HL7 Receives ANSI Approval of Three Version 3 Specifications Including CDA, Release 2

ANN ARBOR, Mich.—May 5, 2005— Health Level Seven (HL7), one of the world’s most prolific healthcare standards developers, today announced that it has received approval from the American National Standards Institute (ANSI) for three of its Version 3 (V3) specifications including \textit{Clinical Document Architecture, Release 2}, \textit{Individual Case Safety Report, Release 1}, and \textit{Accounting and Billing, Release 1}. HL7 Version 3 enables the exchange of complex healthcare information across multiple organizations. It encompasses dozens of specifications all based on the HL7 Reference Information Model (RIM), which defines and relates all data that exist for HL7.

“CDA Release 2 gives us the functionality and expressivity of the RIM, including the Clinical Statement model, and is fully harmonized with related initiatives within HL7 and in Europe,” said Liora Alschuler, a co-editor of the standard and HL7 board member. “We now have a document structure on which we can build local and regional exchange networks which will support everything from discovery and retrieval of scanned document images to disease registries and decision support.”

The HL7 Clinical Document Architecture (CDA) is a document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange. A clinical document has the following characteristics:

- Persistence – A clinical document continues to exist in an unaltered state, for a time period defined by local and regulatory requirements
- Stewardship – A clinical document is maintained by an organization entrusted with its care
- Potential for authentication - A clinical document is an assemblage of information that is intended to be legally authenticated
- Context - A clinical document establishes the default context for its contents
- Wholeness - Authentication of a clinical document applies to the whole and does not apply to portions of the document without the full context of the document
- Human readability – A clinical document is human readable

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Also receiving ANSI approval under the umbrella of V3 was *Individual Case Safety Report, Release 1* and *Accounting and Billing, Release 1*. The Individual Case Safety Report (ICSR) topic area captures the information needed to support the reporting of adverse events or product problems associated with the use of drugs, therapeutic biologics, vaccines and devices. Over time, the scope of the messaging may be expanded to support other types of products such as food, dietary supplements, cosmetics or veterinary products and services. The message is specifically designed to support individual case safety reports, and not support population-based case reporting for disease surveillance or outbreak events. In addition, the message is designed to support international safety reporting between public health organizations such as the World Health Organization, and regulatory authorities in the US, Canada, Europe and Japan using the International Conference on Harmonisation (ICH) E2B M2 ICSR message transmission standard.

Meanwhile the Accounting and Billing (AB) domain covers the creation and management of patient billing accounts, primarily for the purpose of collecting charges and credits to support the submission of a claim or invoice for reimbursement.

**About HL7**

Founded in 1987, Health Level Seven, Inc. ([http://www.HL7.org/](http://www.HL7.org/)) is a not-for-profit, ANSI-accredited standards developing organization 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 more than 2,000 members represent approximately 500 corporate members, including 90 percent of the largest information systems vendors serving healthcare. Recently, HL7 joined 12 other healthcare stakeholders in a collaborative response to the Request for Information (RFI) issued by the Office of the National Coordinator for Health Information Technology (ONCHIT) to learn how widespread interoperability of health information technologies and health information exchange could be achieved through a National Health Information Network (NHIN). The Collaborative response can be viewed in its entirety at: [http://www.hl7.org/Library/General/Collaborative_RFI_Responsefinal.pdf](http://www.hl7.org/Library/General/Collaborative_RFI_Responsefinal.pdf). The HL7 additional response specific to *Standards and Policies to Achieve Interoperability* can be found at [http://www.hl7.org/Library/General/HL7Q14-18_final.pdf](http://www.hl7.org/Library/General/HL7Q14-18_final.pdf).

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HL7’s endeavors are sponsored, in part, by the support of its benefactors: Capgemini; Centers for Disease Control and Prevention (CDC); Documentum; Eclipsys Corporation; Eli Lilly & Company; the Food and Drug Administration; GE Medical Systems; Guidant Corporation; IBM; IDX Systems Corporation; InterSystems Corporation; Kaiser Permanente; McKesson Provider Technologies; Microsoft Corporation; Misys Healthcare Systems; NHS Connecting for Health; NICTIZ National ICT Institute for Healthcare in The Netherlands; Oracle Corporation; Partners HealthCare System, Inc.; Pfizer, Inc.; Philips Medical Systems; Quest Diagnostics Inc.; Science Applications International Corporation; Siemens Medical Solutions Health Services; the U.S. Department of Defense; Military Health System; the U.S. Department of Veterans Affairs; and Wyeth Pharmaceuticals.

International affiliates have also been established in 27 countries throughout the globe including Argentina, Australia, Brazil, Canada, China, Croatia, Czech Republic, Denmark, Finland, France, Germany, Greece, India, Ireland, Italy, Japan, Korea, Lithuania, Mexico, The Netherlands, New Zealand, Poland, Spain, Switzerland, Taiwan, Turkey and the United Kingdom.

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