September 11, 2014

Dr. Karen DeSalvo, MD, MPH, MSc
Coordinator
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
Attention: 2015 Edition EHR Standards and Certification Criteria Proposed Rule
Hubert Humphrey Building, Suite 729
200 Independence Avenue SW
Washington, DC 20201

Dear Dr. DeSalvo:

HL7 appreciates the opportunity to provide feedback on the ONC's general solicitation for public input pertaining to the Nationwide Interoperability Roadmap and related issues. Health Level Seven International (HL7) is a not-for-profit, ANSI-accredited standards developing organization (SDO) dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services. HL7's 2,300+ members represent approximately 500 organizations that comprise more than 90% of the information systems vendors serving healthcare in the U.S. Globally, HL7 is the authority on standards for interoperability of health information technology

Given the importance of issues in the solicitation and its relevance to our mission and members, HL7's leadership and Policy Advisory Committee contributed notable time and effort to these comments. HL7's input is also being submitted through the Confluence public comment template. We would be happy to answer questions or provide further information to you and thank you for your continued efforts to put interoperability at the heart of the national HIT conversation.

Sincerely,

Charles Jaffe, MD, PhD   Stanley M. Huff, MD
Chief Executive Officer   Board of Directors, Chair
Health Level Seven International   Health Level Seven International

HL7 Responses to ONC Questions for Public Input - Nationwide Interoperability Roadmap and related issues

1. What are the 3 most important priority items that should be included in the national interoperability roadmap that will help advance interoperability nationwide?

HL7 Response

1. ***Identity and Location Management****:* Ability to uniquely and securely identify all stakeholders (patients, providers, systems, etc.) to enable linking records reliably. The creation of a global master set of data elements/terminology is mandatory. All interoperability relies on tenets of patient identity, record location, directories, and privacy and security (authentication, authorization, audit) handling. Identity and location management are fractured in today's environment, and both need attention for efficient, effective, and secure interoperability. HL7 also emphasizes the importance of accessing data below the document level, e.g., section level. To do so will require a clear level of granularity definition when referencing "data elements". In the HL7 context (FHIR resources, C-CDA sections or V2 segments), this means sufficient patient/consumer/subject identifying information depending on purpose.
2. ***Patient Engagement****:* Expanding the standards base for patient-generated health data to be transmitted as part of documents, services, and messages. To best enable this, new information management tools must be available to providers as well as automated means for ensuring appropriate trust frameworks, governance and provenance.
3. ***Testing Tools:*** The availability of implementation guides and related testing tools is essential to establish consistent interpretation of the standard to enable interoperability.

These priorities, and any others, should be applied in the context of:

1. Focus on clear use cases that have an opportunity for a high value return on the investment in the development of standards, software, and deployment across all stakeholders. These use cases must be supported by an initial group of providers and software developers to establish the value and ensure the standards can be widely implemented both operationally and technically.

2. To establish the best minimum set of interoperability standards, a focus on end-to-end interoperability, not the development of piecemeal standards. Consequently, interoperability pilots are essential to ensure the use cases that are fully implementable before wide roll-out to avoid the challenges currently encountered with the deployment of Direct and Transitions of Care.

2. What other topics should be included in the national interoperability roadmap that may not have been explicitly mentioned in the 10-year vision paper?

HL7 Response
Regarding key priority items and topics that should be included in the national interoperability roadmap, HL7 recommends that ONC should focus on education in a number of critical ways. First, formal training programs should be supported to: meet skilled labor demands in health IT, prepare a workforce that will rise to the challenge, and close gaps that currently exist.
For individuals already employed, we ask if there could there be certificate programs developed from ONC funding to complement the current Clinical Informatics board certification process and also to address non-clinical professionals entering health IT as a career change, with little or no

formal education. The AMIA 10x10 program has been successful and perhaps its outreach could be expanded. Noted also is the AMIA (Academic Forum) effort to create Clinical Informatics certification for non-clinical persons. For students who have yet to enter the workforce, HL7 suggests a focus on what should informatics curricula look like, and how could ONC support the expansion of these kinds of programs (i.e. more enrollment into these programs and having more universities add these programs to their inventories.)

A second critical issue regarding key priority items and topics that HL7 believes should be included in the national interoperability roadmap, is coordination with states to reduce variability. It is counter-productive for states to enact their own variety of interoperability on different schedules.

> a. In terms of content, ONC should strive for a national model of maintaining a superset of capabilities that states can use a subset as appropriate.
> b. In terms of privacy & security, ONC should strive to work towards a single model that is adopted across all states.

