Health Level Seven® International
Unlocking the Power of Health Information

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Ms. Marilyn Tavenner
Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health & Human Services
Washington, DC 20201

Dr. Farzad Mostashari, M.D., ScM
National Coordinator
Office of the National Coordinator for Health IT
U.S. Department of Health and Human Services
Washington, DC 20201

Re: Advancing Interoperability and Health Information Exchange RFI

Dear Ms. Tavenner and Dr. Mostashari:

Health Level Seven International (HL7) appreciates the opportunity to provide feedback and comment on the Request for Information on Advancing Interoperability and Health Information Exchange (Interoperability RFI). Exploring and promoting interoperability across providers is particularly relevant as health information exchange (HIE) programs are currently gaining momentum yet facing challenges in achieving their intended goal.

HL7 is actively developing and improving standards and implementation guides that support cross-provider HIE. While these standards are crucial, without infrastructure, culture and sustainable funding/business models, they will be insufficient to drive meaningful interoperability. All of these activities must be actively pursued to provide better care that improves the health of our population and at lower cost.

HL7 also feel there is a critical need for similar standards across care settings. The Deficit Reduction Act of 2005 moved the industry in this direction by improving consistency within long term and post-acute care setting, and HITECH achieved similar results across hospital and ambulatory settings. Agreement on a consistent yet manageable set of standards across all settings will simplify deployment of EHRs, reduce barriers to patient-centered care, enable consistent measurement of quality and other data, and set the stage for payment reform.

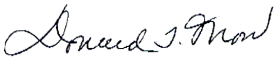
Below are HL7's responses to those RFI questions relevant to its work and additional comments relating to the broader policy framework addressed by the questions in the RFI.

3300 Washtenaw Ave., Suite 227 • Ann Arbor, MI 48104-4261 • USA
Office: +1 (734) 677-7777 • Fax: +1 (734) 677-6622 • E-mail: hq@HL7.org • Website: www.HL7.org

HL7 appreciates the opportunity to provide input and stands ready to assist in relevant initiatives as needed.

Sincerely,

Charles Jaffe, MD, PhD, FACP, FACMI
Chief Executive officer



Donald T. Mon, PhD
Chairman of the Board

3300 Washtenaw Ave., Suite 227 • Ann Arbor, MI 48104-4261 • USA
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General Considerations

HL7 offers the following general considerations relating to the overall policy framework needed to establish successful interoperability across providers:

Culture

The healthcare industry must promote a culture of cross-providers data sharing that is based on the need for data to follow the patient as he/she crosses the continuum of care. Without this culture, there is no demand for health information exchange, the value of HIE will be limited, and efforts to promote HIE will fail as funding dries up. When payment models that promote cross-provider collaboration are established, a culture of data sharing will follow.

Infrastructure and Funding

As this culture evolves, so will the need for a secure infrastructure that protects privacy and includes well-defined standards and implementation guides to support relevant exchange scenarios. This will require funding acquired from savings elsewhere in the system or other sources. In either case, the appropriate policy levers must address the role of payers, including CMS, in funding the infrastructure from which they should ultimately benefit.

Standard Specifications

Over the last two decades, data exchange standards such as HL7's V2, V3 and CDA provided a level of flexibility that enabled individual providers and their software developers to create interoperability solutions that meet the needs of their unique environments. It has become clear over the last 5-10 years that successful interoperability within one provider organization does not easily translate into successful national, cross-provider interoperability. Conflicting vocabularies and conflicting interpretations of the standards (most being valid interpretations) are just a few of the many challenges that must be resolved to enable consistent cross-provider exchange at a national level.

There are some positive trends. National programs are, in part, driving the emergence and acceptance of vocabularies such as LOINC and SNOMED that level semantic understanding across providers. Similarly, implementation guides such as HL7's Consolidated CDA (C-CDA) and its Laboratory Orders/Results are increasingly addressing the need for consistent, less ambiguous interpretation of the foundation standards that support cross-provider interoperability.

While these trends are encouraging, more work is needed to expand the library of commonly accepted implementation guides and harmonize vocabulary and data representations across implementations by different organizations.

We believe that CMS has a number of levers available to help develop the culture and fund the infrastructure. Most notable are the potential measures referenced in RFI questions 4 and 5 to extend the coverage of the electronic HIE for interoperability across the acute, post acute, long term care and behavioral health. In its complementary role, ONC can urge and incent relevant SDOs, including HL7, to develop standards and implementation guides that support cross-provider HIE. HL7 and ONC's S&I Framework, for example, have collaborated to create several implementation guides, and HL7 is committed to continuing this collaboration.

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Responses to Select Questions

We offer the following feedback on the introduction to the RFI and specific questions relevant to HL7's areas of expertise.

Quote (page 14796, column 2, sub B. Low Rates of HIE Across Settings of Care and Providers): *"HHS can collaborate in the development of new e-specified measures of care coordination that encourage electronic sharing of summary records following transitions in care. This could be incorporated into and aligned across multiple programs including the EHR Incentive Program, and other CMS quality reporting programs. "*

- HL7 has developed standards to communicate e-definitions (HQMF) and quality reports (QRDA) consistently across providers and between providers and government agencies. We continue to work with ONC and CMS stakeholders to ensure that these standards meet the ever-evolving definition of quality measures. HL7 encourages e-measure definitions that can be easily derived from existing data produced by clinical and administrative processes already supported by Health IT. This approach allows quality reports to be populated without duplicative and/or cumbersome data collection. Converging and aligning measures used for reporting clinical conditions, processes and outcomes, and reimbursement will assist the process.

