HIT Standards Committee
FINAL
Summary of the April 22, 2015 Meeting

ATTENDANCE (see below)

KEY TOPICS

Call to Order

Michelle Consolazio, Office of the National Coordinator (ONC), welcomed participants to the meeting of the Health Information Technology Standards Committee (HITSC). She reminded the group that this was a Federal Advisory Committee (FACA) meeting with two opportunities for public comment (3-minute limit), and that a transcript will be posted on the ONC website. She instructed members to identify themselves for the transcript before speaking. Members introduced themselves.

Remarks

Acting Deputy National Coordinator and Chairperson P. Jon White recognized the hard work by staff over the past months. Three NPRMs were published. An updated privacy and security guide was released. A report was submitted to the U.S. Congress Recently signed legislation has repealed the EHR incentive program and rolled it up into other incentive programs and advanced payment models. The use of certified products is required. The expected effect over the next 10 years is very significant.

More Remarks and Review of Agenda

Vice Chairperson John Halamka noted the importance of the agenda items. The agenda had been circulated in advance of the meeting. Although the government can do many positive things, it can cause harm by being overly prescriptive. The role of the HITSC is to advise on balance. In considering the Certification NPRM, the committee must decide whether to focus on a few aspects or many. He asked about revisions or corrections to the summary of the March meeting, which was circulated with the other meeting materials. Hearing none, he called it approved.

> **Action item #1: The summary of the March 2015 meeting was accepted as circulated in advance of the meeting.**

Data Update

Dawn Heisey-Grove, ONC, presented graphs. EP registration continues to increase. Registration is used as a marker of intent to participate. More Medicaid EPs have registered than originally estimated. 86% of Medicare-registered EPs have attested to meaningful use compared to 32% of Medicaid-registered EPs. Less than half of all Medicaid-registered EPs attested to meaningful use in the year immediately following AIU payment. Although 4 in 10 registered EPs were scheduled for stage 2 in 2014, progress to stage 2 differed between the two programs. 56% of all Medicare-registered EPs were scheduled for stage 2 in 2014 compared to 8% of Medicaid-registered. Over 90% of EPs scheduled for stage 2 in 2014 were participating in the Medicare arm of the program. Medicare data for the period are currently being analyzed and will be reported at a future meeting.

Q and A

Members asked no questions.

2015 Certification NPRM

Steve Posnack and Michael Lipinski, ONC, presented an overview of the Certification NPRM preliminary to the committee's official comments. Staff had assigned sections of the NPRM to the various workgroups in order for them to prepare draft comments to be acted on at the May meeting. The purpose of the presentation was not to receive comments but rather to understand the content of the NPRM. According to Lipinski, the NPRM proposes a more accessible ONC health IT certification program to support a diverse health IT system, including but not limited to EHR technology. There is no Complete EHR certification in the 2015 Edition or future editions. The rule supports health IT across the care continuum, including long-term and post-acute care settings. ONC does not include policy to support the EHR incentive programs. Each program sets its own requirements (e.g., CMS defines the CEHRT definition in its rule). The certification program is agnostic to settings and programs, but can support many different use cases and needs. This allows ONC's health IT certification program to support multiple program and setting needs. It contains new and updated vocabulary and content standards for the structured recording and exchange of health information. The 2015 Edition Base EHR Definition focuses, at a minimum, on the functionalities that all users of certified health IT should possess. It ensures that the minimum functionalities required by the HITECH Act remain in the Base EHR Definition. The requirements can be met using a combination of certified health IT modules. Lipinski reviewed the 2015 Base EHR Definition certification criteria, which include the following: demographics § 170.315(a)(5); problem list § 170.315(a)(7); medication list § 170.315(a)(8); medication allergy list § 170.315(a)(9); smoking status § 170.315(a)(12); implantable device list § 170.315(a)(20); CDS § 170.315(a)(10); CPOE (medications, laboratory, or diagnostic imaging) § 170.315(a)(1), (2) or (3); CQMs – record and export § 170.315(c)(1); ToC § 170.315(b)(1); data portability § 170.315(b)(6); application access to a common clinical data set § 170.315(g)(7); and Direct Project § 170.315(h)(1) or Direct Project, Edge Protocol, and XDR/XDM § 170.315(h)(2). Next, he showed slides describing the common clinical data set and compared those data elements with ones previously used. Lipinski reviewed a series of slides that delineated proposed rules related to each of the broad goals. For example, to enhance patient safety, certification will include patient matching, recording and exchange of UDIs, and safety-enhanced design. The latter focuses on: a conditional certification requirement for an expanded set of certification criteria compared to the 2014 Edition, and health IT developers must submit information about the user-centered design processes used and applied. A quality management system is also proposed. The identified QMS system must be compliant with one established by the federal government, or mapped to one or more QMS established by the federal government or standards development organizations. Attesting that a QMS was not used is no longer permitted. Addressing health disparities will be enhanced by the proposed certification criteria capabilities; more granular recording and exchange of patient race and ethnicity information; recording of psychological and behavioral health data; and accessibility of health IT.

