



Health Level Seven[®] International

Unlocking the Power of Health Information

An ANSI accredited standards developer

February 7, 2011

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National Institute of Standards and Technology
100 Bureau Drive, Stop 1070
Gaithersburg, MD 20899-1070

RE: Standardization Feedback for Sub-Committee on Standards

On behalf of the Board of Directors of Health Level Seven International (HL7), we are pleased to offer our comments on the effectiveness of federal agency participation in the development and implementation of standards. Our responses are organized according to the RFI's four broad headings:

- Perspectives on government's approach to standards activities
- Issues considered during the standards setting process
- Adequacy of resources
- Process review and improvement metrics

Perspectives on government's approach to standards activities

HL7 has worked with multiple government agencies over the course of the last two decades. During 2010, a number of these agencies participated as organizational members of HL7, including Agency for Healthcare Research and Quality, (AHRQ), Centers for Disease Control and Prevention (CDC), Centers for Medicare & Medicaid Services (CMS), Department of Defense (DoD), Food and Drug Administration (FDA), the National Cancer Institute (NCI), the National Library of Medicine (NLM), the National Institute of Standards and Technology (NIST), and the US Department of Veterans Affairs (VA). A number of state public health agencies also maintain membership within HL7.

HL7 has forged strong and successful partnerships with many federal agencies to develop and bring needed standards to the marketplace. One of HL7's earliest collaborations was with the CDC in the early 1990s to develop messages permitting the transmission of immunization records from care providers to local and state public health agencies and on to CDC immunization registries, queries of these registries for immunization public health records, and the return of these immunization records to care providers. These messages are still in widespread use today and CDC continues to maintain and distribute the current code sets for these messages

The National Committee for Vital and Health Statistics (NCVHS) and CMS worked closely with HL7 and X12 through the HL7 Attachments Work Group to develop the supplemental information needed to support healthcare insurance and other e-commerce transactions. Started in 1997, the work group has created and balloted implementation guides and attachment specifications that use HL7 Version 2.x messaging and the HL7 Version 3 Clinical Document Architecture (CDA[™]) standards. These were incorporated into a notice of proposed rulemaking ([NPRM](#)) under HIPAA in 2005, and work continues today for an update and expected future publication of final rule on transactions to support attachments for both claims and referral authorization.

In the mid 1990s, HL7 worked with the NLM on a three-year project to develop and apply methods to ensure that the UMLS Meta-Thesaurus was aligned with the HL7 vocabulary standards. This work was undertaken to ensure Consolidated Health Informatics (CHI) vocabularies as distributed through NLM's UMLS Metathesaurus are usable with HL7 and to develop implementation guide(s) for the use of HL7 to transmit electronic health record (EHR) data and documents between two systems, independent of source and destination architectures.

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The FDA has been an active participant in, and founding member of, the HL7 Regulated Clinical Research Information Management Work Group, a joint collaboration between HL7, the FDA and the Clinical Data Interchange Standards Consortium (CDISC). This group develops standards to improve or enhance information management during clinical research and regulatory evaluation of the safety, efficacy and quality of therapeutic products and procedures worldwide. Among other work products, this group has developed two very successful standards: the Structured Product Labeling (SPL), a document markup standard approved by HL7 and adopted by FDA as a mechanism for exchanging product information; and the Biomedical Research Integrated Domain Group (BRIDG) Model, a domain analysis model representing protocol-driven biomedical/clinical research. The FDA has also worked with HL7 to develop the Individual Case Safety Report (ICSR) standards for reporting adverse events and product problems to regulatory agencies, and the Common Product Model for periodic reporting of safety updates in relation to medicinal products in pre- and post-marketing.

In 2001, at the request of the then DHHS National Health Information Infrastructure (NHII) and now ONC, the VA partnered with HL7 to fund the creation of an internationally-focused Electronic Health Record System Functional Model (EHR-S FM). Subsequently, HL7's EHR Work Group has created an internationally-focused Personal Health Record System Functional Model (PHR-S FM) and conformance requirements that provide guidance in the development of functional profiles (which are realm-, application- or care setting-specific constraints of the EHR-S FM and PHR-S FM).

AHRQ funded and supported HL7's recent efforts to create a forum for clinicians to bring their needs and knowledge to HL7 without being burdened by the technical requirements of standards developments. This effort ultimately resulted in the formation of the Clinical Interoperability Council, an active work group within HL7 that provides a nexus of communication and bridge to the standards development framework, organizational processes and forums for the clinical community to define content, flow, and other domain requirements necessary to the development of robust health data standards. More recently, substantial HL7 cooperation and collaboration with ONC contractors produced a balloted implementation guide that met ONC's requirements for clinical laboratory messaging.

In recent years, the National Cancer Institute (NCI) has collaborated with HL7 to develop the Services Aware Interoperability Framework (SAIF). SAIF is an architecture framework for achieving interoperability via HL7's artifacts including support services, messages, and clinical documents created with HL7's V3 [Clinical Document Architecture \(CDA\)](#). This architecture framework is in use at the NCI and is being implemented across HL7.