Quote (page 14797, first column, second bullet): *"CMS could promote the use of BlueButton. The Blue Button provides easy electronic access to personal health information for consumers. To strengthen its success, ONC released guidelines for data holders and application developers that support the growth of an ecosystem of tools to help consumers manage their health. The Blue Button Plus guidelines include specifications for a structured data format (consistent with Meaningful Use Stage 2), and enable updates of the information contained in individual consumer's health records to be sent automatically to the applications of their choice. Tools built on Blue Button Plus specifications could be made available to all CMS beneficiaries, and widely promoted by healthcare providers and via avenues such as the Medicare Handbook, Medicare.gov, and Medicare Advantage plans."*

- HL7 supports the continued harmonization of the Blue Button payload document with similar summary of care documents that are based on the C-CDA family of document types. This will reduce duplicative and potentially conflicting standards definition and implementation efforts, thus promoting consistent exchange of documentation both between both providers and patients and across providers.

Question 1: *"What changes in payment policy would have the most impact on the electronic exchange of health information, particularly among those organizations that are market competitors?"*

- As mentioned in our introductory remarks, HL7 believes there is a critical need for common standards deployed across all settings. The use of different standards in different care settings adds complexity and cost, not only to standards adoption, but to payment policy. Measuring care across the spectrum of care requires a single set of standards deployed across all settings.

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Question 2: *"What changes in payment policy would have the most impact on encouraging electronic health information exchange: Hospital readmission payment adjustments, value-based purchasing, bundled payments, ACOs, Medicare Advantage, Medicare and Medicaid HER Incentive Programs (Meaningful Use), or other medical/health homes? Are they any aspects of the design or implementation of these programs that are limiting their potential impact on encouraging care coordination and quality improvement across settings of care and among organizations that are meting competitors?"*

- HL7 believes that the interoperability standards cited under Meaningful Use are also applicable to other care settings (such as nursing homes), and consistent use of these standards will stimulate care coordination and quality improvements. We can better achieve the goals of patient-centered care by adopting a common set of standards across all settings.
- We also feel there may be a need to modify the Meaningful Use Stage 2 quality reporting criteria to better embrace the needs of patient-centered care, ACOs, and care coordination across settings. Meaningful Use 2 requires that all data for quality measures be derived from a single certified EHR. However, determining the overall quality based on new models of care may require data to be gathered from multiple certified systems. HL7 therefore suggests that this requirement be re-examined in Meaningful Use 3.

Question 3: *"To what extent do current CMS payment policies encourage or impede electronic information exchange across health care provider organizations, particularly those that may be market competitors? Furthermore, what CMS and ONC programs and policies would specifically address the cultural and economic disincentives of HIE that result in "data lock-in" or restricting consumer and provider choice in services and providers? Are there specific ways in which providers and vendors could be encouraged to send, receive, and integrate health information from other treating providers outside of their practice of system?"*

- HL7 supports "incrementalism", particularly as new care settings are added to the Meaningful Use requirements. We suggest introducing a Meaningful Use criterion for creating and receiving narrative Consolidated CDA documents to encourage the flow of large volumes of data at relative low cost. Once the documents are flowing, a smaller incremental criterion to layer prioritized structured data elements into these documents can be added.

Question 4: *"What CMS and ONC policies and programs would most impact post acute, long term care providers (institutional and HCBS) and behavioral health providers' (for example, mental health and substance use disorders) exchange of health information, including electronic HIE, with other treating providers? How should these programs and policies be developed and/or implemented to maximize the impact on care coordination and quality improvement?"*

- HL7 believes that the adoption of data elements that are high priority in non-HITECH settings (e.g., skin integrity and functional status in nursing homes) can have a beneficial effect on EHR systems available for use in these other settings. For example, introducing skin integrity and functional status templates into Consolidated CDA, with requirements for adoption of these data elements under Meaningful Use 3, will have a positive trickle-down effect on other settings.

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Question 7: *"How could the EHR Incentives Program advance provider directories that would support exchange of health information between Eligible Professionals participating in the program. For example, could the attestation process capture provider identifiers that could be accessed to enable exchange among participating EPs?"*

- HL7 produced the *Healthcare, Community Services and Provider Directory* (ANSI/HL7 V3 HCSPDIR 2010) standard, which defines the functionality needed to maintain searchable provider directories that are interoperable across provider organizations. This standard has been adopted by the Object Management Group (OMG), the developer of the Unified Modeling Language (UML) and other related standards. It served as the basis for industry-endorsed SERV-D specifications and reference implementations that enable discovery and maintenance of information to assemble, address, and secure interoperable messages. Implementation is based on a services-oriented approach that addresses the decentralized and distributed nature of provider directories. Maturing and then incorporating these standards into a future EHR certification Incentive Program would help establish a viable infrastructure. While using annual reporting processing to help maintain the directories would be helpful, introducing directories and EHR capabilities based on these standards offers a more robust, continuous process for maintenance and widespread communication of relevant provider directory content.

Question 9a: *"What specific HHS policy changes would significantly increase standards based electronic exchange of laboratory results?"*

- Through CLIA or related regulations adopt the same *Laboratory Test Compendium, Orders, and Result* implementation guides currently referenced in the *Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition* and upcoming editions as a certification of the laboratory to ensure consistent exchange between LIS and EHR. We recommend that the Clinical Laboratory Improvement Amendments (CLIA) be updated to require laboratories to be able to support electronic data exchange using the same standards as certified electronic health records technology (CEHRT). CMS also should consider providing laboratories with safe harbors from CLIA requirements for accountability for the correct display of lab results to providers when the provider is using CEHRT.

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