Lipinski went on to talk about the draft test procedures, which give more transparency to the testing and certification processes and early access to developers and all stakeholders. The outcome-based test procedures streamline the test procedure format, and promote more innovation through less prescriptive testing. He moved to another major section--modifications to the certification program. For privacy and security, a module would need to meet applicable privacy and security certification criteria depending on the other capabilities included in the health IT module. The proposal removes the responsibility from the provider to ensure that they possess technology certified to all the necessary privacy and security criteria. There are new requirements for in-the-field surveillance. ONC-ACBs should

ensure that certified modules can perform certified capabilities in a production environment. Both reactive and randomized surveillance will be required. ONC-ACBs must ensure health IT developers disclose broader and more detailed information than is currently required in the 2014 Edition. This information will include the additional types of costs users may incur to implement or use health IT for any purpose within the scope of its certification (not just for achieving MU objectives). Potential limitations (including contractual restrictions) that would limit a user's ability to implement or use health IT for any purpose within the scope of its certification will be described. Health IT developers will be required to attest to voluntarily providing this information. Another proposal is to convert the CHPL to an open data file to make the reported product data (e.g., test results) more accessible for product analysis. It is proposed to require that ONC-ACBs report an expanded set of information in the open data file for increased product transparency.

In total, 68 certification criteria are proposed. They can be categorized as: available proposed 2015 Edition criteria for certification (n=19); criteria proposed as always required for 2015 Edition certification (n=2); criteria proposed as conditional for 2015 Edition certification depending on capabilities in scope (n= 10; proposed 2015 Edition criteria pointed to by CMS for stage 3 and to implement the statute for Base EHR definition (n=37); and available proposed 2015 Edition criteria for certification (n=19). Moving to the comparison of the 2014 Edition versus proposed 2015 Edition bottom line and the minimum requirements for 2015, he summarized that 45% of criteria are unchanged or minimally revised for the ambulatory setting. 42% of the criteria are unchanged or minimally revised for the inpatient setting. A provider needs to do approximately 60% of the proposed 2015 Edition criteria to participate in stage 3. The total minimum number of criteria needed to participate in stage 3 remains the same for EPs and almost the same for EHs and CAHs. Exclusions can further affect the number of criteria required. Finally, he described how these can be adapted to long-term and post-acute care and behavioral health.

The 2015 Edition Proposed Rule was published in the Federal Register on March 30, 2015. The comment period is open until May 29, 2015. See
http://www.regulations.gov/#!documentDetail;D=HHS_FRDOC_0001-0572

Q and A

Leslie Kelly Hall asked about criteria for consumer applications that are not constrained by HIPAA. She referred to slide 29 and mandatory versus optional criteria, and wondered about optional accessibility guidance. Steve Posnack responded that the criteria apply to the source and not the application. He wants comment on the sufficiency of the specifications for developers. Lipinski referred to slide 29, saying that the criteria in the first column are always required. With regard to accessibility design, the preamble delineates a list of recognized standards. A developer can list those tested for. The far-right column lists the optional criteria. He referred to web content accessibility guidelines for which comments are being solicited.

