

NEWS

UNLOCKING THE POWER OF HEALTH INFORMATION

Health Professionals and HL7: We Need Each Other

By Russell Leftwich, MD, Chair of HL7 Health Professional Engagement

Health professionals who are engaged daily in care delivery are end-users of an ever-expanding range of HL7 standards. As healthcare IT adoption expands, an ever-increasing number of those individuals are leaders in implementation efforts in their organizations and in their own clinical practice. The number of systems and devices utilizing HL7 standards continues to grow, as does the number and variety of settings where these systems and devices are used. Health professionals who use these systems and devices need knowledge and understanding of the HL7 standards to facilitate implementation, workflow reengineering and optimization. HL7 needs to obtain the insights of these health professionals on their clinical workflows, data needs, and health information exchange needs to continue to develop and evolve the standards, implementation guides, and educational programs it publishes.

Early in 2012, HL7 created a caregiver membership category, now officially named Health Professional Membership. This membership is open to health professionals actively engaged in care delivery. The scope includes the entire care team: physicians, nurses, pharmacists, behavioral health

professionals, nutritionists, physical and occupational therapists, and other licensed



Russell Leftwich, MD

professionals with clinical practices. The annual fee of \$100 USD for the membership allows these professionals to participate in HL7 work group activities and standards development; receive discounts for HL7 meetings, tutorials, webinars, and certification testing; and view content on the HL7 website.

Entering the next phase of its effort to involve more health professionals in the development of standards and implementation guidance, HL7 has created a Health Professional Engagement initiative to coordinate outreach efforts through health professions schools, other academic institutions, and professional societies and to provide a friendly welcome and on-board guidance to those new Health Professional members. List serves have been established in the public list serve section of the HL7 website for those established HL7 members who wish to join the effort and for the new Health Professional members.

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The Health Professional Membership offers many values to the holder. Practitioners benefit from a working understanding of the standards underlying their systems in order to optimize their use. Just as important, an awareness of what HL7 has to offer in standards and implementation guidance, as well as a view over the horizon of what is under development, can be invaluable in developing solutions to problems in one's own institution and in innovation to deliver better care. Health professional members are enabled to better support their organizations in making wiser purchase decisions about EHR systems and medical devices, as well as guiding future strategy and transformation.

There are also less tangible benefits for the health professional members: developing insight into the processes of standards development and the benefits of standards; networking with others in your own domain as well as those from other domains; and the opportunity to join in the advocacy for standards adoption. Beyond these benefits, health professional members can help to improve the quality and usability of HL7 standards, and in turn, the systems and devices that use them to ultimately improve the quality and efficiency of care for patients.

HL7 as an organization is dependent on participation by the full spectrum of health

professionals to have an effective standards development process and to assure the quality and usability of standards and implementation guides developed. The insights of health professionals about clinical workflows and data needs in their practices is critical to development of the domain analysis models on which the standards are based. Existing standards can be improved based on feedback from the health professionals using them. Looking to the future, the increasing need for coordinated care for individuals in a complex system requires enabling that care coordination by HIT adoption and development of standards that recognize the complex workflows and data exchange needs of care planning and coordination. The knowledge of those workflows and data needs that health professionals possess and their participation and collaboration across HL7 work groups will be increasingly important, in fact, critical.

The transformation to a patient-centered healthcare system with a care team that includes the patient and all of the health professionals involved in their care makes the relationship between those health professionals and HL7 – a win-win for the patient and their entire team. Learn more and join if you are a qualified health professional at www.HL7.org/caregivers.

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HL7 and IHE Sign Statement of Understanding to Ballot IHE Profiles through HL7

By Andrea Ribick, HL7 Director of Communications

Health Level Seven® International (HL7®) and Integrating the Health-care Enterprise (IHE), an organization dedicated to improving health-care by providing specifications, tools and services for interoperability, recently announced an agreement to launch a pilot project to explore balloting IHE profiles through HL7. This

Statement of Understanding (SOU) further expands on their previous collaborative efforts, which were initiated in 2005.

As part of the collaborative relationship between HL7 and IHE, the two organizations have worked together to avoid conflict and duplication of

effort, as they engage in activities that support the global adoption of healthcare information technology (IT) standards. The new SOU strengthens the existing ties with the goal of improving the interoperability and implementation of healthcare IT standards and implementation guides. As part of the pilot, one

solidifies our efforts and brings us closer to validating that interoperability can be achieved in our lifetime. It ensures that HL7 standards and



Andrea Ribick

Agreement represents increased collaboration between the organizations and will improve the interoperability and implementation of healthcare information technology standards



or more IHE profiles based on the HL7 Clinical Document Architecture (CDA®) will be submitted for ballot through the HL7 Structured Documents Work Group. The pilot will be used to assess the feasibility of balloting other IHE profiles based on HL7 standards and potentially jointly publishing them as implementation guides.

"HL7 and IHE have enjoyed a long history of collaboration," said Charles Jaffe, MD, PhD, and CEO of HL7. "This agreement further IHE implementation profiles are tightly coordinated and will facilitate further strides in interoperability as we rise to the challenge of providing the building blocks necessary to achieve meaningful use in healthcare."

