



Health Level Seven® International
Unlocking the Power of Health Information

An ANSI accredited standards developer

August 28, 2015

The Honorable Lamar Alexander Chairman
Committee on Health, Education, Labor and Pensions United States Senate
455 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Patty Murray Ranking Member
Committee on Health, Education, Labor and Pensions
United States Senate
154 Russell Senate Office Building
Washington, DC 20510

Dear Senators Alexander and Murray:

Health Level Seven International (HL7) appreciates the opportunity to provide our comments and feedback to the Senate Committee on Health, Education, Labor and Pensions (HELP) about how best to encourage health care innovation and reach more patients with cutting-edge medical treatments. Through the committee's hearings and bipartisan working group on electronic health records, the importance of interoperability standards has come into focus, and is addressed further in our attached recommendations.

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 members represent approximately 500 organizations that comprise more than 90% of the information systems vendors serving healthcare in the U.S. In the interest of informed public policy, HL7 also convenes in-depth policy dialogues on current and emerging health care issues. Our recent summit on genomics and interoperability (<http://bit.ly/1WQDUQ>) is one example.

Given the importance of Senate HELP Committee discussions and any resulting action in supporting the development of interoperable health IT infrastructure and a meaningful, patient-centered health system, HL7 is making the following four key recommendations that build on discussions over the past year:

- Focusing on business cases and return on investment (ROI) objectives first;
- Requiring pilot and demonstration projects before national mandates of standards and implementation guidance;
- Ensuring national health information technology standards development organizations (SDOs) are engaged in the development of health IT standards guidance, along with other stakeholders from patient, provider and industry groups; and
- Establishing a minimum floor for standards and implementation guidance.

More details are in the enclosed document. Please e-mail HL7's Ticia Gerber at tgerber@hl7.org if you or your staff have questions or need further information.

Sincerely,

Handwritten signature of Charles Jaffe in black ink.

Charles Jaffe, MD, PhD
Chief Executive Officer
Health Level Seven International
Sincerely,

Handwritten signature of Stanley M. Huff, MD in black ink.

Stanley M. Huff, MD
Board of Directors, Chair
Health Level Seven International

HL7 Position Statement and Recommendations: Advancing Interoperability in the US Health Information Technology Space

HL7 has played a significant role in the advancement of interoperability and ensuring the public's health since the organization was founded in 1987, developing messaging standards to support data exchange between computer systems used **within** provider organizations. A strong business case for improving care delivery and optimizing clinical and business processes increasingly led healthcare providers to require interoperability. In doing so, providers and software developers work through HL7 and other SDOs to create the necessary standards that ensure predictable data exchange and that adapt to the widely varying vocabularies, systems, and business/clinical practices in use across the United States and around the globe.

With the shift in focus to data exchange **across** provider organizations, providers and software developers again came to SDOs such as HL7 to establish further standards and guidance that harmonize variances across systems and improve communication across provider organizations. Despite this progress, the national interoperability infrastructure, which supports data exchange across provider organizations and with patients, is not yet fully scalable. Payment model changes, the passage of incentive -based legislation and other factors, have substantially accelerated standards development and uptake, but more needs to be done to achieve widespread, comprehensive, complete, unambiguous, predictable exchange of data across the full spectrum of stakeholders and systems including providers, patients, payers, biomedical researchers, public health agencies, patient registries and research networks.

Both the public and private sector have critical roles to play in achieving this goal. HL7 plays a leadership role in a number of important initiatives that emphasize private sector innovation. An example is the Argonaut Project spearheaded by HL7 in collaboration with leading health industry organizations. This initiative focuses on developing a first-generation API and Core Data Services specification to enable expanded information sharing for electronic health records, documents, and other health information based on the HL7 FHIR specification. More information can be found at <http://hl7.org/implement/standards/fhir/2015Jan/argonauts.html>.

Private sector initiatives are tackling important interoperability challenges where business drivers are aligned, e.g., patient identification and record location using standards/guidance, establishing a trust framework for data exchange, document query guidance across networks, and supporting referral processes. Federal policy should recognize and encourage these types of initiatives, thus legislating with a light touch, focused on fundamental business drivers/incentives, and only when absolutely necessary.

Based on HL7's experience to date, the federal government also has an important role to play. The following are HL7's recommendations on how the federal government can facilitate effective and efficient expansion of a national interoperability infrastructure that serves the needs of its stakeholders:

- **Focus on business cases and ROI objectives first.**
 - The prescription of standards and guidelines for interoperability needs to be driven by sustainable business cases that present opportunities for efficiency and clear value to the end users (providers, patients, etc.) Standards and implementation guides are only a means to an end, not an end in and of themselves.
 - In the past, many standards have been developed without a clear business case and ROI for the primary stakeholders (patients, providers, payers, etc.) resulting in lack of uptake and utilization.

- With appropriate business cases and opportunities for ROI, sustainable data sharing networks can emerge to provide the infrastructure necessary to facilitate data exchange, which in turn will also identify and drive the need for further relevant, focused standards and implementation guidance development.
- **Require pilot and demonstration projects before national mandates of standards and implementation guidance**
 - Interoperability takes time to advance and mature - involving multiple iterations to get it right.
 - Standards and implementation guides can benefit from practical realities before being “finalized.”
 - Funded pilots and demonstration projects should be encouraged through legislation; they must involve real business cases and address all aspects needed to make interoperability successful: vocabulary alignment, trust frameworks, privacy & security harmonization, physical infrastructure, process enhancements, training, communication protocols, directories, exchange formats, etc. One example may be a genomics focused project that can identify and resolve the challenges to share genomic data across the direct care and research communities.
- **Ensure health standards development organizations (SDOs) are engaged, along with other stakeholders**
 - SDOs are essential to encapsulate shared knowledge arising from interoperability initiatives into accepted standards and guidance that can be endorsed.
 - No single SDO has all the knowledge and capabilities necessary to bring together all critical components to drive successful interoperability.
 - Fund SDOs to substantially accelerate the administrative support of developing standards and implementation guidance. A process that uses consensus-based input to focus on required content is essential.
 - Interoperability standards and guidance must be able to draw on a complete vocabulary/terminology that can be shared across providers and systems, to enable a variety of analysis and decision support tools. Today there are significant gaps in the available vocabularies that will require coordination among multiple standards and vocabulary groups to fill. One such gap in the modeling of orders is hampering implementation of clinical decision support services across institutions. The National Library of Medicine (NLM), professional societies, and SDOs need funding if they are to accelerate completion and harmonization of the necessary clinical, financial, and systems vocabulary/terminology to support interoperability standards.
- **Establish a minimum floor for standards and implementation guidance**
 - As standards and implementation guidance are established, they should be prescribed as minimum requirements that systems must be able to support without limiting opportunities for innovation and the ability of systems to also support approaches based on other standards.

Adoption of the above recommendations will support innovation and all healthcare actors successfully moving into the new era of personalized, precision medicine.

