Standards Development and HIM: HL7's IT Standards Work and Its Uses in Health Information Management

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Health Level Seven (HL7) is an American National Standards Institute-accredited standards developing agency that specializes in developing healthcare standards. Its vision is to "create the best and most widely used standards in healthcare."

For HIM professionals, understanding HL7 and how it affects the electronic health record is something that may often be overlooked in the day-to-day operational issues. However, understanding HL7 standards can assist HIM professionals in evaluating their organization's current electronic health record functions. It can also expand their knowledge in electronic health records and prepare them for the future of healthcare.

HL7's Work

HL7 has developed a variety of standards in both the healthcare and information infrastructure domains to promote the use of supportive and compatible standards. It collaborates with healthcare IT users to ensure that its standards meet real-world requirements, and it initiates appropriate standards development efforts to meet emergent requirements.

Any standard that HL7 publishes and submits to the American National Standards Institute for approval must be developed and ratified by a process that adheres to ANSI's procedures for open consensus. This process is done by the use of a ballot, which allows input from a variety of sources to review and make comment on proposed standards. HL7 standards are added or modified based on a ballot process. This is very similar to the process that takes place with the federal regulations.

HL7 produces a draft standard that is voted on by the members, and the resulting comments are taken into consideration to produce the final standard. Information on the balloting process along with actual ballots can be found on the HL7 Web site at www.hl7.org.

Current HL7 standards include:

Messaging standards. HL7 messaging transactions are used to transfer patient demographic information (such as admission, transfer, and discharge data) from patient management systems to ancillary systems. These standards define header information to enable the exchange of reports and results from ancillary and transcription systems to clinical repositories.

HL7 messaging standards affect how clinical information is used for an organization's daily business activities. They ensure an accurate exchange of clinical data between a hospital and outside entities such as reference laboratories.

An example can be seen in the transfer of a lab result. A hospital order includes the test type, specimen description, and patient identification. The laboratory system sends back the result type, description, and patient identification for the accurate exchange of information.

Electronic Health Record System (EHR-S) Functional Model . The HL7 EHR-S functional model describes the functions that may be present in an EHR system and provides a common language for its capabilities. The model is segmented into sections: direct care, supportive, and information infrastructure. Each section is further broken down into categories that list specific criteria for individual divisions.

The specific criteria designate whether the function "shall," "should," or "may" be required for individual conformance criteria within categories. For example, under the information infrastructure section is a subsection for security. Among the conformance criteria is the statement: "The system **shall** authenticate principals (i.e., users, entities, applications, devices, etc.)

prior to accessing and EHR-S application or EHR-S data." There are hundreds of individual conformance criteria within the EHR-S functional model.

The functional model serves as the foundation for the Certification Commission for Healthcare Information Technology EHR criteria. CCHIT works to accelerate the adoption of interoperable health IT through product certification. Since its inception in 2004, CCHIT has issued modular certification criteria for ambulatory and inpatient products.

Clinical Context Object Workgroup (CCOW) Standard. Another HL7 standard integrates point-of-use applications so the clinical user's experience is one of interacting with a single system, even when he or she may be using multiple, independent applications from many different systems, each via its native user interface. The standard goes beyond the messaging type of transaction where data is being physically transferred between different applications. CCOW's work has been approved by ANSI.

HL7 Work in Progress

HL7 is also currently working on a number of new standards and profiles for future use in the healthcare industry. These include:

Records Management and Evidentiary Support functional profile. The profile identifies the key infrastructure functions that support the management of health records within the system for business and evidentiary purposes. Understanding this profile will assist HIM professionals in developing and supporting a legal health record within their organizations. It is imperative that HIM professionals communicate the need for inclusion of this standard within their organization and with their vendors to ensure legally compliant electronic health record systems.

In December 2007 HL7 issued a ballot for the records management and evidentiary support criteria, which was created by the Legal EHR-S Functional Profile Workgroup. The ballot proposed that an "EHR-S must be able to create, receive, maintain, use, and manage the disposition of records for evidentiary purposes related to clinical and business and transactions for an organization." It outlined conformance criteria for security, digital signatures, legal hold, document version control, seamless interoperability, hardcopy and electronic output, and other functions that directly affect health information management.

The Legal EHR-S Functional Profile Workgroup is currently in the process of reconciling ballot comments for a second ballot later in 2008.

Clinical Document Architecture. Document content requirements set standards for electronic history and physical and consultation reports. These data content standards will assist HIM professionals in identifying when these reports are deemed complete. The information will increase the data integrity of electronic health records and will set the basic infrastructure for a complete record. The standards use a combination of HL7 headers and defined report structure within XML (extensible markup language) documents.

The use of standard data content will enhance the ability to share complete documents between different care provider organizations that today may not be similar. Using the HL7 content standards will improve efficiency and maintain integrity of the documentation. Finally, the Clinical Document Architecture can be used to implement privacy management and control features in health information exchanges.

While the standard is more prevalent in Europe, it is under consideration for more extensive use in the United States to support developing interoperability objectives.

Personal Health Record System Functional Model. A subgroup of the EHR Technical Committee is working on a functional model for personal health records that would serve a similar purpose as the EHR-S functional model. The model is segmented into personal health, supportive, and information infrastructure sections. Refinement of the draft standard is taking place this year. The PHR and its potential interaction with the EHR are emerging concerns for HIM.

A Role for HIM Professionals

Standards development organizations such as HL7 will continue to shape the functionality and interoperability of electronic health records. HIM professionals are dedicated to ensuring the integrity, legality, and confidentiality of the health record, and HIM's involvement in the standards development area can only benefit the end result in electronic health records.

HIM professionals can become involved by joining HL7 and serving on work groups. By providing input at the standards-setting level, HIM professionals can ensure that stable information management practices are built into final IT standards. Additionally, HIM professionals can provide input on draft standards during public comment periods.

Within their facilities, HIM professionals can promote the use of HL7 standards in evaluating potential health IT systems or in conducting analyses of existing systems.

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