Arien Malec said that he appreciated the one-pager mapping results. In the future, that information could be combined with CMS requirements. Regarding application access, it seems to apply to a data holder. In March, the HITSC approved recommendations from the Standards and Interoperability (S&I) Initiative Task Force. Does ONC have a formal process to evaluate and test proposed certification criteria? Several of the proposed criteria are not real world tested. Posnack said that there is an internal process, but trade-offs must be considered. Staff considers where we feel the regulatory process can improve the environment. ONC then proposes rules for comment. So some criteria are not as mature as would be preferred. Where pilot results are known, they are used. ONC must take into account the missions of federal agencies. Malec suggested consideration of other policy tools in such cases as well as flagging those criteria not tested and not yet ready for other programs. White added that proposed criteria are not plucked from thin air. Constructive comments are appreciated.

David McCallie declared that he approved of the API requirement as proposed. But he was dismayed that the optional categories are not specified in functional modes. He referred to a premature specification of untested approaches. Posnack said that the purpose of public comment is to solicit such advice. Halamka interjected that functional specifications would be welcome.

Dixie Baker thanked them for listening to the recommendations of the Transport and Security Standards Workgroup. She referred to the chart on security criteria, noting that data integrity is omitted: Is that a mistake? Lipinski explained that the omission is intentional because it will be applied and tested when data are transmitted and exchanged. Baker referred to a recent workgroup recommendation on API and OAuth for authorization and authentication of apps. Posnack said that he looked forward to seeing recommended alternative language.

Wes Rishel referred to the race and ethnicity specificity. He observed that the biggest problem in interoperability is when the intended recipient needs data but the collector does not need them. He wondered about the customer for these data, which appear to be for research purposes. The data enterer will likely add whatever specificity to complete the task without attention to validity. Also, he said that implementation and training costs should be considered. Regarding QMS, do these go to the level of the FDA: Can potential customers see the QMS outputs? According to Lipinski, the vendor will just state what was used. Rishel continued. He asked how surveillance will be funded. Will ABCs increase their fees or is there another source of funds? Staff responded that the certification bodies have their own business models for setting rates; the criteria for surveillance are required. Rishel had another question about the use of standards in the future to transmit data collected in the past. Posnack said that providers can work with their developers on the appropriate levels of granularity.

Eric Rose expressed concern at Posnack's response about proposing something questionable in the NPRM to get feedback. A federal agency should do more to ascertain readiness prior to a proposed rule. The HITSC can advise on readiness. That 45% of the certification criteria are new to the 2015 Edition is quite a leap. Physician-users are referring to tone-deafness on the part of ONC. How and when does staff know enough is enough? Posnack referred to slide 29, saying that it shows the results of an analysis to support the statutory requirements. Balance and trade-offs are always considered. The Kaizen and LEAN were efforts to take out as much guess work as possible before the final rule. White said that there is room for removal or change of criteria. Jodi Daniel, ONC, added that everything in the NPRM is based on feedback and requests from experts and stakeholders. Now feedback from a broader audience is sought. Committee proceedings, listening sessions, S & I Framework forums, and a rigorous internal process were conducted prior to the publication of the NPRM. In response to a question about the HL7 Pedigree, Lipinski explained that there is a choice of HL7 Pedigree or SNOMED-CT.

Cris Ross referred to the straw that broke the camel's back. Now is the time to distinguish between vital information and nice-to-have information. This is the time to trim back to the achievable. In response to his question about the grid and legend on one of the slides, staff said that these are the revised criteria. For some, there are new standards available. Staff tried to improve functionality for the provider. Ross referred to slide 19 and inquired about the intent for #3. Posnack said that the certification of the product will focus on the common clinical data set and read access demonstration. Access by data element by data element request by FHIR will be acceptable but not required. No guidance on optional data is anticipated.

Kelly Hall asked about APIs, certification for access only and PGHD. Posnack said that there is considerable flexibility for developers.

Malec declared that balancing is best done when mapping to clear standards readiness. There is not a clear chain of policy to action here. He opined that someone seems to be pushing HED back onto the list,

contrary to recommendations. Certification is for situations in which there is a clear chain from policy to action.

McCallie repeated his request for requiring functions rather than the use of specific standards. Liz Johnson reported that the industry is very concerned about being ready, in particular, with regard to public health reporting. Regarding the table and the diagnostic imaging denominator, she asked for clarification on the change. Lipinski indicated that the change is due to CMS requirements. Johnson responded that for providers the distinction between certification and CMS reporting is not useful.