"Health IT standards are paving the way towards interoperability, which will mean seamless and secure access to health information whenever and wherever it's needed. This effort to ballot IHE profiles through the HL7 process is but one example of how our organizations are working together to improve the quality, value and safety of healthcare. This collaborative effort shows how the industry should - and does - come together to advance health information exchange," said Joyce Sensmeier, MS, RN-BC, CPHIMS, FHIMSS, FAAN, president, IHE USA.



Update from Headquarters

HL7 Enters a New Era

By Mark McDougall, Executive Director, HL7



Mark McDougall

New Era for HL7

As was suggested by Carl Dvorak during an annual HL7 Advisory Council Retreat several years ago, HL7's vision statement is rather straightforward: To create the best and most widely used standards in healthcare. The decision by the HL7 Board to license much of our HL7 intellectual property (IP) at no cost is both supportive of this vision statement and also brings HL7 into a new era.

The decision to license much of its IP at no cost covers all currently published standards, implementation guides and other select IP as determined on a case-by-case basis. In all cases, prior to downloading HL7's IP, individuals will be required to provide contact information, insight on their planned use for the IP, and agree to the terms of the license agreement. Details on accessing this library of HL7 IP will be available by clicking on the "Standards" section or the "Free IP" banner on the HL7.org home page.

For clarification, this new policy change does not provide free HL7 membership and, in fact, HL7 will continue to rely on your membership dues to fund the current operations as well as several new membership benefits that are being developed, which are anticipated to include an expansion of deeply discounted or free education programs and training; special access to HL7 experts; exclusive certification of HL7 conformance; a professionally supported Help Desk; and enhanced testing of individual

expertise in HL7 development, training, and implementation. The new membership structure and benefits will be rolled out later this year.

January Meeting

There were 428 attendees at our January Working Group Meeting held in Phoenix, Arizona, January 13-18, 2013. Over 40 HL7 work groups convened meetings, of which 14 conducted co-chair elections. Attendees also took advantage of 31 tutorials and three certification tests that week.

Board Changes

We recognized two outgoing Board members who served terms on the HL7 Board of Directors: Catherine Chronaki and Jill Kaufman, PhD. Catherine has served two terms on the HL7 Board as an Affiliate Representative. She also led the charge to open an HL7 Europe office in Brussels, Belgium and has overseen HL7's involvement in several European Commission projects. Jill first served one term as a Director-at-Large, and most recently has served two terms as the Secretary of the HL7 Board of Directors during which she also chaired the Gover-



Catherine Chronaki



Jill Kaufman, PhD





Incoming Board Members Calvin Beebe and Helen Stevens

nance and Operations Committee.

It is also noteworthy that Michael van Campen resigned from the HL7 Board after serving terms on the HL7 Board as the Affiliate Representative and most recently as the Treasurer of

the Board. Calvin Beebe, who has chaired the Finance Committee, will serve in the Treasurer position for the balance of 2013.



Michael van Campen

All three contributed heavily to many important and valuable roles for the HL7 organization throughout their many years of service to HL7. I am pleased to extend a sincere thank you to Jill, Catherine and Michael for their many years of service to HL7.

Meeting Sponsors

I am also pleased to recognize the following organizations that sponsored key components of our recent January Working Group meeting in Phoenix:

• Beeler Consulting LLC



- Gordon Point Informatics
- iNTERFACEWARE
- JP Systems Healthcare IT
- SPARX Systems

The additional sponsorship support provided by these organizations greatly contributes to HL7's meeting budget and is much appreciated.

HIMSS

For over 20 years, HL7 has exhibited each year at the annual conference of the Healthcare Information and Management Systems Society (HIMSS). This year's HIMSS convention convened in New Orleans, Louisiana during the week of March 4, 2013, and reportedly attracted over 35,000 people.

HL7's Director of Communications, Andrea Ribick, oversaw the production of 27 thirty-minute presentations on HL7 standards and relevant topics. Many of the presentations attracted crowds that filled the theater area and led to standing room only crowds. I also wish to express our sincere thanks to the many individuals who volunteered to staff our HL7 booth at HIMSS and/or make presentations in our booth, including:



Chair-Elect Dr. Bob Dolin presenting at HL7 HIMSS13 booth

- Calvin Beebe
- Woody Beeler, PhD
- Keith Boone
- Hans Buitendijk
- Gary Dickinson
- Bob Dolin, MD
- Grahame Grieve
- Freida Hall
- Ed Hammond, PhD
- Chuck Jaffe, MD, PhD
- Bob Jenders, MD
- Russ Leftwich, MD
- Ken McCaslin
- Don Mon, PhD

- John Quinn
- Scott Robertson, PharmD
- Joyce Sensmeier
- Corey Spears
- Howard Strasberg, MD
- Sandy Stuart
- Grant Wood

Benefactors and Supporters

We are thrilled to have attracted the all time highest number of HL7 benefactors and supporters, who are listed on page 19. Their support of HL7 is very much needed and sincerely appreciated. We are pleased to recognize our benefactors in all of our HL7 newsletters, on the HL7 website, in all of our HL7 press releases, and at all of our HL7 Working Group Meetings. A special thank you is extended to the list of firms that represent our 2013 HL7 benefactors and supporters.

