Revised HL7 Standards Takes EHR Management to a New Level

By Mark Crawford

A new version of international EHR standards is paving the way for the development of more robust health IT and health records.

Health Level Seven International (HL7), an organization accredited by the *American National Standards Institute* that develops standards for electronic health information, collaborated with many healthcare leaders to introduce an EHR functional standard in 2004.

This was a great first step in providing standards and conformance criteria for EHR systems, as well as a common language for discussing various functions and processes.

AHIMA played a key role in developing the Electronic Medical Record System Functional Model (EHR-S FM) Release 1.0 (R 1.0). This model provided a framework for health IT system vendors and users to develop and utilize products and services for EHR systems.

Now, eight years later, the HL7 EHR Work Group is balloting the long-awaited "Release 2.0" of EHR-S FM (R 2.0).

"The ink wasn't even dry on R 1.0 when work started for R 1.2 and then 2.0," said Lisa Spellman, director of HIM Solutions for AHIMA. "Much was learned during the balloting phase for R 1.0 and 1.1, so it was expected that R 2.0 would grow into new areas."

With the way EHR systems have developed so rapidly, R 2.0 was greatly needed to keep up with "current and anticipated needs of healthcare providers, both in the US and abroad, as well as provide updated consensus-based guidance to the healthcare industry," said Gary Dickinson, co-chair of the HL7 EHR Work Group and director of healthcare standards for CentriHealth. "It also provides benchmark requirements and criteria for EHR-S certification activities, such as the Certification Commission for Health Information Technology (CCHIT)."

The HL7 E HR Work Group solicited input from many sources to develop R 2.0, such as EHR-S Profiles, the EHR Interoperability Model, and other industry initiatives like certification, health information exchange, and data usage. Officially designated ISO/HL7 10781 EHR System Functional Model, R 2.0 "has been broadened to accommodate advances in the industry," said Patricia Van Dyke, HIM specialist with Delta Dental Plans Association. "It's also been made more flexible to allow adoption by other countries or care-specific environments."

Significant Changes

The number of functions and criteria in R 2.0 has essentially tripled, compared to the original model. One of the most expanded components is the focus on end-user perspectives. R 2.0 does a better job of demonstrating the standards in user-oriented language to better engage non-technical stakeholders.

"Additional content has been added to more clearly define how a product can conform to the functional domain profiles that underlie the overall model," Spellman said. "Functional profiles are selected sets of functions that typically apply to a particular domain, user, purpose, or care setting."

R 2.0 also expanded guidelines and advice for creating functional profiles that conform to the functional model, with specific steps and core principles to keep in mind. "Staff can build use cases by selecting from a long list of functions," Spellman

added. “For example, clinical purchasers can more specifically define and constrain which functions they wish a system to perform, and vendors can more clearly indicate product capabilities.”

Other major improvements include increasing conformance criteria from 972 in R 1.0 to 2,310 in R 2.0 as well as expanding the glossary, which now includes over 230 active terms and 50 deprecated terms.

Chapters have also been reorganized . “Direct care and supportive chapters in R 1.1 are now expanded into four new R 2.0 chapters, focused on care provision, care provision support, population health, and administrative support,” Dickinson said. “The R 1.1 information infrastructure chapter is now expanded into two R 2.0 chapters, focused on record infrastructure and trust infrastructure. We also added an overarching chapter to call out functions and criteria broadly applicable to all EHR systems.”

A Collaborative Effort

R 2.0 was developed as a five-way joint effort including HL7, the International Organization for Standardization (ISO), The European Committee for Standardization (CEN) Healthcare Informatics, the International Health Terminology Standards Development Organisation (covering SNOMED CT), and Clinical Data Interchange Standards Consortium (CDISC) (covering international clinical research-related standards).

Changes were first reviewed for inclusion by small teams of subject-matter experts (SMEs) and ultimately approved by the full HL7 EHR Work Group prior to ballot publication.

Each of the five voting organizations follows their own ballot process and rules.

“For example, in HL7 each member is given the opportunity to join the ballot pool, cast votes, and include related comments,” says Dickinson. “All negative votes must be accompanied by comments indicating areas of concern. In ISO, it’s one vote per country with comments reflecting composite national views.”

Once the ballot closes, the work group addresses each comment submitted, regardless of whether it is accompanied by an affirmative or negative vote. Reconciliation is typically accomplished by small SME teams, with suggested resolutions brought back to the full work group for approval.

Another ballot round is required for only substantive changes to the functional model. “The first HL7 R2 ballot round yielded more than 850 comments,” Dickinson said. “The other four international organizations should close their first round ballots no later than September 26, 2012.”

Compatible with Other Standards

R 2.0 does not conflict with other standards. “We referenced other standards while doing this work,” Van Dyke said. “Our goal is to create an international standard that is not duplicative of other international standards.”

The HL7 EHR Work Group added functions and criteria specifically based on the proposed stage 2 “meaningful use” EHR Incentive Program criteria. If stage 2 meaningful use EHR system certification criteria can be matched with corresponding function and conformance criteria of ISO/HL7 10781, developers can meet both benchmarks simultaneously.

“Thus vendors meeting (meaningful use) requirements are simultaneously leveraged into competitiveness in broader markets by meeting internationally recognized EHR functionality standards,” Dickinson said. “This (is an) advantage (for) all vendors, but also recognizes that the majority of stage 2 meaningful use-certified vendors and products are US-based.”

Both CCHIT and NIST have used EHR-FM conformance criteria as models for their own certification criteria development, so it is very likely they will also embrace R 2.0, resulting in even more widespread conformity.

Public Health and ISO/HL7 are in the process of developing a similar standard called PHR-FM. “Because there is natural overlap and synergy between these standards, much effort is going into creating a natural seamless flow between R 2.0 and

PHR-FM," Spellman said. "There has been active involvement by a wide range of public health professionals, including the Public Heath Data Standards Consortium and the Centers for Disease Control and Prevention."

New Standards Add EHR Dynamics

R 2.0 is a dynamic tool that enables key stakeholders to provide input on EHR operation and management. "HIM professionals are one of these key groups that are highly qualified to understand all the uses of health records and what functionality is necessary to ensure data integrity and quality," said Lydia Washington, director of HIM Solutions at AHIMA.

One of these HIM professionals is Beth Acker with the Department of Veterans Affairs in Cantonment, Florida.

"R 2.0 offers more specific and robust system capabilities," Acker says. "Functions such as audit and meta data, introduced in R 1.0, are much more advanced in R 2.0. Authentication, information attestation and authorship, record correction, amendment and alterations, record retention (provenance), and health record output also have functional requirements represented in the model.

"These are key concepts when addressing a sound business record needed for legal purposes."

R 2.0 will make it easier for request-for-proposal teams to more clearly define their needs. Vendors will also benefit because they too can use the framework to outline in more detail what their products do and do not offer.

"Most importantly," Spellman said, "patients benefit because EHR functions are easier to understand and utilize by everyone in the circle of care. R 2.0 offers the potential to significantly improve processes around clinical care and administration."

HL7 and ISO teams have invested thousands of hours in developing R 2.0, but the work is not over yet.

"While there is still more work to do to extend this records and information management functionality, HIM professionals can be assured that their voice is heard at HL7," Washington said. "AHIMA has played a very active role in developing the EHR functional model and we hope to engage more AHIMA members in these efforts in the future."

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