Halamka summarized that although all priorities are valid ones, time and resources limit what can be done. Opportunity costs must be considered. The scope is too great. Functional criteria may be a way to circumvent these concerns. What scope is right? What standards are ready? What should be functional rather than prescriptive? The HITSC is here to help.

Interoperability Roadmap Comments

Five workgroups had been assigned specific sections of the Roadmap. Preliminary reports were given at the March meeting. Each workgroup reported again, this time with final recommendations for action. The order of agenda items was changed.

Interoperability Roadmap - Semantic Standards Workgroup Comments

Semantic Standards Workgroup Co-chairperson Jamie Ferguson reminded the members that at the March meeting he presented 19 preliminary comments organized under four categories. Since the members had not questioned those comments, he concluded there was no need to repeat them. Noting that all are listed in the slide deck, he called attention to two additions from the previous meeting. Under the category of additional focus areas needed, the following was added: usage of FDA Unique Device Identifiers (UDIs) should be more explicit in the roadmap. Device identifiers should be captured and included in a patient's EHR to identify the source of information acquired from health care devices. This includes devices that are used for laboratory tests and whose results are included in a patient's EHR. The identifiers also enable post-market surveillance of health care device performance and regulatory authority safety reporting. Under the category of things missing or misconstrued, this was added: The roadmap should include the seamless integration and use of health care device information (e.g., physiological monitors, infusion pumps, … personal health and public health), including unique identifiers, observations, settings, alerts and waveforms using standards such as UDI, ISO/IEEE 11073, LOINC and SNOMED CT

Discussion

Halamka asked about being prescriptive regarding RDF. Ferguson reminded him that the subject is the Roadmap not certification. Much work needs to be done prior to any readiness for certification. Halamka was concerned about contents of the Roadmap eventually finding a way into certification. McCallie agreed with Halamka on RDF. He talked about another model—SEMI—that was more promising and wondered whether the workgroup had considered it. Ferguson explained that the workgroup looked at RDF for models mapping purposes. According to McCallie, RDF is good for finding mismatches but not for resolving them.

Interoperability Roadmap - Transport and Security Standards Workgroup (TSS WG) Comments

Transport and Security Standards Chairperson Dixie Baker presented slides on the assigned questions and the workgroup's responses.

> E1 (a). What should the federal government (specifically) focus on first to move towards a uniform approach to enforcing cybersecurity in health care (keeping HIPAA and CEHRT Rules in

mind and possible new cybersecurity legislation)? The TSS WG recommends that ONC partner with the National Institute of Standards and Technology (NIST), the Office of Civil Rights (OCR), other federal agencies, and industry stakeholders in several ways to enable a uniform approach to enforcing cybersecurity in health care. First, ONC should work to advance a consistent trust framework across the health IT ecosystem. Such a trust framework should allow for diversity in organizational policy, while enabling a foundational basis for mutual trust among organizations. Second, ONC should endorse a set of appropriate baseline security controls that are uniformly applied to health IT technologies that enter the ecosystem. Third, ONC should work with industry to accommodate a diversity of emerging health IT technologies across infrastructures within the health IT ecosystem. Health IT infrastructures must be flexible, in that they should permit any certified health IT solution to operate within the ecosystem. Fourth, ONC should provide guidance on proper governance in cybersecurity, which is essential for building trust and security throughout the ecosystem. Finally, the ONC should bring together federal, state, and industry stakeholders to address the goal of reducing variations in cybersecurity enforcement

E1 (b). Are there frameworks, methodologies, incentive programs, etc. that the health care industry has not, but should, consider? ONC should consider the following in further establishing trust across the health IT ecosystem: First, ONC should consider including the Trustmark Framework developed in a NIST National Strategy for Trusted Identities in Cyberspace (NSTIC) pilot, PCI Security Standards, and the ISO 27000 series as possible frameworks for establishing electronic trust among health care organizations across the Internet. Second, cybersecurity needs to be considered for both enterprises and for interconnections among enterprises. Third, the health care industry needs a minimum set of standards and metrics for measuring the strength of security protections. A number of minimum standard sets exist and can be drawn from. These include, but may not be limited to: OCR's minimum standards for control areas, the Certification Authority Browser (CA/B) Forum Baseline Requirements, and the questions asked by cybersecurity insurance companies and financial auditors. Fourth, the existing security control frameworks (including NIST's cybersecurity framework) should be considered for alignment and guidance when gaps occur.