Organizational Member Firms

As listed on pages 19-21, HL7 is very proud to recognize the all time largest list of 799 organizations who are HL7 organizational member companies. We sincerely appreciate their ongoing support of HL7 via their organizational membership

continued on page 6



January 2013 Working Group Meeting Sponsors

Photos courtesy of Ken Rubin Photography



Find or Be a Volunteer for HL7

By Karen Van Hentenryck, HL7 Associate Executive Director; Member, Process Improvement Committee

Several months ago, the Process Improvement Committee (PIC) sponsored a project to develop and promote a wiki site designed to match volunteers with Work Groups needing assistance. Woody Beeler graciously designed the wiki site, which can be found at http://wiki.hl7.org/index.php?title=Find_or_Be_a_Volunteer_for_an_HL7_Work_Group

Last year, PIC co-chairs, Rita Scichilone and Sandy Stuart, announced the availability of the site during one of the Working Group Meeting (WGM) Monday night co-chairs dinners, and following the January 2013 WGM in Phoenix, the site was advertised to the first-time attendees. Unfortunately, no work groups have posted any volunteer needs and no volunteers have posted profiles. The intent of the profiles and help wanted templates is to provide just enough information to allow a volunteer and a work group to begin discussing mutual interests. They are not intended as places to list full resumes or job descriptions. Some of the "jobs" that HL7 work groups will frequently need to fill are listed below (and described on the site itself):

- Business Analyst
- Conformance Facilitator
- Domain Expert
- HL7 Mentor
- Modeling and Methodology Facilitator
- Project Facilitator
- Publishing Facilitator

- Steering Division Project Facilitator
- Vocabulary Facilitator

PIC invites all work groups to consider posting their needs to this site before the May WGM as we feel that having "want ads" on the site will encourage volunteers to review the opportunities and submit a profile. PIC is confident that the site will be useful once people begin to use it.



Karen Van Hentenryck

One of the nice features of this site is that volunteers can create a profile that can be moved between Occupied and Available status to indicate when they are or are not available. Profiles can also be updated as more experience in a particular area is gained.

Instructions for creating a Volunteer Wanted template are available at:

http://wiki.hl7.org/index.php?title = Template:Volunteer_ Wanted

Instructions for volunteers wishing to create a profile can be found at the following link:

http://wiki.hl7.org/index.php?title = Template:Volunteer_ Available

Update from Headquarters, continued from page 5

dues. Along with our individual members, HL7 currently has over 2,395 members.

In Closing

I look forward to seeing many of you at our May 5-10 Working Group Meeting in Atlanta, Georgia. Until then, may you and your loved ones be blessed each day with plenty of smiles and laughter.



The 2013 HL7 Board of Directors Photo courtesy of Ken Rubin Photography





Andrea Ribick

HL7 Names Two New Advisory Council Members

Joyce Sensmeier and Walter Suarezto serve on HL7 Advisory Council

By Andrea Ribick, HL7 Director of Communications

Health Level Seven recently announced that HL7's Board of Directors has named Joyce Sensmeier, MS, RN-BC, CPHIMS, FHIMSS, FAAN, Vice President of Informatics for HIMSS, and Walter Suarez, MD, PhD, Director of Health IT Strategy of Kaiser Permanente, to serve a two-year term on HL7's Advisory Council.

"We are pleased to have Joyce Sensmeier and Walter Suarez join HL7's Advisory Council," said Charles Jaffe, MD, PhD, CEO of HL7. "Ms. Sensmeier provides a unique perspective to the Council with leadership roles in HIMSS and Integrating the Health Enterprise (IHE) as well as her expertise in nursing informatics. Dr. Suarez brings a wealth of national and international experience, including serving as a member of the National Committee on Vital and Health Statistics (NCVHS) and as a member of the HIT Standards Committee of the Office of the National Coordinator for Health Information Technology."

Joyce Sensmeier MS, RN-BC, CPHIMS, FHIMSS, FAAN, is Vice President of Informatics at HIMSS, the largest U.S. notfor-profit, cause-based association focused on providing global leadership for the optimal use of information technology for the betterment of healthcare. She is responsible for the areas of clinical informatics, standards, interoperability, privacy and security.



Joyce Sensmeier, RN-BC

Dr. Suarez serves as cochair of the Sub Committee on Standards of the NCVHS and co-chair of the Privacy and Security Work Group of the HIT Standards Committee of the ONC. He has provided project management, technical and policy consulting services and project/program evaluation services to health care provider organizations, health plans, Med-



Walter Suarez, MD

icaid and Medicare programs, Public Health agencies and vendors in the areas of Health IT/HIE, public health data standards, health disparities, quality measurement, health information privacy and security standards, and HIPAA standards including Transactions and Code Sets (TCS) and the National Provider Identifier (NPI).

