



HIT Standards Committee Meeting
March 29, 2011

Agenda

Background

The **Health IT Standards Committee** is charged with making recommendations to the National Coordinator for Health IT on standards, implementation specifications, and certification criteria for the electronic exchange and use of health information. In developing, harmonizing, or recognizing standards and implementation specifications, the Health IT Standards Committee will also provide for the testing of the same by the National Institute for Standards and Technology (NIST).

Opening Remarks

Farzad Mostashari, MD, Acting National Coordinator for Health Information Technology

- Agreement among stakeholders that we are on the right track and want to keep moving down this track
- Understand that there will be new challenges
- HIT Strategic Plan released on Friday, March 25, 2011. Public Comment available through April 22, 2011 at [Health IT Buzz Blog](#) identifies key areas for moving ahead
 - Continue guiding principles of:
 - Openness and transparency in process
 - Having achievable goals
 - Adapting to real work conditions and being evidence based
 - Putting patient's interest at the center of everything – ex. privacy and security
- Remainder of the year, ONC will be busy working with federal partners on:
 - Meaningful Use Stage 2
 - Certification & Standards
 - Governance role

Timeline & Milestones: Certification & Standards NPRM Stage 2 – Project Plan

Discussion

Doug Fridsma, MD, PhD, Director of the ONC Office of Interoperability & Standards

- Dr. Fridsma provided [an update on the status of the Standards and Certification Criteria Stage 2 regulatory project plan](#).
- Interestingly, the process is calling for an NPRM for Stage 2, rather than an Interim Final Rule.
- Timeline for release is suggested as The NPRM must be drafted and undergo regulatory clearance well before publication

- Dr. Fridsma's presentation covered the key milestones and the timeline for the Certification & Standards NPRM, strategic principles and core themes,

Key timeline constraints:

- Publication of Final Rule must allow time for public comment period, analysis on these comments, and rule drafting and regulatory clearance
- Certification tests must be developed
- EHRs must have lead-time for software development, certification, installation, and training

Strategic Principles:

- Standards and criteria should couple low regret and high leverage

For Discussion: Core Themes:

- Pragmatic vocabulary - Need to reduce alternatives in vocabularies
 - Identify a core subset of vocabulary – 95% subset of volume and value
- Upgrade from paper to electronic data transmission
 - Reduce alternatives and increase specificity of data transmission standards
 - Need to be explicit about what people can expect to receive and what they are expected to send
 - Lab, individual engagement, and engaging the public are going to be important parts of upgrading from paper to electronic
- Need to update the NWHIN specifications to include content and transport standards for Meaningful Use

For Discussion: Philosophy for Vocabulary

- Need to converge to a singular vocabulary for a single purpose – ex. Administrative transactions may need a single vocabulary
- Focus on ambulatory domain, quality reporting, and public health
- Focus on interoperability
- Work to address 95% most commonly used elements and certify on that 95% subset

What does it mean to settle on a 95% subset?

For Discussion: Core Specifications Needed



During the dialogue with HITSC members, Question by David McCallie – should the community stop working on CONNECT? Should the

Answer from Dr. Fridsma: When looking at current NwHIN specifications, you need to be able to participate in the entire suite of functions and requirements. Dr. Fridsma suggests that there may be instances where only a few functions and requirements are necessary. Need to find an approach for modular and extensible involvement. ONC and the Standards Committee should be required to make clear and unambiguous standards, identifiable specifications, and test processes that can be used. NOT REQUIRING EVERYONE TO have the same system or base code.

Direct Project Live Implementations Final Review

Arien Malec, Office of the National Coordinator

- Arien Malec [presented on the latest status of the Direct Project Live Implementations](#), the NwHIN Exchange, and the CONNECT Project.
 - Direct Project Live Implementations:
 - Secure, Direct, Exchange via the Internet
 - Simple
 - Secure
 - Scalable
 - Standards-based
 - Live Implementations Reviewed in several states
 - Minnesota – Hennepin County Medical Center and the Minnesota DoH
 - New York – MedAllies sharing data for transition of care in the Hudson Valley
 - Rhode Island –RI Quality Institute serving as R.E.C., Beacon, and HIE
 - Maryland/DC – Secure Exchange Solutions, Inc. on information exchange between Maryland and DC (primary and specialty care)
 - Virginia – Dominion Medical Center and MedVirginia – PCMH information
 - Missouri – Heartland Health and Lewis and Clark Information Exchange
 - Certificate Management has taken on different approaches.
 - Scalability is going to be difficult



- If Certificate Management tools don't trust each other, there may be problems.
 - Policies and governance requirements are critical to the success of scalability.
 - Challenges
 - Speed of information sharing
 - Near real-time latency on information queries
 - Support for Direct is evident across multiple providers, vendors, states, etc. (See slide #28 of presentation)
 - End State for Direct
 - Widespread adoption of Direct Standards by vendors by late 2012
 - Differences over how Direct information is going to be incorporated in to workflow will be a challenge
 - Simple Exchange support by Wes Rischel and David McCallie has put this initiative on the map
 - Detailed Reports for States is Available on [Direct Website](#)
- PCHR – Patient Controlled Health Record (Untethered)
- Fridsma – Direct – Clear use cases for the program. Not intended to be
 - NwHIN Exchange – 10 participants that are the core for the pilots that are on-going. Tripling of participants over the next year. 9 applicants from Beacon Communities, State HIEs and partners that are undergoing review of specifications. 5 (see slides)
 - Governance structure – around same time as the MU rule and the Standards and Certification Specifications.
 - Governance Workgroup Recommendations
 - Working on the process for structuring the Governance Rule.
 - Rule will be voluntary. Conditions of trust and interoperability will
 - CONNECT
 - MITRE – shared development environment for federal partners
 - Aegis – working on VLER participation build out and long-term testing capability
 - Program leads and release cycles updated
 - Automated testing environment is in the future
 - Contested contract will be completed by late spring 2011
 - Creation of the CONNECT Open Source environment