E2. Are there other gaps (aside from lack of policies and guidance for implementing encryption) in technology and standards for encryption? ONC should work with OCR, other federal partners, and industry stakeholders to address the following issues related to technology and standards for encryption. First, ONC should provide guidance on encryption key lifecycle management. Second, ONC should provide guidance on a method for encryption key escrow recovery. Third, ONC should publish guidance on key oversight and authorization, addressing the people or entities that maintain access to encryption keys. Finally, ONC should also consider providing guidance on a minimum set of circumstances in which encryption should be used to secure data (i.e., medical devices, systems, and software).

Section F F1. What ID proofing and authentication standards, policies, and protocols can we borrow from other industries? Is health care that different from banking, social media, or e-mail? Yes, although good cybersecurity best practices can be applied similarly across different industries, ONC should acknowledge that because of the sensitivity and criticality of data used in the health care industry, and the need for convenient access to data, sometimes in emergency circumstances, health care is notably different from banking, social media and email. Credit cards can be replaced, and new e-mail accounts can be generated, but deeply personal genetic or treatment information cannot be replaced or recalled once it is disclosed. Some harm may be irreparable. Many security protections (e.g., access control, audit, digital signature) are

dependent upon user identity, and for this reason, health information requires a high level of assurance in the processes and mechanisms used for identity proofing and authentication. ONC – together with OCR, other federal partners, and industry stakeholders – should continue to support the NSTIC program and to draw from existing pilots, where applicable. ONC should support NIST's effort to update SP 800-63 and to help assure its applicability to and utility for health care use cases. ONC should provide guidance on the use of third-party identity proofing services, including trusted Internet identities used by individuals for everyday life activities such as banking, social media and shopping. Such guidance should affirm that the use of such third-party Internet identities should be contingent on their use of high-assurance methods for identity verification, consistent with evolving health care laws and regulatory requirements.

G1. What standards should we put forward in the 2016 standards advisory for basic choice? Today's standard for basic choice is a paper document that is hand-signed by the patient. Full end-to-end electronic capture, representation, exchange, and interpretation of patient consent is technologically possible and currently used in limited circumstances. However, we know of no mature standards that are widely used to electronically capture or represent patient consent decisions. Various efforts are underway, including work by Oasis and HL7, and ONC should continue to monitor these developments.

G2. How much work should ONC be doing on other standards while clarifying permitted uses? If standards development needs to be done, what should we be working on (DS4CDS v. DS4P v. something else)? Rather than commit resources to creating new standards, ONC should monitor and, where appropriate, engage in existing efforts to capture consent electronically. This includes the development of emerging consumer consent technologies. We recognize electronic (computable) consent is valuable for the future of health IT. ONC should also provide guidance that defines computable, discrete data fields needed for negotiating patient consent and access to health information. Common semantics for discrete data fields would further assist in determining whether the protected health information or personally identifiable information should be shared. ONC should continue to monitor SAMHSA pilots and the application of DS4P technology, and derive lessons learned from those efforts.

E1. Cybersecurity (2): ONC will coordinate with the Office of the Assistant Secretary for Preparedness and Response (ASPR) on priority issues related to cybersecurity for critical public health infrastructure. The TSS WG said that critical public health infrastructure should be replaced with critical health infrastructure. In considering the cybersecurity needs of the nation's health infrastructure, availability and resiliency, data integrity, and confidentiality should all be considered as part of the critical components for organizational preparedness and response. In addressing issues related to preparedness and disaster recovery for cyber-attacks, ONC should consider learning from, and building upon, the National Disaster Medical System (NDMS). Today, the NDMS public health system works offline and has been tested in prior public health emergencies.

E1. Cybersecurity (3:) The TSS WG supports this action. For the out years, ONC should provide guidance and reference implementations for enabling health care organizations to electronically consume threat information to minimize the risk and impact of cyber-attacks.

G4. Technical standards for basic choice *(3):* ONC should consider changing this from 2018-2020 to 2015-2017.

G4. Technical standards for basic choice *(4):* Due to the advancements in genomics, ONC should consider changing this from 2021-2024 to 2018-2020.

G4. Technical standards for basic choice *(5):* Since this is happening already, ONC should consider changing this from 2021-2024 to 2015-2018.

