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August 29, 2013

Farzad Mostashari, MD  
National Coordinator for Health Information Technology  
U.S. Department of Health and Human Services  
Attention; FDASIA Report  
Hubert H. Humphrey Building  
Suite 729D  
200 Independence Avenue SW  
Washington, DC 20201

Dear Dr. Mostashari

Health Level Seven International (HL7) appreciates the opportunity to provide feedback on the “Food and Drug Administration Safety and Innovation Act (FDASIA): Request for Comments on the Development of a Risk-Based Regulatory Framework and Strategy for Health Information Technology” published in the May 30, 2013 *Federal Register*.

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 2,300+ members represent approximately 500 organizations that comprise more than 90% of the information systems vendors serving healthcare in the US. As the global authority on standards for interoperability of health information technology, HL7 appreciates the opportunity to offer feedback to ONC, the FDA and the Federal Communication Commission (FCC) on the FDASIA Request for Comments. We would be happy to answer questions or provide further information on our response.

Sincerely,

A handwritten signature in black ink that reads 'Charles Jaffe MD, PhD'.

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

A handwritten signature in black ink that reads 'Donald T. Mon'.

Donald T. Mon, PhD  
Board of Directors, Chair  
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## **HL7's Comments - Food and Drug Administration Safety and Innovation Act (FDASIA): Request for Comments on the Development of a Risk-Based Regulatory Framework and Strategy for Health Information Technology**

The FDASIA Request for Comments notice on pages 32390-32391 of the May 30, 2013 *Federal Register* outlines three potential topics for discussion: 1) taxonomy; 2) risk and innovation; and 3) regulation. HL7's comments in these areas are detailed below.

### **TAXONOMY**

#### HL7's Comments

HL7 urges HHS and other relevant federal agencies to actively engage the health care standards community from the outset regarding new and emerging areas to:

- Seek input on the context and appropriateness of regulatory terms, definitions, frameworks and taxonomies in the context of available and planned standards;
- Gather perspectives from key stakeholders contributing to the standards necessary to help realize initiatives across the various agencies;
- and
- Enable harmonization of terminology and definitions between the traditional medical device community and the health informatics field within the US and across countries.

### **RISK-BASED FRAMEWORK**

#### HL7's Comments

Current eHealth projects, such as those supported by the federal government, reinforce the power of health information technology (HIT) to support patient safety goals, promote innovation and mitigate many of the hazards associated with traditional paper based processes. From data acquisition, through transformation, and communication of data, patient safety issues may arise that require appropriate controls to manage their risk within acceptable boundaries.

Interoperability focuses on the effective and efficient communication of data across systems to enable various stakeholders to share and access patient data. Interoperability consequently must be an essential element in a risk-based regulatory approach for HIT. Standards supporting the many facets of interoperability, e.g., the syntax, semantics, security, and privacy, and the SDOs developing them should therefore be an integral part of a risk-based framework.

For decades, the use of HL7 standards has supported the effort to reduce medical errors. And, HL7 continues this important work by contributing expertise and effort to the national meaningful use movement and to the deployment of an effective Standards and Interoperability Framework for the US.

As the federal government steps up its work, so does HL7. HL7 and its member experts are helping to substantially improve interoperability between stakeholders throughout a project, product or transaction lifecycle and therefore have the potential and opportunity to positively impact patient safety. Specifically, HL7 focuses on how to support and enable:

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- Consistent, unambiguous, secure and privacy-protective uses of data across stakeholders including areas for which HL7 provides standards for interoperability;
- Data integrity across providers in terms of both syntax and semantics; and
- Data provenance (i.e., the ability to ensure data is associated with the right patient through effective patient identification standards).

HL7 also continues to inform the relevant outputs of federal agencies such as the Agency for Healthcare Research and Quality (AHRQ) who coordinates the development of Common Formats for reporting patient safety events to Patient Safety Organizations (PSOs) for acute care hospitals and skilled nursing facilities. HL7's long-standing standard development work to arrive at a common patient safety reporting format provided a solid basis for the AHRQ Common Formats reporting system. The Common Formats reporting system is based on the HL7 Clinical Document Architecture (CDA) and provides critical data on patient safety incidents, near misses or close calls and unsafe conditions.

## **REGULATORY**

### HL7's Comments

In regard to regulatory issues, HL7 has three specific areas of comment.

First, however the risk-based regulatory framework for health IT is established, it is important to HL7 members that there is clarity on responsibilities to avoid ambiguity, overlap, and/or conflict. Within the framework, HL7 and other standards development organizations should be subject to the same considerations as other health IT stakeholders to ensure consistency and minimize the risk of inadvertently degrading data integrity which increases the risk of adverse patient safety events. Overall, HL7 supports the risk-based regulatory framework for health IT suggested through the Bipartisan Policy Center as a practical starting point and perspective. We also support a framework that achieves its aims in an effective, efficient manner without unnecessary regulatory burden or expense.

Our second area of comment in relation to regulatory issues relates to international conformance. HL7 would like to highlight the issue of international regulatory conformance and how our organization can be helpful. HL7 members are public and private sector HIT experts, many of them leaders in national eHealth experiments around the world. HL7 is a truly global organization with affiliates in over 30 countries on five continents. Given our deep reservoir of field expertise, HL7 can provide authoritative views on challenges and opportunities for regulatory conformance across borders in the area of standards and interoperability.

Our third regulatory comment area relates to recommendations on a new Federal Advisory Committee. The development and implementation of a risk-based regulatory framework and strategy for health information technology will be a long-term process with many important issues with which to wrestle. The FDASIA Committee's January 2014 report represents the kick-off of this process. HL7 recommends a new Federal Advisory Committee with representation from all appropriate stakeholders be formed to process and deliberate on on-going issues relating to a risk-based HIT framework.

In closing, HL7 welcomes your outreach and always stands ready to offer perspectives about policy and regulatory issues relevant to its mission.

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