- Dave Riley and Vanessa Manchester created the Alembic Foundation and established the Aurion open source approach
- Aurion Does Not replace CONNECT.
 - Some concern that CONNECT 3.2 and Aurion 4.0 may have divergent paths.
 - Intention is that if the projects are based on same standards, they should be interoperable

Privacy & Security Standards Workgroup Recommendations

Dixie Baker, Chair [presented on the latest activities of the Privacy & Security Standards Workgroup](#).

Lisa Gallagher , HIMSS Senior Director of Privacy and Security, is a new member of the workgroup

Workgroup has been charged to produce recommendations for 2 standards

- Digital certificate standard
- Enterprise-level provider director

Criteria for Digital Certificate:

- An electronic document that certifies that the subject has been issued a pair of encryption keys that are related in such a way that if one key is used to encrypt something it can be decrypted only by someone holding the other key
- Digital certificated are issued by a certificate authority (CA), and digitally signed by the issuing CA
- CAs periodically publish a certificate revocation list (CRL) that identifies those certificates that no longer are valid and that have not expired

Digital Certificate Basics:

- Used for a number of purposes, including:
 - To authenticate the identity of an entity or person using a challenge-response mechanism
 - To digitally sign a message



- To share a secret key to be used to exchange private or sensitive information
- The trustworthiness of a digital certificate is dependent upon how much the user trusts the issuer of the certificate

Recommended Requirements:

- Digital certificates must conform to the X.509 V3 certificate profile defined in RFC 5280 (May 2008)
- Digital certificates to support Direct exchanges
- Digital certificates to support NWHIN exchanges
- CLR must conform to the X.509 V2 CRL profile defined in Section 5 of RFC 5280 (which supports both Online Certificate Status Protocol (OCSP) and full CRL retrieval)
- Nothing in these requirement precludes the specifications of a single standard for a certificate usable for both Direct and NWHIN exchanges

Recommendation: Need for investigation of alternatives for cross-certifying digital certificate issuers with federal bridge CA

- All digital certificates used by federal agencies must link back to the Federal Common Policy Framework Certificate Authority (CA) and must include the assurance level under which the certificate was issued
- Certificates used to support exchanges between federal agencies and state agencies must be issued by a CA that is cross-certified with the Federal Bridge CA
- To enable health exchanges between the NWHIN

Recommendation to ONC: To enable Direct users to exchange health information with federal health agencies, the HITSC Privacy and Security Workgroup recommends that the ONC investigate architectural and operation alternatives for cross-certifying Direct CAs with the Federal bridge CA, including implications on cost, market dynamics, and complexity

- Are the requirements to becoming a cross-certifying CA pretty strong? Asking ONC to look at this because we don't know what the total cost of becoming cross-certified is.
- Recommendation should be for ONC to do a cost-benefit analysis.

Certificate Trust Issue:

- A digital certificate can be trusted only to the extent to which the user trusts the CA who issued the certificate
- Anyone can set themselves up as a CA and issue certificates
- Certificates used by the Direct Project entities may be issue by any CA – and the decision



Recommended Policy Question for the HITPC: Policy and governance are needed around CAs who issue certificates for use in health exchanges, such as Direct

- Defining mechanism for establishing the legitimacy and trustworthiness of a CA
- Defining minimum level of trustworthiness for CAs

There were no objectives to sending these recommendations on to ONC

Walter Suarez gave an update on the Specification of Requirements for Entity-Level Provider Directories (ELPDs)

Overviewed HITPC approved recommendations on ELPDs

Standards Requirements:

- Guidelines for verification/validation
- Standard for ELPD structure and content
 - To support discoverability requirements
 - To support links with Individual-Level Provider Directories (ILPDs)
- Standard for ELPD submission to national registry
- Query/response messages
 - Language
 - message
- For EHRs to support ELPD messages
 - Certification Standards and Criteria

HITPC Information Exchange Workgroup scheduled to present recommendations for ILPDs on April 13

Expect to deliver recommendations on ELPDs and ILPDs to HITSC at May meeting

Clinical Operations Workgroup Update

Jamie Ferguson

Jamie Ferguson, Chair of the Clinical Operations Workgroup, recapped yesterday's full day hearing on medical device interoperability

Workgroup plans to reconvene to consider possible recommendation based on yesterday's meeting



Strong sense of the meeting was that it would be highly desirable to set the direction for those standards in Stage 2, even though the requirement would not be until Stage 3

Concern that identification should not be done in middleware – that it should somehow be done in the instrument

A HIMSS summary of the meeting will be posted on the HIMSS website

Implementation Workgroup

Judy Murphy, Liz Johnson

Creating a work plan for the next nine months

Will be turning attention to the certification process and Meaningful Use Stage 2