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HL7 Product Lines and Product Families



Austin Kreisler

By Austin Kreisler, Chair, HL7 Technical Steering Committee

At the HL7 January Working Group Meeting in Phoenix, we announced HL7 was moving towards organizing our standards products into product lines and product families. Over the past couple of years, HL7 has gone through the process of creating briefs for each of our standards products. As part of creating the product briefs, we tried to organize those standards to make it easier for members as well as non-members to access our standards. The results can be found on the HL7 main website under "Standards". The process of developing those standards product briefs and trying to put them into some coherent framework really brought home the fact that HL7 has a large number of products but little, if any, overarching strategy for managing those products. The lack of a coherent strategy has led to the risk that standards products may overlap and in some cases may contradict one another.

While HL7 was developing the various product briefs, the organization was also identifying a set of strategic initiatives to provide a direction for the products and services developed by HL7. Two of the high-level strategic initiatives are directly relevant:

- Streamline the HL7 standards development process
- Develop standards that are easier to implement and more responsive to customer needs

During the past year, the Technical Steering Committee (TSC), working with the Architectural review Board (ArB), began a series of projects to implement the above two strategic initiatives by moving the HL7 organization towards a product family/product line approach to developing our standards products. The ArB was charged with developing a Business Architecture Model that utilizes the HL7 Services Aware Interoperability Framework (SAIF) concepts of governance, management and methodology to implement a product family/product line based organizational structure for HL7.

What do we actually mean when we talk about product lines and product families? Here are the working definitions used by the TSC and ArB:

- Product Line: "A Standards Product Line is a set of specifications that share a common, managed set of capabilities satisfying the specified needs of a particular market segment and that are developed from a common set of core resources in a prescribed way." (Adapted from the Software Engineering Institute definition of a software product line).
- Product Family: "A Product Family is a collection of products that share common elements, methodologies, and tools as viewed from a design perspective."

These two viewpoints complement one another. The product family viewpoint focuses on how HL7 develops products and aligns with the strategic initiative for streamlining HL7's standards development processes. The product line viewpoint focuses on the needs of HL7 customers, principally HL7 members, who often use HL7 standards to address their own needs or the needs of their downstream customers. The product line viewpoint aligns with the second strategic initiative focused on producing standards that are easier to implement and are responsive to customers needs.

Product Lines

A Product Line is a collection of products, components, identifiable entities, etc. produced for a particular set of customers that share a common context of use. Product lines tie to HL7 customer's business use cases and focus on providing solutions to business problems. The products bundled together in a product line may span multiple product families. A real example of this occurs in the work done by the Cross-Paradigm Interoperability Implementation Guide for Immunizations project (http:// www.hl7.org/Special/committees/ soa/projects.cfm?action = edit&Projec tNumber = 863). This project focuses on a specific immunization use case and is identifying standards such as HL7 Version 2.x Immunization Messaging, CDA and SOA services to implement the use case. Although today these standards are not part of formal HL7 Product Families, in the future, they will likely be in different HL7 Product Families. The same product might appear in multiple product lines.

O_



Product Families

The goal of establishing Product
Families is to maximize the efficiency
of individual product production
through the use/reuse of common
base elements, inputs, methodologies, processes, and/or tools. Product
Families are differentiated based on
three core dimensions:

- Common Resources Base elements, constructs, etc. used in producing a given Product or collection of Products.
- Common Production Shared production tooling, production methods, production processes, and/or production methodologies
- Common Governance Shared governance, management and methodology overseeing the entire product family

The example we have today of a product family is the Fast Healthcare Interoperability Resources (FHIR) standard. The TSC is using FHIR as a test case for determining how to formalize product families within HL7. As part of establishing a FHIR Product Family, the TSC has established the FHIR Governance Board (FGB) and FHIR Management Group (FMG).

The FGB sets the strategic direction for the FHIR initiative in the HL7 organization. The FGB also oversees the structures, rules and processes that govern the creation, maintenance and review of FHIR-related artifacts. The FMG is responsible for coordinating and overseeing content development and balloting. The FMG also deals with cross-WG issues, execution of processes, etc. Finally, the Modeling and Methodology work group (MnM) has responsibility for overseeing and developing the FHIR methodology.

HL7 will establish similar governance structures for new product families going forward. HL7 has a number of groups of products today that will

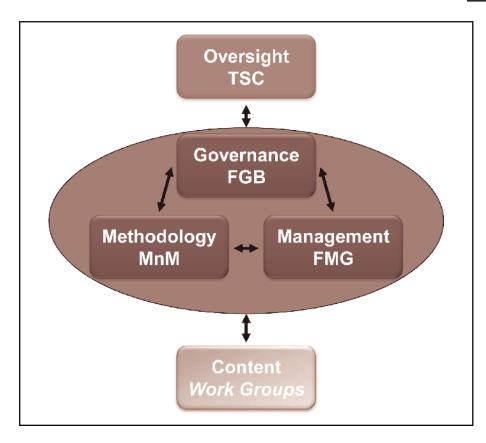


Diagram representing the governance structure of a product family; in this case, FHIR

likely be organized into formal product families including:

- Version 3 Product Family
- Version 2.x Product Family
- CDA Implementation Guide\ Product Family

Each of the above has some elements of the common characteristics of a product family (common resources, common production, and common governance). Creating a formal product family will require establishing all three of the common elements for a product family. The TSC and ArB are currently identifying the steps necessary to start up new product families.