Discussion

White referred to the ONC should statements, wondering whether ONC should coordinate with partners would be a better phrasing. Baker responded that the recommendations are directed to ONC, and ONC staff can decide who to involve and how to respond.

Malec asked about the Trust Framework ISO 27000. What about including the NIST Cybersecurity Framework in the list for consideration? Baker and TSS WG Co-chairperson Lisa Gallagher agreed it should be listed. Next, Malec said that organizational identify assurance is as important as individual identity assurance. Baker and Gallagher agreed it should be added.

Kelly Hall asked about the level of authentication for patients. Baker called it a policy issue. Standards apply across roles. The Privacy and Security Tiger Team made applicable recommendations on identity proofing some time ago. Gallagher agreed that it is a policy issue.

Wes Rishel expressed concern about the tendency of standards experts to propose policy. Communication across groups is important. He agreed with Malec on the importance of cultural issues and consent. Referring to the considerable reliance on NIST guidance, he described a personal experience with device encryption. He attempted to use NIST guidances but found that they often lacked clarify. A forum for interpretation of NIST standards outside of NIST is needed. Gallagher replied that the workgroup recommends that ONC give guidance. Rishel talked about a need to work on communication across interests.

McCallie referred to the intersection of policy and standards on security. Perhaps a floor could be established for consent management. He suggested that components of a floor be identified. Baker talked about this being done at the international level. Regarding the identity proofing of patients, the Tiger Team recommended policy. McCallie talked about expenses being involved in the recommendations on key management, which may affect interoperability.

A member pointed out that context is changing to biometric certification of identity. If an individual has certified identity at one place, can it be accepted for health care? Gallagher said that is the purpose of the NIST guidance. There are some issues such as multiple identities, which may matter in health care but not in other places. As yet not all limitations are known. This point can be added to the explanation in the recommendations.

Halamka recalled that the HITSC is expected to act on each set of workgroup comments. He asked whether there were any objections to forwarding both the Transport and Security Standards Workgroup comments and the Semantic Standards Workgroup comments. No objections were expressed. Malec referred to a few clarifications.

Action item #2: The comments from the Transport and Security Standards Workgroup and the Semantic Standards Workgroup were accepted without objection.

Agenda Item Added – Formation of another Task Force

Posnack announced that he is forming a new task force—the Interoperability Standards Advisory Task Force. The comment period ends May 1. The new task force will consider the public comments from the HITSC perspective. The task force will meet June – August. He called for volunteers and suggestions on membership to be sent to Consolazio. Consolazio referred members of the public to the FACA website for information and to submit nominations.

Public Comment: None

Interoperability Roadmap Comments Continued - Content Standards Workgroup

Content Standards Workgroup Chairperson Andrew Wiesenthal reminded the members of the assignment and questions for section J. He indicated that few changes had been made in the recommendations since the preliminary presentation in March. This statement was added to the list of key concepts: Many of the initiatives listed including FHIR, CIMI, DAF (should limit to these three). The recommendations called for achieving national scale with selected standards as a top priority. Consolidated CDA release 2 and Direct Project are key first steps with a multi-year cycle time for standards to be absorbed nationally. A broad group of stakeholders need time to respond to changes. Furthermore:

- Use all available levers to pursue nationally, encourage aligned adoption of specific named standards
- Focus on specifying universal codes and getting data from the source to the provider and others in need of the data
- Assure that all federal payers are aligned with common core of standards and incentivize commercial payers to follow

To obtain greater specificity in standards, the workgroup said:

- Be specific on how the standards support prioritized use cases for each wave of interoperability
- Refine those standards over time, but limit structural change
- Include concepts related to improving interoperability between research and clinical domains, stakeholders should consider these and provide input on the use cases in that space that would create the greatest value and subsequent actions
- Suggested vocabularies and code sets do not align well with widely used research and clinical standards, including those defined by the United States and international agencies and SDOs (e.g., CDISC)
- Know where we are going: greater specificity in Learning Health System definition
- Need to consider the constraints of policy, privacy and security
- APIs by themselves will not open up clinical systems for learning
- Great references (e.g., IOM, Learning Community, ESTEL, ONC Query Health)
- Select a few use cases that will deliver high return on investment for interoperability instead of the large number included now (56)
- The clinical, research, public health and other programs may find that the use cases that they deem most valuable cannot be addressed in the first wave of interoperability
- The highest return targets for interoperability may come from other communities, while use cases for other communities are intended to follow as we gain traction and skill in the review process and requirements-gathering to which these use cases must be subjected
- The important gaps are not in standards, but in policy maker attention to the need to deliver clinical data from the source to the users. Seems not to be on the radar screen

The presentation also included 31 slides with specific comments per Roadmap item.

