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The Standard for electronic data exchange in health care

An ANSI accredited standards developer

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David J. Brailer, MD, PhD
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
Attention: NHIN RFI Responses
Hubert H. Humphrey Building, Room 517D
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. Brailer:

Health Level Seven is pleased to be a part of the unprecedented collaborative, coordinated by the Connecting for Health organization, which proposed a Common Framework for the National Health Information Network. Although we endorse the consensus response the collaborative developed and submitted, HL7 has additional input relevant to *Standards and Policies to Achieve Interoperability*.

HL7 Version 2 is widely accepted and implemented by the industry and supported by most healthcare system vendors. It has been applied on a regional and national scale by the crafting of "hardened" specifications, analogous to implementation guides, that simply the negotiations inherent in most interface implementations. In the short term this approach to interoperability is recommended because it leverages existing widely installed versions of the HL7 standard. In the long term, however, Version 3 provides a methodology that will make semantic interoperability more achievable and rigorous, especially for the highly complex clinical information required to support detailed evaluation and improvement of quality, safety and effectiveness in healthcare.

HL7 has shifted the bulk of its development efforts from Version 2, focused on syntactic interoperability or messaging, to Version 3 and the tenets of scalable semantic interoperability. With the formal binding of standard vocabularies to standard models, and a flexible document architecture, HL7 Version 3 represents a mechanism for the exchange of “understandable” information able to be reused in multiple application contexts at the highest common level of shared meaning - semantic interoperability.

The HL7 Development Framework (HDF) is a process for developing use cases and establishing requirements for information exchange whose adoption will lead to semantic interoperability on the National Health Information Network. Once the use cases are stable, the HDF can also establish semantic interoperability among the various standards with domain intersects in a given profile; in essence “standardizing the standards.”

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We believe this approach will facilitate the ultimate viability and efficacy of the National Health Information Network.

Sincerely,

Mark J. Shafarman
Chair, HL7 Board of Directors

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Standards and Policies to Achieve Interoperability

14. What kinds of entity or entities could be needed to develop and diffuse interoperability standards and policies? What could be the characteristics of these entities? Do they exist today?

While the proposed Standards and Policy Entity (SPE) will certainly play a significant role in establishing requirements and recommending policy and regulation; the actual development and distribution of interoperability standards should be left to the standards development organizations (SDO). These organizations possess both the functional domain and appropriate technical knowledge to further the standards in meeting the objectives established by the SPE.

Having operated successfully under ANSI policies for consensus-based standards development organizations, HL7 recommends that such policies be incorporated in the governance of the SPE to ensure broad representation and balanced response.

The ANSI Healthcare Informatics Standards Board (HISB) and the National Committee on Vital and Health Statistics (NCVHS) are representative of entities that demonstrate some of the characteristics envisioned for the SPE; however, neither of these organizations nor any other currently operating possess the funding, staffing, or mandate to function in the role proposed for the SPE. Further study and presumably Federal action will be necessary to bring a fully functional SPE to fruition.

15. How should the development and diffusion of technically sound, fully informed interoperability standards and policies be established and managed for a NHIN, initially and on an ongoing basis, that effectively address privacy and security issues and fully comply with HIPAA? How can these standards be protected from proprietary bias so that no vendors or organizations have undue influence or advantage? Examples of such standards and policies include: secure connectivity, mobile authentication, patient identification management and information exchange.

As with other standards involved in the NHIN initiative, security and privacy standards will benefit from SDO collaboration. The HL7 Security Technical Committee is leading a multi-SDO collaborative whose objective is the convergence and harmonization of standards for identity and access management. Security policy management, role engineering and management, privilege management, access control, secure distribution of software and metadata, and conformance profiles for healthcare security are among the topics to be addressed.

HL7 contends that adherence to ANSI policies for open consensus-based standards development organizations contributes significantly to the development of non-proprietary standards free of undue influence from any single or cohesive group of contributors. Under these principles, members of HL7 come together as a team focused on promulgating standards of benefit to the healthcare community, regardless of the competitive relationship of their employer organizations.

16. How could the efforts to develop and diffuse interoperability standards and policy relate to existing Standards Development Organizations (SDOs) to ensure maximum coordination and participation?

