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July 29, 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 on the Office of the National Coordinator's (ONC) Request for Information regarding an Interoperability Standards Measurement Framework posted April 26, 2017 on ONC's HealthITBuzz blog ("ONC RFI").

HL7 is a not-for-profit, ANSI-accredited standards developing organization dedicated to providing a comprehensive framework and related interoperability standards, including the rapidly emerging Fast Healthcare Interoperability Resources (FHIR), the Consolidated Clinical Document Architecture (C-CDA), and the widely used V2 messaging standards. HL7 is comprised of more than 1,600 members from over 50 countries, including 500+ corporate members representing healthcare providers, government stakeholders, payers, pharmaceutical companies, vendors/suppliers, and consulting firms.

As the global authority on interoperability in healthcare, HL7 is a critical leader and driver in the standards arena. 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.

Key high-level HL7 comments include the following:

- **Scope and Use of Specific Interoperability Standards** - Data on the extent and nature of use for specific interoperability standards would be very helpful to enable the healthcare community to analyze the following dimension of standards: maturity, adoption, readiness for inclusion in a national program, and end-of-support. Access to such information has been an industry-wide gap, with most of this information coming to-date from qualitative stories and general surveys, but not from in-depth measurement, which is the mid-term goal appropriately suggested by the proposed framework.
- **Pro-active Guidance and Additional Measurement Burdens** - This draft framework is thoughtful and does a good job of acknowledging current gaps, challenges, and opportunities. As the work moves forward, we urge ONC to be very mindful of the potential burdens associated with additional measurement and to carefully calibrate the burdens of measurement with expected benefits. In addition, HL7 urges that, as we move from surveys to more automated reporting, ONC focuses on guidance to the industry related to optional, voluntary data collection well ahead of any definitive shift from surveys to automated collection.

In addition, HL7 would like to offer our specific feedback on the proposed measures where SDOs can and should play a role, recognizing that other stakeholders have a better perspective on how to collect such data. The following are our considerations as you further develop this framework.

- **Metadata** - HL7 standards generally have the necessary metadata to support the collection of the proposed volume measures from transactions (e.g., messages, documents, services). However, the metadata may not be populated at all

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times as that depends on the implementer, particularly as not all the metadata is required. Where standards do not have such metadata or it is inadequate to support the desired level of granularity, SDOs should update their standards to accommodate such use.

- **Measuring Beyond Standards** - While the framework references “standards”, we want to emphasize the importance of measuring at the more granular level of versions and particularly implementation guides/profiles (and their version). For example, understanding that 70% of certain transactions used HL7 FHIR has less meaning than 60% used FHIR R2 and 10% FHIR R3, while even more value is obtained from knowing 50% of APIs use FHIR US-Core R1. This applies to all standards being reported on.
- **Conformance Testing Complexity** - Conformance testing is complex. Testing tools typically do not validate for all conformance aspects, while some conformance statements are not easily computable. This particularly involves use of non-use of certain vocabulary, or inclusion or absence of certain data. Performing conformance tests across all transactions would not be practical given the volume and impacts. We suggest that such analysis is conducted using sampling through focused research, and particularly emphasizing the software validation steps, e.g., certification. HL7 also urges ONC to gather examples of interoperability from the field arising from an array of exchange models in order to identify and analyze first-hand how provider organizations, HIT developers, exchange alliances and HIEs are managing conversions among standards. We recognize that the One-Click Scorecard provides a way of testing and has value, but it also is limited in its ability to reach overall conclusions on conformance given the un-scientific sampling.
- **SDOs and Conformance Assessment** - As research and analysis identifies potential non-conformant implementations, SDOs have a role in the conformance assessment to provide insight what is considered conformant or not relative to their standards. This information can then be used as well to provide feedback to the standards development to address gaps and ambiguities. SDOs may also play a role in providing suggestions of areas for deeper research and analysis based on their understanding how standards are frequently used.
- **Prioritizing Clear Access/Exchange Use Cases** - It seems the framework focuses on standards and their use, rather than on access/exchange use cases and how to to achieve that. HL7 believes that having knowledge of non-standard use (different than non-conformant use of a standard) is relevant as well. We therefore suggest that the framework focus should be on clear access/exchange use cases first, and understanding volumes of transactions, stratified by standards used and proprietary formats used, within those use cases second. For example, understanding that C-CDA R2.1 was used in 700 transactions while .pdf files were used in 2000 transactions would be very helpful.

We look forward to providing further input as you develop and implement an interoperability standards measurement framework.

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. 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
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