Discussion

Malec observed that the recommendation on the Consolidated CDA release 2 potentially conflicted with the recommendation of the Semantics Standards Workgroup that CCDA release 2 is premature and with comments from the Implementation, Certification and Testing Workgroup. Wiesenthal said that his recommendations pertained to implementation.

Rishel said that structure should not drive the content, but structure may need modification. According to McCallie, the challenge is whether FHIR will solve such problems. The FHIR approach is to have a core structure and identify suggested vocabularies. The profile becomes a solution to interoperability. It may not be necessary to solve the computability problem. Workgroup Co-chairperson Rich Elmore said that the workgroup supports the role of FHIR, but it may not fit into the time frame.

Kelly Hall asked about patient-friendly vocabulary. Wiesenthal referred to Kaiser Permanente's work, which is available through NLM.

Halamka asked for any objections to approval of the comments from the Content Standards Workgroup. Anne LeMaistre requested the addition of something about short-term wins. No objections having been heard, Halamka declared the comments approved for forwarding to ONC.

> **Action item #3: The comments of the Content Standards Workgroup were approved with one request for an addition.**

Interoperability Roadmap – Implementation, Certification and Testing Workgroup Comments

Implementation, Certification and Testing Workgroup Co-chairperson Cris Ross reported on section I1– Testing Tools. Testing tools need to be available with adequate lead time for pre-certification testing and should be focused in areas that provide value for end users. Where possible, providers should be involved in development of test tools. Testing tools will not have a meaningful impact on interoperability if trading partners are not adhering to same implementation guides and standards used in certification. Clarity on what providers need for clinical use is needed prior to codifying and testing of standards. Vendors and SDOs may not have adequate resources to create test tools for certification requirements that do not reflect work already underway. If not developed by industry, a fee or fundraising for certification may need to be associated with test tool development. CCDA simplification has occurred between Release 1 and Release 2. Practical, effective, and industry-run tools are needed for post-certification testing in support of interoperability, and evolution of vocabularies, technologies and processes between regulatory cycles. Testing for interoperability should be ongoing voluntary conformance testing rather than mandatory and compliance driven. The reference to regular use of testing tools needs further definition.

Workgroup Co-chairperson Johnson summarized comments on I2 – Certification Programs. She recommended exploring the potential for deeming rather than certification for improved efficiency where services are already in place and widely used (e.g. ePrescribing) Where trading partners have existing interfaces in production and exchange partners meet specific requirements (e.g. lab interfaces, public health), products could list production interfaces and/or agencies for which the product is exchange-ready to meet certification requirements. Staff can look to HIPAA EDI for lessons learned. It is better to go for high value, and limit the number and scope of certification criteria where policy links to specific payment for Medicare.

The recommendations continued:

- Do not link to overall ability to participate in Medicare.
- Reference only mature, deployed standards and ensure necessary infrastructure is in place and potential unintended consequences and co-dependencies are well understood.
- Consider tailoring of current criteria for other settings rather than establishing setting-specific certification criteria.
- Continue to hold Kaizen-type meetings with industry for continuous improvement and progress updates as time required to get to level of detail needed cannot be accomplished in shorter hearings.

A new approach for scenario-based testing is needed as previous work has had limited impact. A new approach should include:

- Providers and hospitals to clearly document their scenario workflows and provide feedback.
- Determine how EHRs should respond
- Determine key requirements which can flow into a test case

There should be in place an escalation and reporting process for raising issues or concerns with products post certification, but expending resources on post implementation surveillance and testing seems onerous. She added these general comments:

- Ensure appropriate and concerted effort to be clear as to what substantiates the need for new testing and certification.
- Do not attempt to do too much at once – narrow to a smaller set of items and do them right rather than do too much all at once. Ensure readiness for prime time.
- Certification programs should leverage proven test cases, where draft test cases are published and industry has ability to test and provide feedback early on in the process

Discussion

Malec referred to testing to standards conformance but not clinical standards. If testing tools could be user enablable, the situation would be improved. Ross said that end-to-end testing would have improved the CCDA. He wondered whether anyone is asking is this good medicine.