Summary

Successful implementation of product families within HL7 will support the streamlining of the HL7 standards development strategic initiative by enforcing a consistent set of rules for product development, improving quality of those products, and promoting cross-product consistency of those products. Successful implementation of product lines will help focus our products on addressing customer needs and promote easier adoption of those standards by our customers.

Successful implementation of both the Product Family and Product Line constructs requires a clear understanding by the producer (HL7) of the target market and its customer's short and long-term requirements and objectives. Successful marketing of one or more products or Product Lines requires HL7 (as the producer) to be able to successfully "connect the dots" between the customers' perceived needs and the functionality delivered by the products designed to fulfill these requirements.



News prom the PMO and Project Services Work Group



Dave Hamill

By Dave Hamill, Director, HL7 Project Management Office; and Rick Haddorff and Freida Hall, Co-Chairs, Project Services Work Group

Project Scope Statement Template Updated with TSC Notification Checkbox

A checkbox labeled "TSC Notification Informative/DSTU to Normative" has been added to Section 1 of the Project Scope Statement (PSS) template. Project facilitators should check this box when the project proceeds from informative to normative or DSTU to normative status and forward the PSS to the TSC (via the TSC Project Manager) for notification.

This action will trigger American National Standards Institute (ANSI) Project Initiation Notification (PINS) submission as TSC notification that a project is moving to a normative state is required to fulfill ANSI PINS reporting requirements.

It is not necessary to notify the steering division co-chairs to seek re-approval unless there has been a "major" or "significant' change in the project scope (as described in the PSS FAQ section).

Please refer to the HL7 Governance and Operations Manual and ANSI Essential Requirements for more detail.

Evaluating Project Management Practices in HL7: An International Volunteer Organization

Thank you to everyone that took the HL7 International's Project Management Survey; 114 people participated. The survey was just one part of dissertation research which examined project management practices at an all-volunteer organization. The work was undertaken by Ateeb Chaudry, a student of HL7 International Council Co-Chair, Dr. Philip Scott.

The goal of the project was to analyze findings on problems faced by HL7 when projects are managed by volunteers with a view to provide recommendations as to how HL7's Project Management practices can become more effective.

Objectives included

- How do other work groups view Project Services?
- What can be done to add value to the project management efforts conducted by work groups?
- Is Project Services meeting the expectations of other work groups?



Freida Hall



Rick Haddorff

HL7 Project Management and Tracking Tools

The following HL7 Project Management tools are available on www.HL7.org via Resources > Tools & Resources > Project Management and Tracking Tools.

- Electronic Ballot Charts
- GForge
- HL7 Searchable Project Database
- PBS Metric Guidance for Steering Division Co-Chairs
- PBS Metrics Report
- Project Approval Process
- Project Insight
- Project Insight Tip Sheet
- Project Life Cycle for Product Development (PLCPD)
- Recorded Webinar: HL7 Project Management Tool Overview for HL7 Project Facilitators
- Steering Division and Project Facilitator Responsibilities
- Three-Year Plan Guidelines

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Understanding Meaningful Use with a Focus on Testing the HL7 Version 2 Messaging Standards

By Robert Snelick, National Institute of Standards and Technology (NIST) and Sheryl Taylor, RN, BSN, Booz Allen Hamilton (BAH)

Use of electronic health records (EHRs), especially systems with clinical decision support capabilities, has been shown to enable quality improvement in healthcare as well as reductions in the cost of that care when used regularly in the practice of medicine. These facts contributed to the impetus for Congress to enact the Health Information Technology for Economic and Clinical Health (HITECH) Act, a component of the American Recovery and Reinvestment Act (ARRA) of 2009. The HITECH ACT provides funding for incentive payments to physicians and hospitals that adopt health information technology (HIT). Initially focusing on adoption of EHRs, approximately \$17 billion in Medicare and Medicaid (CMS) incentive payments are available through

CMS's HITECH-based EHR Meaningful Use (MU) Program, to be paid to providers that attest to or demonstrate "meaningful use" of "certified" EHR technology (CEHRT). In response to this mandate for use of CEHRT, the Office of the National Coordinator (ONC) established a certification program and published EHR certification criteria. The National Institute of Standards and Technology (NIST) developed test procedures and conformance test tools based on the ONC's EHR certification criteria. This article briefly explains the history

and purpose of the ONC certification program, and provides insight into the test procedures and testing process for the Health Level 7 (HL7) Version 2 (V2) messaging standards. It also presents an overview of the test tools that are used by testing laboratories to ensure that vendors' EHR technologies meet the requirements of CEHRT.

Adoption and use of CEHRT is required for eligible professionals (EPs) and eligible hospitals (EHs) to become "meaningful users" and to receive payments from the CMS EHR Incentive Program. On January 3, 2011, the ONC released the Final Rule to establish a permanent program for certification of Health IT. This "ONC HIT Certification Program" was launched on October 4, 2012, replacing the pre-

vious temporary program.

