privacy functions. This catalog includes detailed system level requirements that are actionable and testable. Profiles of this functional model are available for many functional systems including an EMR and PHR.
- **HL7 Version 3 Standard: Transport Specification, MLLP, R2** -- The HL7 transport specifications include transport security (e.g. TLS)
- **HL7 Security and Privacy Ontology** – Informative Ballot, May 2011 - serves to name, define, formally describe and interrelate key security and privacy concepts within the scope of Healthcare Information Technology

Goal IV: Empower Individuals with Health IT to Improve their Health and the Health Care System

We agree that ONC should provide more inclusive ways for patients to provide input on the healthcare system. We would also ask that ONC share the information that they learn widely with the healthcare industry for the same reasons. Furthermore, we have noted that while healthcare providers and Health IT vendors have been very much engaged by ONC in the development of Meaningful Use and EHR certification, very little has been done to inform patients of the impacts of this regulation and how they are currently being empowered by it.

As you expand the use cases for patient engagement, HL7 stands ready to support ONC by expanding the existing base of standards and implementation guides. HL7 has already developed standards for connecting EHRs to PHRs using both its Continuity of Care Document and its functional model for Personal Health Records.

Goal V: Achieve Rapid Learning and Technological Advancement

This goal principally addresses what is being done in the Federal Government and does not include participation by industry. We strongly believe that broad industry participation is needed in developing a rapidly learning healthcare system. Rapid learning cannot happen

without this stakeholder engagement. HL7 can provide access to a wide and balanced variety of stakeholders who are already engaged in advancing Healthcare IT.

We look forward to continued collaboration with you and with your Office.

Sincerely,

Charles Jaffe, MD, PhD, FACP, FACMI　　　　　Robert Dolin, MD, FACP, FACMI, FHL7
Chief Executive Officer　　　　　　　　　　　　Chairman of the Board