Employing existing standards with common conformance specifications, while a step in the right direction, will not meet the full and achievable objectives of the NHIN. The effort must be made to "standardize the standards." It is possible for two or more existing standards to interact in the same "problem space" or "domain" with non-interoperable representations of the same information object. A white blood count value may be expressed in a laboratory result standard or in a clinical trials data standard. A prescription is processed by a retail pharmacy using an NCPDP transaction, while an inpatient's medication order is processed via an HL7 transaction. It is imperative to the efficacy of the NHIN that such representations be interoperable across standard's boundaries and multiple application contexts. To ensure such semantic interoperability requires the application of a formal information mapping specification.

HL7 defines semantic interoperability in Version 3 as not only the exchange of information, but the ability to "understand", in a computational sense, the information being exchanged; to be able to reuse the information in multiple application contexts without loss of meaning. Achieving semantic interoperability requires a formal methodology and process, and is based on the existence of a Reference Information Model (RIM). The HL7 RIM has evolved over the past decade to support healthcare information interoperability. It is an ANSI standard, and in process of becoming an ISO standard. Explicit with the use of the RIM is the stipulation of formally binding standard vocabularies, such as LOINC, SNOMED, or ICD9, to standard models.

The formal process for mapping standards for semantic interoperability is defined in the HL7 Development Framework (HDF). Although such mapping may identify minor changes for two standards to become semantically interoperable, it is not in the mode of a "rip and replace" strategy; rather it serves to bridge the semantic gaps between standards with minimal disruption. The HDF is currently being used in two projects to develop mappings for semantic interoperability between standards: HL7 and NCPDP and HL7 and CDISC. The first focuses on a direct mapping between NCPDP SCRIPT 4.7 and HL7 Version 2.3 Rx messaging specifications. There is a longer term strategy to use the HDF to map both standards into HL7 Version 3 models in order to assess mechanisms for achieving transparent semantic interoperability. In the second, the full HDF process was used to map the CDISC model into a Version 3 model, which was used to generate Version 3 messages fully expressing the semantic context of the CDSIC model in an interoperable fashion. It has also been employed in several related contexts. The HL7 Canada Client Registries project used the tenets of the HDF to create a set of semantically interoperable mapping specifications between existing client registry transactions and the adopted Version 3 standard transactions. The HDF was also the basis for expression of the CCR requirements as constraints against Release 2 of the Clinical Document Architecture (CDA R2); allowing the CCR to be presented in CDA R2 XML structures. The HDF also serves to resolve concerns about the semantic interoperability of those concepts which overlap the various domain models in HL7 Version 3.

In the bigger picture of the NHIN, HL7 perceives two key elements of each area or domain of healthcare information; there must be a set of semantically interoperable specifications supporting each area or domain, and there must be a strategy of scalability allowing compliance to the specification at the level most appropriate for any given participant. The creation of a set of formal use cases provides the basis for assessing the validity and scope of the information requirements. Without question there will be a significant number of use cases, many of which will evidence the need for a standard vocabulary necessary to achieve semantic interoperability. The vocabulary selected will depend on the aggregate of requirements; the vocabulary must be of a granularity that supports the most demanding use case under the presumption that lesser granularity is arbitrarily accommodated. However, there must be a strategy for migration appended to each vocabulary, especially those driven by some mandate such as ICD. Consideration must also be given to possible extension of the use case resulting in a need for a more granular vocabulary at some future point. Once consensus is reached on the use cases and appropriate vocabularies identified, the profile of existing standards supporting each use case can be built. Each profile must then be examined for the need to develop semantically interoperable mappings for those standards with overlapping domains.

For presentations concerning the use case for the HL7 Reference Information Model (RIM) approach and "standardizing the standards" please visit:

http://www.hl7.org/Library/General/hl7v3rimusecase.pdf and
http://www.hl7.org/Library/General/HL7ncpdpeprescribing.pdf

17. What type of management and business rules could be required to promote and produce widespread adoption of interoperability standards and the diffusion of such standards into practice?

As our experience with provider reimbursement systems has demonstrated, there can be no national solution without a national specification; the driving factor behind HIPAA administrative simplification. The NHIN will of necessity have to accommodate a plethora of information system

solutions; however there is a much higher probability of success if those systems are mapped to a national specification versus being mapped each to the other across the country. Even on the scale of the sub-network one-to-one mapping would prove catastrophic; participation by only 50 entities would result in 1,225 [50(49)/2] mapping instances. In much the same vein, the various standards that comprise a given profile supporting a use case component of the national specification must be mapped to each other to ensure semantic interoperability. The HL7 Development Framework (HDF) is a proven tool for such mapping; the most recent example being the mapping to ensure semantic interoperability between HL7 and NCPDP standards involved in the e-prescribing initiative resulting from the Medicare Modernization Act of 2003.