As shown in Figure 1, the ONC HIT Certi-



Robert Snelick

fication Program correlates directly to the CMS MU Final Rule as well as the ONC Health IT Standards, Implementation Specifications and Certification Criteria Final Rule (ONC Final Rule). CMS MU requirements are behavioral in scope, specifying how the EPs and EHs must use the CEHRT in order to receive the incentive payments. Based on the MU requirements, ONC defines the technical criteria CEHRT must meet and manages the development and implementation of certification testing procedures.

continued on next page

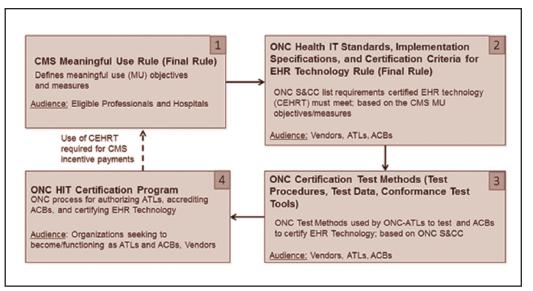


Figure 1: Correlation of CMS MU Final Rule, ONC Final Rule, and ONC HIT Certification Program



Thus far, CMS and ONC have published two sets of requirements for MU and for EHR certification known as Stage 1 or 2011 Edition and Stage 2 or 2014 Edition. Included in the ONC criteria are interoperability standards, such as HL7 Version 2 (V2) implementation guides and vocabulary standards. ONC CEHRT requirements do not represent a comprehensive list of all EHR capabilities that a physician's office or a hospital might want or need, but they are a baseline of capabilities that CEHRT must support. Additional MU Stages are planned, and the requirements are anticipated to become more challenging, demanding more capabilities.

The ONC HIT Certification Program manages the testing and certification of EHR technologies by Accredited Testing Laboratories (ATLs) and Authorized Certification Bodies (ACBs). "Testing" is the process used by an ATL to determine the degree to which the EHR technology meets the specific certification criteria. "Certification" is the assessment and affirmation made by an ACB once it has analyzed the quantitative results produced by the testing and determined that the EHR technology has met all of the applicable certification criteria. ONC reviews the product certification provided by the ACB, and then posts it to the online Certified HIT Product List (CHPL), thereby designating the product as a CEHRT.

In order to verify that EHR technologies meet the ONC certification criteria, a test method was developed for use by the ATLs. The ONC test method is composed of test procedures, test data, and (where applicable) conformance test tools. Test procedure documents provide a standard structure for the content related to the certification testing steps; the test data work in conjunction with the test procedures to further indicate the

intent of the ONC policies behind the certification criteria; and the conformance test tools work with the test procedures and test data to enable automated and semi-automated validation of the EHR technologies' conformance to the certification criteria and the named interoperability standards.

Conformance Test Tools

The 2014 Edition/Stage 2 ONC EHR certification standards and criteria specify four HL7 V2 implementation guides that apply to five certification criteria, including transmission to immunization registries, syndromic surveillance to public health agencies, transmission of reportable lab results to public health agencies, transmission of electronic lab results to ambulatory providers, and incorporation of lab tests and results. NIST has developed the test procedure and conformance test tool for each of these criteria. The links to these test tools are provided along with standards they target:

- Immunization: http://hl7v2-iztesting.nist.gov/mu-immunization/
 - HL7 Version 2.5.1 Implementation Guide for Immunization Messaging, Release 1.4
 - HL7 Standard Code Set CVX--Vaccines Administered
 - Syndromic Surveillance: http://hl7v2-ss-testing.nist. gov/mu-syndromic/
- HL7 Version 2.5.1 PHIN

 Messaging Guide for Syndromic
 Surveillance
- Reportable Laboratory Results (ELR): http://hl7v2-elr-testing. nist.gov/mu-elr/
 - HL7 Version 2.5.1 Electronic Laboratory Reporting to Public Health, Release 1
 - SNOMED CT® and Logical Observation Identifiers Names and Codes (LOINC®)
- Laboratory Results Interface (LRI): http://hl7v2-lab-testing. nist.gov/mu-lab/

- HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface
- Logical Observation Identifiers Names and Codes (LOINC®)
- Note the LRI test tool covers both the transmission of laboratory results criteria and the incorporation of laboratory results criteria

Central to certification is conformance testing of the technical requirements and capabilities of the EHR technology. Testing is facilitated with the use of specific test cases and data. Through consultation and collaboration with subject matter experts from the ONC Standards and Interoperability (S&I) Framework, the Centers for Disease Control (CDC), the Association of Public Health Laboratories (APHL), and the International Society for Disease Surveillance (ISDS), NIST developed test cases that targeted the most important use cases and capabilities specified in the referenced standards.

The test data is provided to assist the tester in verifying that the vendors' EHR technologies are capable of supporting the required functions; verifying the ability to support the specific test data content is a secondary aspect to testing. Testing and verification related to specific content usually is more appropriate for local installations of the EHR technologies; however, for certain aspects of a certification test case, examining exact content is necessary to verify that a capability exists in the EHR technology. An added benefit of providing realistic test data for common use cases is that it reinforces the expected interpretation and use of the referenced standards.

