July 26, 2021

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Chair
Subcommittee on Standards
National Committee on Vital and Health Statistics (NCVHS)
Centers for Disease Control and Prevention (CDC)/National Center for Health Statistics
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Submitted electronically to:
NCVHSmail@cdc.gov

RE: NCVHS Subcommittee on Standards Request for Public Comment on Health Care Standards Development, Adoption and Implementation

Dear NCVHS Subcommittee on Standards Chairs Love and Landen:

Health Level Seven (HL7) International welcomes the opportunity to submit comments on the NCVHS Subcommittee on Standards Request for Public Comment on Health Care Standards Development, Adoption and Implementation. HL7 is the global authority on health care interoperability and a critical leader and driver in the standards arena. Our organization has more than 1,600 members from over 50 countries, including 500+ corporate members representing health care consumers, providers, government stakeholders, payers, pharmaceutical companies, vendors/suppliers, and consulting firms.

The NCVHS Subcommittee on Standards asks for critical and timely input and "seeks to understand the extent to which current and emerging standards for exchanging electronic health-related data under Health Insurance

Portability and Accountability Act (HIPAA) and other applicable federal legislation and regulatory processes are meeting the business needs of the health care system." HL7 offers its input below categorized by the four organizing questions contained in the NCVHS Request for Public Comment.

Key themes in these HL7 comments include:

<u>**Successful Interoperability Transitions**</u>

- Successfully transitioning from the current state to a new state of standardized interoperability requires focused programs that involve both human and financial resources to facilitate the transition with an extended period of simultaneous support for multiple sets of standards for substantially similar purposes.

- Patients should become more aware of the importance of standards-based interoperability and increasingly request it from their providers and apps. Health systems, researchers and other service providers should request standards-based interoperability from vendors. And, lawmakers/regulators should use their tools to encourage or mandate standards-based interoperability when other market forces are insufficiently comprehensive or fast.

- Providers and researchers should be educated and engaged more effectively at the right times in the standards development process, and in the piloting and implementation of standards-based systems.

- All standards mentioned in the ONC's Interoperability Standards Advisory (ISA) should be considered by NCVHS for recommendation to HHS for adoption to support interoperability, burden reduction, or administrative simplification.

<u>**Health Equity and SDOH**</u>

- Development and adoption of common data standards is foundational to identifying inequities, identifying potential interventions, coordinating interventions across agencies, measuring progress, and conducting research and evaluation.

- Requiring that health systems collect standardized data elements indicative of social determinants of health, and report these data, are key to improving the ability to share data that helps our society address inequities.

<u>**Privacy and Security**</u>

- Creating a better awareness of why data sharing matters and how to protect, secure, or release patient information as part of personalizing one's care delivery experience is critical. It is also important to ensure that people from various demographics can validate approaches, reaching as many as possible.

- Consents need to be electronic, and obtained in the clinical workflow, so that sharing is not delayed due to inefficiencies in collecting consent.

Global Issues and Governance

- As humans and diseases continue to travel globally, international coordination between jurisdictions will be increasingly important regarding data represented in USCDI, US Core, and specialized Implementation Guides (IGs).

- The principle: "No aggregation without representation" – represents a desire for collective governance of digital rights for patient groups and communities that should be considered.
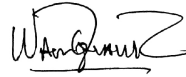
These comments include the combined perspectives of HL7's leadership, Policy Advisory Committee, multiple HL7 Work Groups, and FHIR Accelerators. In addition to focused comments on public health and patient empowerment, specific perspectives on cancer data and related interoperability were gathered by CodeX leaders. CodeX is an HL7 FHIR Accelerator building a community to accelerate interoperable data modeling and applications based on a common, standard language for cancer data - mCODE™, the minimal Common Oncology Data Elements, with supplemental Implementation Guides for particular use cases.

Should you have any questions about the attached, 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 HHS.

Sincerely,

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

Walter G. Suarez, MD, MPH
Board of Directors, Chair
Health Level Seven International

HL7 Responses – NCVHS Subcommittee on Standards Request for Public Comment on Health Care Standards Development, Adoption and Implementation

HL7 offers comments below categorized by the four organizing questions contained in the NCVHS Request for Public Comment.

Organizing Question #1 -How can data sharing be improved between patients, providers, payers, public health system, and other actors in health care? What are the barriers to these improvements?