3. What aspects of BUILDING BLOCK #1: CORE TECHNICAL STANDARDS AND FUNCTIONS are the most important to address?

ONC referenced the following essential services for interoperability in the request for comment:
1. Methods to accurately match individuals, providers and their information across data sources
2. Directories of the technical and human readable end points for data sources so they and the respective data are discoverable
3. Methods for authorizing users to access data from the data sources
4. Methods for authenticating users when they want to access data from data sources
5. Methods for securing the data when it is stored or maintained in the data sources and in transit, i.e., when it moves between source and user
6. Methods for representing data at a granular level to enable reuse
7. Methods for handling information from varied information sources in both structured and unstructured formats

HL7 Response
The first 4 components are essential to establish reliable nodes in the healthcare network. The last 3 components will have to evolve over time. We particularly note with regard to number 6, data granularity, that this should be approached with some caution. Increased granularity expands complexity of maintenance, administration, access controls, etc.

HL7 recommends that the third component: "Methods for authorizing users to access data from the data sources" be amplified to make it clear that these methods should be enforcing applicable jurisdictional, organizational, and patient privacy policies, i.e., consent directives.

4. And what are your recommended solutions or tactics for effectively addressing this building block?

HL7 Response
Standards are never finished and always need ongoing evolution and maintenance, thus need a long-term commitment to maintain the standards. HL7 suggests that ONC work with established SDOs and professional organizations to continue the evolution of relevant standards, and establishes pilot projects that bring providers and software developers together to explore new and innovative approaches that can be more widely deployed in subsequent phases, once value and the ability to implement has been established.

5. What aspects of BUILDING BLOCK #2: CERTIFICATION TO SUPPORT ADOPTION AND OPTIMIZATION OF HEALTH IT PRODUCTS AND SERVICES are the most important to address?

HL7 Response

HL7 believes it is essential to have an established set of recognized tools that enable software developers to continuously validate their interoperability capabilities during the development cycle to enable more efficient validation approaches once software is ready for deployment. Furthermore, increased tooling to assist in the development of tools for implementation of the interoperability specifications to help reduce variations in interpretation can drive improved connectivity, e.g., creation of APIs. With such tools, including evidence through audit logs and public attestation, the current certification process could be further streamlined and reduce some of the effort and cost involved in those processes.

6.And what are your recommended solutions or tactics for effectively addressing this building block?

HL7 Response

We suggest that ONC should work with NIST, testing organizations, as well as SDOs to arrive at such a testing and development tool suite to ensure SDOs can assert that the tools faithfully interpret the standard. Where testing and/or development tools are not developed by the SDO, it is essential that testers participate in the development of implementation guides to improve their overall quality and testability. The close working relationship between ONC, HL7, and NIST, as demonstrated through the Laboratory orders/results initiatives clearly demonstrate the value of such collaboration. As HL7 moves its testing program forward, this will be an essential element of our test tool development.

7.What aspects of BUILDING BLOCK #3: PRIVACY AND SECURITY PROTECTIONS FOR HEALTH INFORMATION are the most important to address?

HL7 Response

While, we do not have input on solutions and tactics on this topic, HL7 highlights two areas within privacy and security protections for health information that are most important to address. First, HL7 recommends facilitating clarifications in the policies that support privacy/security such as HIPAA that was written at a different time with different technology and different models. Establishing clarity on the level of granularity required to manage privacy/security is also critical. Increased data segmentation to manage privacy and security presents a clear challenge with the governance, complexity and administration of controls for providers and patients alike. HL7 has developed a number of standards to address data segmentation challenges technically, and is in the process of balloting CDA guidance to enable provenance tracking, which is an important capability for ensuring trust, reliability, and authenticity, which play important roles in privacy/security management. HL7's Data Segmentation for Privacy, Privacy Consent Directive, and Data Provenance CDA Implementation Guides, Healthcare Classification System, and FHIR's support for audit, provenance, and security labeling standards were designed to advance patients' rights to access, amend, make informed choices about *and control* the disclosure of their electronic health information.
HL7's second recommendation is for ONC to work towards establishing technical standards that facilitate enabling cross-jurisdiction alignment of law, regulations, and practices so there is consistency and clarity as data is exchanged across boundaries.

8.What aspects of BUILDING BLOCK #4: SUPPORTIVE BUSINESS, CLINICAL, CULTURAL, AND REGULATORY ENVIRONMENT are the most important to address?

HL7 Response

HL7 suggests that addressing a clear business case and sustained, meaningful incentives for providers to invest in the exchange of data is the most critical lever that ONC in support of CMS

can exercise. Without a clear need for data exchange that is backed up by a willingness to invest in the infrastructure and ongoing exchange, software developers will be hesitant to develop solutions and adhere to standards that are going to end up on the shelf and under-utilized.