Testing the EHR for Transmitting a Message

When testing the ability to transmit HL7 V2 messages, the focus of the conformance testing strictly centers

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on validating the message produced by the EHR system (the sender). The System Under test (SUT), the EHR, is treated as a "black box"—how the message is created or transformed is not in scope. If we consider a Laboratory Information System (LIS) or Laboratory module as part of the EHR (hereafter lab component), testing is not concerned with the detailed architecture of the lab component, but rather what it produces (a message) based on a given set of inputs (i.e., the test case). The "black box" can be a self-contained lab component or be composed of multiple modules with a data flow between them, for example, a lab component and an integration engine; however, the "black box" must contain a lab component, and test case data must be entered into and originate from the lab component.

The NIST HL7 V2 conformance test

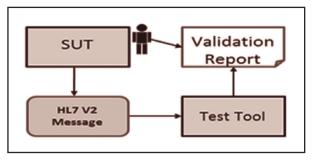


Figure 2: Context-free Validation Test Flow

tools for validating sending systems have two operational modes:

- Context-free
- Context-based

The context-free mode validates any message created by the SUT. It is not dependent on any use case, test case, or specific test data content. Figure 2 illustrates the context-free test flow.

The context-based mode validates messages that are associated with a given use case and test case that includes specific test data that are to be entered into the SUT. The SUT creates a message that corresponds to the test data

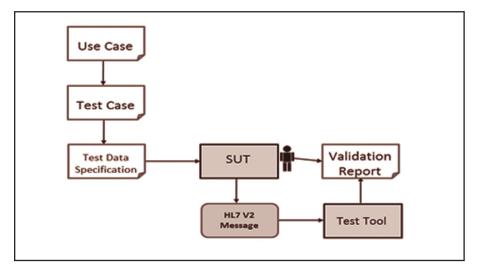


Figure 3: Context-based Validation Test Flow

provided in the test case. Testing assesses the technical requirements and content-specific requirements specified in the test case. Context-based validation expands the test space, enabling more comprehensive testing (e.g., confor-

mance usage constructs such as conditional elements and required, but may be empty elements). Figure 3 shows the context-based test flow.

Although the NIST conformance test tools support both modes of validation, MU EHR certification testing is context-based. However, the context-free validation functionality

provided in the test tool can be used to assist certification testing in certain circumstances and provides a useful tool for local installation testing.

Testing the EHR for Incorporation of a Message

Testing the incorporation of laboratory results presents a set of challenges, since there is no output artifact that can be assessed directly. For this criterion the EHR, as the receiving system, is being examined for the incorporation of laboratory results and seven display requirements (adopted from CLIA, the Clinical Laboratory Improvement Amendments, which

are regulatory US standards for clinical laboratory testing). The MU criterion specifies the Laboratory Results Interface (LRI) implementation guide for import of the laboratory results. Conformance testing employs the use of a juror document (inspection check list) and a human inspector. The content of the juror document is derived from the test case and test message. Figure 4 illustrates the test flow of the NIST conformance test tool for the incorporation of laboratory results test procedure.

The test tool provides a test harness that interacts with the EHR system, simulating the functionality of an LIS. Test cases are developed for the various use cases described in the LRI implementation guide, and for each test case its respective test data are created. Based on the test case and test data, a test message and juror document is automatically generated by the test tool. The test message is sent to the EHR for incorporation. The ATL Tester uses the iuror document to examine the EHR system. The juror document is the test case-specific checklist the tester uses to document the presence

continued on next page or absence of the data in the EHR for data elements transmitted to the



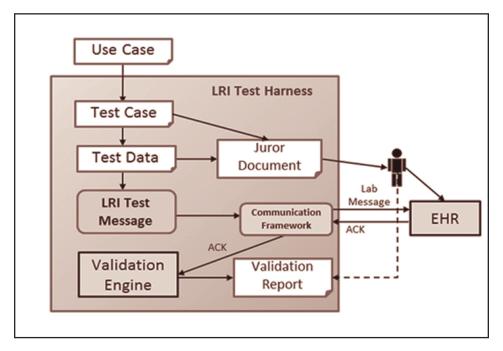


Figure 4: Test Flow for Testing EHR Receiving Transmission of Lab Results

EHR from the LRI Test Harness. The data elements are categorized by how they are verified. For example, some elements are required to be displayed to the clinical user on the EHR screen and stored, while other data elements are required to be stored or derivable. Not all data elements are subject to incorporation testing since they are not relevant to the incorporation of laboratory results (e.g., message processing elements).

Certification Testing: What Does it mean?

Certification of EHR technology is a critical step towards achieving interoperability for exchanging healthcare information, but it is not the end-all. ONC certification testing for meaningful use focuses on assessing the capabilities of the EHR product for a given set of requirements. It is not directed at site-specific installations. Purchasing a certified EHR system provides a degree of certainty that the buyer has obtained a product that meets a level of capabilities established by the ONC. End users of certified EHR products

will need to configure their products according to their local requirements. Although the ONC HIT Certification Program by design does not extend to installation bases, it provides the foundation and a shorter pathway to achieving site-specific interoperability. Incremental progress in terms of the EHR capabilities and interoperability is the intent as advancement is made through the MU stages.

