Health Level Seven’s ANSI-Approved Structured Product Labeling (SPL):
A Model Standard for Present and Future

ANN ARBOR, Mich.— December 31, 2004 — Health Level Seven’s new Structured Product Labeling (SPL) Release 1.0 standard, which received approval from the American National Standards Institute (ANSI) in August 2004, is a model standard that both addresses the practical needs of the present and provides for robust future solutions.

The scope of the SPL is the standardization of the markup of the content of product labeling documents for the purpose of review, editing, storage, dissemination, analysis, decision-support, and other re-use. The SPL specification is a markup specification for the regulatory content of a drug product labeling document (commonly known in the U.S. as a package insert).

“Since its introduction, the SPL Standard has already had an important impact on healthcare,” said Sandy Boyer, Co-chair of HL7’s Structured Documents Technical Committee and the SPL standard’s primary editor.

The SPL effort was initiated in mid 2002 when the U.S. Food and Drug Administration (FDA) approached HL7 with an idea to develop a standard for drug product labeling based on another HL7 document standard — the Clinical Document Architecture (CDA). The FDA needed the standard to facilitate review of labeling and support the DailyMed initiative, which involves provision of up-to-date drug product labeling through a National Library of Medicine (NLM) database.

“The initial requirements for SPL were to identify the major sections of a labeling document and tag certain elements of information about a drug product that would facilitate storage and utilization of the document,” said Boyer.

Boyer says this effort took on added urgency with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), which called on the National Committee on Vital and Health Statistics (NCVHS) to develop standards to support electronic prescribing (e-prescribing) as part of the federal government’s eHealth initiative. A number of NCVHS hearings took place over the next year, culminating in a letter to the Secretary of the U.S. Department of Health and Human Services (HHS) in September 2004 with a set of recommendations in which SPL figured prominently.

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In December 2003, the FDA issued a rule requiring submission of product labeling content electronically (such as in a PDF file) as of June 2004. SPL began to receive widespread attention with the publication of a draft FDA guidance in February 2004 that called for submission of all drug product labeling in SPL format by the end of 2004. That date has since been pushed back, with completion of the switch from PDF to SPL for prescription drug labeling expected to be complete by July 2005.

Then in May 2004, HHS and the U.S. Departments of Defense and Veterans Affairs announced the adoption of 15 standards recommended by the Consolidated Health Informatics (CHI) initiative for electronic exchange of clinical information across the federal government. These recommendations included use of SPL headers for drug labeling sections, as well as CDA for text-based medical reports.

SPL also does not require complete modeling of the data content of the labeling document all at once. Additional data elements can be added over time without having to re-do existing markup. For example, SPL Release 1.0 contains a restricted set of data elements that describe a drug product (brand name, generic name, dosage form, active and inactive ingredients, etc.). Because the underlying model is sound, future additional data elements may be added that describe drug interactions or dosing. The standard can also be enhanced to accommodate other types of labeling (e.g., biologics, blood products, vaccines, devices). This provides important extensibility and, just as importantly, makes thoughtful, measured and incremental development possible based on careful analysis of requirements.

“I believe that SPL Release 1.0 and its design for incremental enhancement is a model for a standard that provides a practical solution for the present and a pathway to an even more robust solution for the future,” Boyer said.

One of the challenges in the development of SPL Release 1.0 has been (and will continue to be) the necessity to balance the requirements of FDA, which initiated its development, with those of other potential users of this open standard — a very broad community including the pharmaceutical industry, publishers, applications developers, and more.

“The development of SPL Release 1.0 was a model of collaboration among all stakeholders that should be encouraged and nurtured,” Boyer said. “If the SPL/CDA principles defined in the specification and the interoperability and open development principles of HL7 continue to be respected, that should ensure that the standard will live up to its promise.”

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**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.

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