ONC must encourage SDOs to focus attention on the development of clear, unambiguous implementation guides that promote the use of standard vocabulary. These guides should be accompanied by well-defined testing tools/methods that can assert conformance to the implementation guide. We note that a reduction in ambiguity should not be equated to a reduction in optionality as is at times noted in discussions. Changing optional capabilities to mandatory will quickly result in everybody having to send everything to everybody else. Rather, we encourage further dialog between provider organizations and SDOs to find the balance between providing too much or too little data given specific use cases and requirements. A mix of push and pull methods should be available to enable minimal, but essential data sets to be exchanged with opportunity for follow-up queries to get more. We have to be careful to turn, e.g., C-CDA into a one size fits all document.

On a specific issue, we emphasize the significant ROI of creating registries for CDS algorithms and disease registries for most diseases, particularly rare diseases. These registries should have consistent data exchanges built in rather than every registry taking their own approach on how they want to receive or get data.

HL7 also recommends a focus away from clinical informatics to just informatics. This is critically important to enhance interoperability among genomics, clinical research, health and health care, public health and population health. In regards to these issues, standards for defining what data should be exchanged, what expressions should be terminologized, how to capture patient reported outcomes, and more are needed as well as an understanding of how to capture genomic data, biomarker data, and environmental data and include it in the EHR or HIT tools.

9.And what are your recommended solutions or tactics for effectively addressing this building block?

HL7 Response
Achieving the goals in building block #4 requires agreement, engagement, and buy-in from a wide variety of stakeholders. Regarding this issue, HL7 recommends:
- Providing incentives for all stakeholders (providers, software developers, payers, etc.) to contribute to S&I Framework activities; whether financial or other incentives such as an ONC endorsement for providers and software developers that successfully pilot a specification.
- National standards development efforts should make greater and better use of existing mechanisms for standards development (i.e., encouraging people to use existing SDO processes).
- Taking an agile approach, with more dialog and communication early on and structured conversations with relevant HIT, EHR and health care trade groups.

Note, HL7 has no response on BUILDING BLOCK #5: RULES OF ENGAGEMENT AND GOVERNANCE OF HEALTH INFORMATION EXCHANGE.

10.What priority use cases should be considered for the 0-3 year agenda in the national interoperability roadmap?

To move interoperability forward, HL7 recommends ONC establish clear and compelling patient and provider business cases, which should include provision of sustained, sufficient and meaningful incentives. Economic incentives should include ensuring that both patients and providers control who is allowed to accrue the economic value generated by secondary users of the health information about or generated by patients and providers.

As to use case focus, they should be aligned with a vision of the future, not tethered by the present. Also, use cases should not be focused on what we think we can do, but what we as a nation need to do. As with standards making, use cases should be proactive not reactive.

Regarding specific issues, HL7 recommends:
1. Making the current 2014 Edition interoperability scope work and maintain it with future editions. E.g., focus with SDOs on improving / disambiguating existing implementation guides (e.g., C-CDA, LOI, LRI, Infobutton, etc.) before introducing new ones.
2. Establishing pilot projects to explore advanced interoperability use cases, such as:
   1. Use Appropriate Use Criteria (AUC) to establish a first use case for CDS knowledge artifact and services. Knowledge exchange and/or actual services to provide AUCs are mandated over the next 2-3 years by law. AUCs are a perfect example of DSS, which is also represents more advanced interoperability than other use cases. Rather than in the rush of getting AUCs done we end up with unique, one-off protocols on how to exchange AUCs based on the third party involved, it would be more appropriate and fitting that any mechanisms, as referenced in the law, to support AUCs are based on the emerging CDS standards for knowledge artifacts and services. As much as the law is about 2-3 years out, CDS interoperability is in its infancy.

11.What priority use cases should be considered for the 3-6 year agenda in the national interoperability roadmap?

HL7 Response
HL7 recommends:
3. Progressing CDS knowledge artifacts and services beyond those necessary for AUCs.
4. Progress then critical use cases through improved implementation guides and tooling.

12.What priority use cases should be considered for the 6-10 year agenda in the national interoperability roadmap?
HL7 has no response to this question as this time period is quite far into the future.

13.Do you have any general suggestions or feedback?

HL7 Response
HL7 observes first that while it is hard, a steady, predictable progression will do more to establish reliable interoperability than the current rush to solve all the shortcomings when comparing current interoperability to the ideal end state.

HL7 also observes that ideal standards enable interoperability. Best standards are invisible in that they are available and adequate as needed. That means work on standards continues, driven by changing technologies, stakeholders, and requirements.