It is also important to recognize that the ONC certification program targets the EHR technologies and not the systems that interact with them. For example, the transmission to immunization registries certification criterion and associated tests assesses whether the EHR product can create HL7 V2 messages in accordance with the requirements given in the referenced standard. It does not, however, place any requirements on the receiving system, in this case the immunization information systems (IIS) used by the registries. In order to achieve interoperability the receiving systems must implement the corresponding requirements. The Meaningful Use program envisions that these systems will, over time, acquire such capabilities due to market forces and the benefits gained (e.g., the public health agencies will want to take advantage of the standardized interfaces).

One of NIST's roles in developing the test tools is to strictly interpret the requirements as written in the standards and the ONC EHR certification criteria, and then develop test cases to test to those requirements accordingly. This process has led to the discovery of underspecified and ambiguous requirements in the standards and gaps in the certification criteria. These discoveries have necessitated the collective efforts of numerous clinical subject matter experts and NIST to resolve, making the MU program a useful endeavor in perhaps unexpected ways. The findings have been recorded in clarification documents that supplement the HL7 V2 implementation guides. NIST, the ONC S&I Framework, the CDC, the AHPL, the ISDS, and the HL7 Conformance and Guidance for Implementation and Testing (CGIT) Work Group have begun efforts to establish and apply more concise rules for specifying conformance and best practices for writing HL7 V2 implementation guides. The result of these efforts will improve the HL7 V2 referenced standards for future MU editions.

In summary, meaningful use of EHRs is a key element in improving both quality and cost of healthcare. Two stages of the CMS MU and ONC HIT Certification Programs have been initiated, each stage representing incremental progress in the improvement of EHR systems' interoperability and capabilities based on the named standards in the ONC certification criteria. NIST develops the HL7 V2 conformance test tools in accordance with implementation guide requirements and vocabulary standards mandated by

continued on next page



Member Spotlight on Ken McCaslin

Ken McCaslin is the Director, Healthcare Standards at Quest Diagnostics based at their worldwide corporate data center located about 45 minutes west

of Philadelphia. Ken has been with Quest Diagnostics since 1982. He has been married to his wife Cheri for over 30 years. They have two adult children, three grandchildren and one due in October.

In 2002, Ken began the discernment process for ordained ministry in the Episcopal Church. He began his seminary studies in 2004 and will graduate this May with a Masters of Arts in Religion. In 2008, Ken completed the requirements for ordination and in June 2008 was ordained a perma-

nent Deacon in the Episcopal Church. He is on staff at Christ Episcopal Church in Pottstown, PA where he preaches often and is involved in several ministries. In September, Ken will lead a new ministry in the local Pottstown hospital. He will train, supervise and manage a lay ecumenical hospital visitor program. Ken wrote the training material and has used it to train lay hospital visitors at other hospitals. Recently, while investigating cyber bullying for a seminary class, Ken discovered that the church has very little information available to those who may be seeking it.

Ken was able to convince the Episcopal Church in

the Diocese of Pennsylvania to develop a page on their website dedicated to providing guidance to youth leadership on the subject of bullying and how they can help our youth with this

very complicated social issue.
The Lutheran Church has also agreed to create educational material for their website.

Ken and Cheri love to travel.
Cheri retired more than 5 years ago and has been very active in mission trips both in the US and abroad; including Guatemala and Uganda. When the January 2011 HL7

meeting was in Australia, Cheri joined Ken and they traveled to New Zealand. Last summer they cruised the Mediterranean and plan to cruise the Baltic Sea later this year. The McCaslins try to spend part of the year in Florida. Their daughter's family lives in Nashville, and their son's family lives in Tampa. No trip to Florida is complete without a stop in both cities.

Understanding Meaningful Use, continued

the ONC. Knowing that unambiguous, "testable" requirements are critical to development of robust certification testing tools, NIST as a neutral participant devotes time and resources to the collaborative process of creating the HL7 V2 implementation guides, reconciling the ballot comments for the draft versions, and determining content for the various clarification supplements. The

ONC-ATLs use the NIST test tools to perform automated and semi-automated validation in a consistent manner for certification of EHRs based on requirements included in the standards. It cannot be over overemphasized that the effectiveness of a certification program is dependent upon a combination of the quality of the underlying standards and the thoroughness of the test tools based

on those standards.

Certification of EHR technologies is a critical step in achieving interoperability for exchanging healthcare information, as it provides a foundation that can be built upon. Much progress has been made and significant knowledge has been gained in the first two MU stages. MU Stage 3 promises to build further upon this foundation.



Congratulations *************

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For more information, please visit http://www.worldofhealthit.org/

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For more information, please visit http://www.e-healthconference.com

medinfo2013

Copenhagen, Denmark August 20 - 23, 2013

For more information, please visit http://www.medinfo2013.dk/

e-Health 2013 Accelerating Change

Ottowa, Ontario, Canada May 26 - 29, 2013

For more information, please visit https://www.infoway-inforoute.ca/ index.php/events/e-health-2013accelerating-change

International Health Informatics Conference

Beijing, China August 3 - 4, 2013

For more information, please visit http://ai.arizona.edu/ihic2013/

ISO/TC 215 Health Informatics Working Group Meeting

Sydney, Australia October 21 - 25, 2013

For more information, please visit http://www.iso.org/iso/iso_technical_committee?commid = 54960

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Project Services

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