<u>**Overarching Perspectives – Standards, Interoperability and the Digital Divide**</u>

- The HHS Secretary should allow the Standards Development Organizations (SDOs) that are responsible for the specific standards to update **adopted** health care standards to newer versions without rulemaking in order to encourage innovation, and to implement new functionality that can improve interoperability and promote patient safety.

- Transitioning from the current state to a new state of standardized interoperability is difficult without focused programs that involve both human and financial resources to facilitate the transition with an extended period of simultaneous support for multiple sets of standards for substantially similar purposes.

- Funding of pilot projects is critically important to enable adoption and broader implementation. There is a chicken and egg issue of testing and adoption that can interfere with large-scale adoption. Many vendors and other organizations cannot adopt new standards until there is general acceptance of the standard and pilots have been completed, but it is hard to gain that necessary level of acceptance because no one is able to engage in early testing and feedback, as the standards aren't generally accepted. For example, it can be difficult to add profiles to HL7 FHIR US Core before there is widespread adoption of them, but it can also be problematic to get vendors and other groups to test and pilot standards that aren't in US Core.

- The Federal Data Strategy, Practice 20 calls for the federal government to "Leverage Data Standards: Adopt or adapt, create as needed, and implement data standards within relevant communities of interest to maximize data quality and facilitate use, access, sharing, and interoperability." Continuing to take a primary role in orchestrating the development and adoption of standards is a key role the federal government can play. Participating in and supporting the HL7 communities developing standards with human and financial resources are investments the federal government should make to speed and scale standards development and adoption.

- The benefit of advancing the development and adoption of common data standards, which will enable data to be interoperable among patients, providers, payers, public health system, and other actors in health care, is foundational to identifying inequities, identifying people for interventions, coordinating intervention across agencies, measuring progress, and conducting research and evaluation. Requiring that health systems collect standardized data elements indicative of social determinants of health and collect these data are also key to improving the ability to share data that helps our society address inequities.

- As our society becomes more attentive to prioritizing health equity, significant barriers in the form of the digital divide – along with gaps in digital and health literacy – continue to prevent populations from having equitable access to their health data and tools of communication with their providers. Barriers also exist in the form of the ability (funding, staff resources) of parts of the health safety net to invest in technology

implementation that will enhance connectivity and data sharing while also ensuring privacy and security of data.

- Lack of standard electronic health records in key settings for certain vulnerable populations (e.g., those in long-term care settings) results in difficulty for providers, beneficiaries, and caregivers accessing the most current data. Furthermore, data frequently do not travel with the person from setting to setting effectively/efficiently. This may lead to medical errors or duplicative screening, diagnostic workups, and care.

- Trust – in understanding why data are being collected, how it will be used, and by whom – is an ongoing barrier to data sharing among organizations and by the people whose data is desired.

- Providers and researchers who focus in areas outside of IT sometimes do not understand the importance of data standards to patient care and research, so it is harder to engage them. More effective ways should be sought for educating and engaging providers and researchers at the right times in the standards development process (not all the time), and in the piloting and implementation of standards-based systems.

- Federal agency hesitancy to embrace a single standard in some of its new payment models perpetuates heterogeneity in standards used and adopted in the field and can become a barrier to data sharing.

Public Health Perspectives

- The limited scope of data elements called out by the USCDI and supported by the US Core FHIR Profiles means that key Public Health reporting data elements are inaccessible via standard FHIR APIs related to EHR implementations. Access to data relating to pregnancy, delivery and maternal and child health are particularly inaccessible despite the critical roles these elements play in a wide variety of Public Health reporting requirements.

- Public Health programs lack sufficient resources (time, personnel and funding) to develop, test and implement the tools and processes necessary to onboard reporting providers and health care organizations at scale.

- Due to limited resources and competing priorities EHR systems often don't support standards not part of certification requirements or regulations.

- Neither Public Health programs nor Health IT vendors have the resources necessary to regularly participate in HL7 FHIR Connectathon activities or otherwise review and test emerging standards.

Patient Empowerment Perspectives

- Provide a complete patient-centered longitudinal record that is both accessible by the patient and can be shared by patient-mediated exchange.

- Consents need to be electronic and obtained in the clinical workflow so that sharing is not delayed due to inefficiencies in collecting consent.

- Ability to appropriately segment or partition data is enhanced to allow individuals with concerns about privacy for some of their data to participate in data sharing.