NIST is also a long-time HL7 member and has made a number of contributions to our standards development process. While HL7 fully supports accredited processes, we also recognize that there are other equally good and effective processes. NIST has studied and published a number of findings relative to the characteristics of good process that result in successful standards adoption and has brought some of those findings and processes into HL7 without conflicting with our own ANSI-accredited processes. NIST is well qualified to provide guidance and advice to federal agencies relative to good processes and characteristics of processes that should be implemented nationally to meet the goals of the American Recovery and Reinvestment Act of 2009 (ARRA) Title XIII Health Information Technology for Economic and Clinical Health Act (HITECH Act).

Finally, a number of federal agency employees have also participated in the governance of HL7 by serving on its Board of Directors. Other federal agency employees serve on HL7's Advisory Council and/or Technical Steering Committee (TSC). Both HL7 and the federal agencies have benefitted from these activities and collaborations and we anticipate continuing to work with these groups in the future.

Issues Considered During the Standards Setting Process

HL7's intellectual property takes the form of copyrights on its balloted standards and implementation guides, and various trademarks on its name and key products. Our standards are registered with the US Copyright Office and are covered under the protections of that agency. As a not-for-profit organization, HL7 derives its revenues from licensing fees, which are then re-invested to provide services to HL7

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members and participants in the form of meetings and meeting support, balloting services, and Internet-accessible products and services. HL7 therefore asserts control of its intellectual property and assumes that all users, including the US government, will pay appropriate license fees to access and use HL7 intellectual property.

There are a number of apparent discrepancies around federal agency funding of standards, particularly those that federal agencies have helped develop. HL7 recommends timely resolution and publication of guidance with respect to these discrepancies. For example, [the National Technology Transfer and Advancement \(NTTA\) Act of 1995](#) directs federal agencies to use standards developed by voluntary consensus bodies. However, HIT guidance from Federal CIO Sept 17, 2010 directs certain federal agencies to “Incorporate shared Federal standards and terminologies where available, and contribute to their ongoing development where needed.” Other legislation indicates that a standards development organization cannot enforce its own copyright against a free distribution of its standard, and USC § 105 indicates that the US government owns the copyright to work completed by contractors hired by a federal agency. Likewise, there is currently no shared understanding as to how much of American National Standards Institute (ANSI)-accredited standard the government can use without compensating the SDO for fair and reasonable IP rights. Such discrepancies create confusion and will continue to hinder collaboration and successful adoption of needed standards. HL7 requests clarification on the apparent discrepancy in the law and letters above.

HL7 recognizes that an individual’s health does not respect jurisdictional borders and therefore is committed to the development and use of international standards. We recommend that the US government include this criterion in its standards selection process. The FDA already respects this criterion, with the proposed use of the GS1 standard for unique device identifier being a recent example.

Finally, HL7 agrees wholeheartedly that innovation is crucial to the successful launch of our national healthcare reform initiative. However, such innovation cannot be so inwardly focused as to overlook the work and accomplishments of our colleagues in other countries.

Adequacy of Resources

There is ongoing federal support for maintenance and free access to the Systematized Nomenclature of Medicine – Clinical Terms (SNOMED CT) and Logical Observation Identifiers Names and Codes (LOINC), two federally mandated vocabulary standards. These represent successful case studies, and federal support of these standards should continue. Expansion of this approach to encompass other standards required for national healthcare reform, including Digital Imaging and Communications in Medicine (DICOM), the National Council of Prescription Drug Programs (NCPDP), HL7, etc., or the creation of a subscription service to ensure easy access to and understanding of the licensing requirements, will enable standards organizations to develop the tools and implementation guides crucial to successful standards adoption. NIST is well qualified to guide and advise the federal agencies in the development of licensing and/or subscriptions arrangement suitable for this purpose.

While HL7 has enjoyed and benefitted from the participation of federal agency employees, there is an increasing and continuing need for federal involvement in the accredited standards development process. Ensuring that federal agencies are involved early in the standards development and that most, if not all, of the relevant federal agencies are actively engaged would be helpful. As a beneficiary of successful standards adoption, the federal government should feel compelled to support the infrastructure needed to develop and maintain standards, particularly those that are mandated. Canada Health Infoway and Standards Australia are just two of the many examples of standards activities that enjoy country-wide support as a result of government sponsorship.

A number of changes within HL7 are making our standards more enticing to the communities but adoption will be hindered without faster development of tools to assist with the implementation of robust interoperability standards across international environments. The federal government can assist this effort by assuming some of the licensing or tools development costs.

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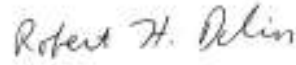
Process Review and Improvement Metrics

Substantial process improvement can be realized by upfront harmonization rather than retrospective review. The industry is aware of the good and critical work of IHE, the Standards and Interoperability Framework initiatives, HL7 and other standards groups, and it is incumbent on the federal government to help fund the standards lifecycle and the corresponding infrastructure of all of those groups to enable improvement. Only then can we ensure development and adoption of the interoperability standards that will be required for the greatest endeavor of all time.

Sincerely,



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Chief Executive Officer



Robert Dolin, MD, FACP, FACMI, FHL7
Chairman of the Board