Admittedly the national specification must be scalable from the most basic to the most advanced participant in a sub-network configuration as envisioned by the collaborative. An example of such scalability is the HL7 Clinical Document Architecture (CDA), an ANSI accredited standard. Employing the CDA an organization may progress from a simple text-based records system to whatever level of sophistication is desired or required under the aegis of its own business plan. Scalability such as that provided by the CDA, which allows organizations to control their own destiny, will contribute significantly to the adoption and implementation of interoperability standards

Whatever the future holds, the NHIN will first build on existing exchanges of health information and the standards involved in those exchanges. In the domain of patient care and clinical information exchange HL7 Version 2 is by far the dominant standard in that it is supported by most vendors and used in most hospitals and among those entities in Integrated Delivery Networks. On a broader scale, V2 is used on a regional basis in the Indiana Network for Patient Care; is being developed in California for pay for performance; and is the basis for the Electronic Health Reporting for Public Health specification published by the CDC. The practice within individual healthcare organizations has been to exercise optionality in HL7 specifications and to tolerate vendors who are not fully compliant. All regional or national efforts must produce "hardened" specifications eliminating optionality and enforce them. The NHIN will have to follow the same process. Nonetheless, it will be far less burdensome on vendors and provider organizations to map their HL7 specifications to the hardened national specification than it would be to start over with a new standard. In the long term, however, it is expected that systems will evolve to Version 3, which provides a methodology that makes semantic interoperability more easily achievable and rigorous. This transition will be particularly important to furthering the use of highly complex clinical information for detailed evaluation and improvement of quality, safety, and effectiveness in healthcare.

Another important consideration is the availability of a cadre of mentors capable of facilitating the transition to the national specification. Such personnel would play an important role as resources to local stakeholders intent on participating in the NHIN. Of course, the availability of robust implementation guides and interactive tools for conformance and validation would be equally important. Tools may also be used to foster scalability as evidenced in Canada during the effort to implement HL7 Version 3 claims and encounter reporting at the province level. HL7 Canada and the Canadian Institute for Health Informatics (CIHI) developed and released a set of API software modules providing the interface between the user's data base and the creation of the various V3 message constructs. Each user then simply loads the API instead of creating software to generate the transactions themselves. While conceived as an automated process, the API could also be populated by data entry via a web-based client

18. What roles and relationships should the federal government take in relation to how interoperability standards and policies are developed, and what roles and relationships should it refrain from taking?

The federal government is critical to the process of driving incentives for the adoption of technologies critical to the success of the NHIN and funding, with the private sector, formation of the SPE and subsequent definition and dissemination of the Common Framework. In addition, the federal government has a key role to play in developing the rigorous use cases necessary to the creation of semantically interoperable standards. Various agencies of the federal government are among the largest consumers of health information (the Centers for Medicare and Medicaid Services (CMS), the Centers for Disease Control and Prevention (CDC), the National Institute of Health (NIH) and the National Cancer Institute (NCI), and the Food and Drug Administration

(FDA) being representative) while others are responsible for creating and maintaining the health records for a large segment of our population (the Department of Defense and Veterans Health Care). The active involvement of such agencies is essential to the development of critical use cases necessary to the creation of semantically interoperable information standards and profiles which will ultimately comprise the Common Framework.

The industry has already benefited from the collaboration between a number of government agencies and HL7, resulting in standards relating to Structured Product Labeling, Electronic Laboratory Reporting (ELR) for Public Health, the Electronic Health Record, and numerous facets of the exchange of healthcare information in general. In addition, the National Institute of Standards and Technology (NIST) has provided HL7 with technical insight significant to healthcare IT gained from experience in other industry sectors. HL7 is also collaborating with the National Library of Medicine (NLM) to ensure that HL7 standard vocabularies are represented in the UMLS meta-thesaurus. Such collaboration must be encouraged and broadened to ensure that standards development organizations produce the comprehensive, innovative and semantically interoperable standards necessary to the implementation of the NHIN.