- Where blockchain is used for data sharing there should be consideration of standards harmonization

- Create a better awareness of why data sharing matters, how to protect, secure, and release patient information as part of personalizing one's care delivery experience, and ensure that people from various demographics can validate approaches, reaching as many as possible.

Organizing Question #2 - Are there any new standards or use cases available or under development that should be considered by NCVHS for recommendation to HHS for adoption to support interoperability, burden reduction and administrative simplification? Some examples might include new information sharing in health care, such as data or semantics for social determinants of health, public health case reporting, or All Payer Claims Databases. Please do not limit responses to these examples.

Overarching Perspectives – Standards, Interoperability and the Digital Divide

- We request that the United States Core Data for Interoperability (USCDI) continue to be implemented in FHIR as "US Core". Clarifying this relationship to a broader community would be helpful.

- As humans and diseases continue to travel globally, international coordination between jurisdictions will be increasingly important regarding data represented in USCDI, US Core, and specialized Implementation Guides (IGs).

- On top of US Core, specialized Implementation Guides will need to be developed in a coherent manner for specific applications across health. This will foster improvements in care and research and reduction of burden and cost. mCODE (https://confluence.hl7.org/display/COD/mCODE) is an example of a specialized IG focused on data that should be collected for every cancer patient. mCODE is being tested and improved with the CodeX HL7 FHIR Accelerator against several use cases (RWD clinical trials, finding trials, registry reporting, etc.). The "mCODE approach" is also being considered for other areas, including cardiovascular disease and Alzheimer's/related dementias.

Public Health Perspectives

- All standards mentioned in the ONC's Interoperability Standards Advisory (ISA) should be considered by NCVHS for recommendation to HHS for adoption to support interoperability, burden reduction and administrative simplification. Important examples include:
  - Newborn screening (EHDI, CCHD, DAR and DBS use case in LOI and LRI)
  - Birth Defect Reporting (CDA and draft FHIR)
  - Cancer Reporting (CDA and draft FHIR)
  - Immunization Decision Support
  - Occupational Data for Health

Patient Empowerment Perspectives

- The HL7 International Patient Access (IPA) specification will extend the reach of US Core to the international level.

- The principle: "No aggregation without representation" – represents a desire for collective governance of

digital rights for patient groups and communities that should be considered.

- Consider support for emerging network topologies to enable patient mediated exchange of health data.

- The HL7 Patient Empowerment Workgroup is working on an Implementation Guide for Patient Request for Corrections - providing a standard way to communicate and support this request would help improve the quality of health care information.

- The HL7 Patient Empowerment Workgroup is also working on a white paper to define the field of patient *contributed* data. Note that this is much more than PGHD (patient *generated* data, e.g. data from a fitness watch) - it includes any types of information that the patient and family say are important, whether or not those data types are currently modeled in health data systems. This is an essential aspect of the shift to patient-centered care.

- The Advance Directive Interoperability (ADI) Community is working on improving data sharing by allowing people to create, update, and make their goals, preferences, and priorities for treatment - which will drive data sharing from the main user of health care services, the patient themselves. This work should be considered.

Organizing Question #3 - How have other industries effectively implemented, tested, and certified standards for data and their exchange that could be considered for health care?

Overarching Perspectives

Successful, open standards systems provide value to most players in an ecosystem, and remove waste (burden, cost, delay, middle-players who profit on chaos). Successful standards are also developed with input from stakeholders and with the benefit of real-world testing. Standards are implemented widely when they address motivations of actors in an ecosystem. Related to this, patients should become more aware of the importance of standards-based interoperability and increasingly request it from their providers and apps. Health systems, researchers and other service providers should request standards-based interoperability from vendors. And, lawmakers/regulators should use their tools to encourage or mandate standards-based interoperability when other market forces are insufficiently comprehensive or fast.

Six examples follow, of other industries that have effectively implemented, tested, and certified standards for data and their exchange that could be considered for health care are below that are successful in terms of interoperability.

- Global Financial System in the Internet Age: Increasing transparency, less burdensome/costly currency flow, etc. depends on data standards (like SWIFT https://en.wikipedia.org/wiki/Society_for_Worldwide_Interbank_Financial_Telecommunication, FIX https://en.wikipedia.org/wiki/Financial_Information_eXchange, etc.) as well as practice standards and regulatory oversight/coordination.

- Global Logistics Automation: Starts with data standards for unique identification of things using unique IDs, barcodes, RFID, descriptions of things, locations, business entities, data exchange formats and protocols, practices etc.   On a less technical level, standards for the dimensions of shipping containers have been important to increasing efficiency. https://en.wikipedia.org/wiki/Logistics_automation.

- Telecommunications: Standards for equipment, frequencies, hand-off between towers/networks/countries, and data exchange, coupled with regulations https://en.wikipedia.org/wiki/Interoperability#Telecommunications.

- World-Wide Standardized Seismographic Network: For decades, seismologists needed practice and instrumentation standards to share data between institutions in order locate earthquakes and understand the interior of the earth. Early seismographic observations were exchanged on paper, telegraph, and telephone. The WWSSN, implemented in the early 1960s, was a major step forward. The WWSSN was primarily funded to monitor global underground nuclear testing. The network also substantially increased our understanding the structure and tectonics of the Earth. The WWSSN included advanced standards for seismometers, global timing, measuring signals, formatting and exchanging data, and using the data to detect, locate and identify seismic events https://en.wikipedia.org/wiki/World-Wide_Standardized_Seismograph_Network Subsequent implementations for global geophysical monitoring have built upon the WWSSN standards-based model. E.g., https://www.ctbto.org/verification-regime/background/overview-of-the-verification-regime/.

- Internet and World Wide Web: Starting with US-based projects and standards, ANSI (https://www.ansi.org/), ISO (https://www.iso.org/), IETF (https://www.ietf.org/) and the W3C (https://www.w3.org/) evolved international standards such as TCP/IP, HTTP, URL, HTML, and others that power and make more accessible the internet and World Wide Web. There are useful lessons here regarding what led people to demand an open Web, over its predecessors on the Internet (Prodigy, Compuserve, AOL, etc.). There are also useful learnings regarding challenges posed by widespread interoperable data systems, value, and abuse.

- Airline Schedule and Reservation Sharing: E.g. https://www.iata.org/en/publications/store/standard-schedules-information/ The SSIM is the official set of standards, guiding the industry with recommended practices, messaging formats and data processing procedures that are to be used by all IATA member airlines and their business partners for the exchange of airline schedules, communication of airport coordination information and minimum connect time data. Airlines also share standardized data to help travel agents and applications present travel options to travelers, help travelers book trips, etc.

Organizing Question #4 - What short term, mid-term and long-term opportunities or solutions do you believe should be priorities for HHS?

HL7 recommends:

Short-term:
- Leverage standards for demographic concepts like Social Determinants of Health https://commons.wikimedia.org/wiki/File:Social_Determinants_of_Health_Infoviz.jpg to prioritize work based on potential to improve health and research, reduce inequities, and reduce cost and burden. The United States Core Data for Interoperability now includes SDOH and SOGI data elements: https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi#uscdi-v2. Resources such as the SDOH-focused HL7 Gravity Project should be maximally consulted and leveraged.
- Review and leverage existing strategies, like the draft National Strategy for Digital Health and the Federal Data Strategy to prioritize actions and propel momentum to key milestones.
- Continue to clarify and coordinate roles of government agencies.
- Increase financial support for open consensus health IT standards development organizations, and clarify which organizations are responsible for which standards.

- Ensure the new National Institutes of Health Advanced Research Projects Agency for Health (ARPA-H) has as one of its foci standards-based interoperability and its impact on health. ARPA-H and all agencies should require researchers to use standards, where applicable. More information on ARPA-H can be found at: https://www.nih.gov/arpa-h.
- Expand the USCDI to include core data elements crucial to Public Health reporting.

Mid-term:
- Focus on gathering stakeholders to collaborate to demonstrate in real-world settings the value of proposed standards before they are finalized. Provide funding and resources for pilot projects on emerging standards. Implementation and testing fora like the HL7 Accelerator Program are proving to be effective in this regard.
- Develop a strategy to ensure that code/terminology systems required for interoperability are easily available for implementers and users. Consider a national licensing scheme, or direct funding to the code system custodians to lower financial barriers to adoption, implementation, and use of these standards.
- Work with patients and other stakeholders to develop a strategy for patients and caregivers to control their health data from birth to death and beyond.
- Develop a strategy for appropriate worldwide collection and sharing of health data.

Long-term:
- Finalize implementation of strategies, measure progress, update as needed.