Baker asked about the difference between deeming and attestation. Ross responded that deeming is like vendor attestation.

McCallie talked about using a test bed server for round trip testing for direct messages, query and other functions. Ross asked what organization would provide this service and how would it be funded. Malec preferred the Direct Trust process to ONC certification. Deeming would be an advantage.

Rishel talked about certification as a regulatory requirement that imposes a cost on the regulated. So ONC has taken the road of minimizing those costs. A government program is not the solution. A vendor funded program is not a solution. There will never be universal concurrence on what should be tested. A semi-official entity to call the shots for industry with resources to test and certify is needed. Ross said that the workgroup talked about that same need. But it is difficult to identify such an entity.

Kelly Hall wondered about the government saying this is equivalence and then another body applies and tests for it. Johnson talked about being creative and making deeming executable. Malec said that data sharing networks could do deeming. Ross said that deeming and the test bed are different functions.

Halamka asked for approval of the workgroup's comments. No objections were voiced. He declared them approved.

> **Action item #4: The comments of the Implementation, Certification and Testing Workgroup were approved without objection.**

Interoperability Roadmap – Architecture, Services and APIs Workgroup Comments

Following the enthusiastic response to the health IT hourglass at the March meeting, the Architecture, Services and APIs Workgroup incorporated it into the recommendations on the Roadmap. Co-chairpersons McCallie and Malec presented a 10-page transmittal letter for approval, saying that the content had been presented without objection at the March meeting. McCallie referred to the graphic slides and described the hourglass again with mapping to composition of API. Next, Malec explained recommendations for defining a roadmap towards the health IT hourglass:

- To create greatest modularity, move towards parsimony of composables for transport, security and data compatibles and extend with common orchestration patterns such as pluggable apps and CDS as a service. Adopt a deliberate policy of rebalancing the standards portfolio towards the health IT hourglass model
- Allow sufficient time to develop, adopt, and use core composables and orchestration patterns to allow for demonstrations of success during the rebalancing period
- As recommended in the joint Health IT Policy and Health IT Standards Committees recommendations from the JASON Task Force, provide flexibility for detailed policy governance of specific use cases to be performed by data sharing arrangements

Identify critical priorities for 2015–2017

- Create a glide-path to core composables and orchestration
- Reduce friction and distraction to adopters and implementers

Identify roadmap priorities for 2018–2020

- Refine and extend core composable services, profiles, and orchestration patterns
- Expand the number of piloted use-cases based on the core composable model
- Address needs for national-scale services such as MPI, RLS, Directories, etc.
- As data sharing networks emerge, address needs for network-bridging services
- Consider mature APIs, orchestrations, and use-cases as candidates for addition to Certified HIT
- Begin transition from non-core/orchestration standards and APIs

Identify roadmap priorities for 2021–2024

- Address complex data profiles that require more robust data models (as may be needed for the learning health care system
- Contemplate transition to new core and orchestration

These recommendations were supplemented by 12 slides showing additions and deletions to specific Roadmap items.

Discussion

Rishel referred to the hourglass and pointed out that an interoperability use case is out front and center. It is a good approach. He suggested naming it HIHMM. Halamka said that the hourglass is clear and makes sense. White concurred.

Halamka asked for any objections to approval of the Architecture, Services and APIs Workgroup's transmittal letter and recommendations. Hearing none, he declared approval.

> **Action item #5: The letter and recommendations of the Architecture, Services and APIs Workgroup were approved as presented without objection.**

Halamka remarked on the accomplishments of the committee. He noted that his term ends in January, and the terms of several members end in June.

Public Comment: None

SUMMARY OF ACTION ITEMS:

> **Action item #1: The summary of the March 2015 meeting was accepted as circulated.**
>
> **Action item #2: The comments from the Transport and Security Standards Workgroup and the Semantic Standards Workgroup were accepted without objection.**

Action item #3: The comments of the Content Standards Workgroup were approved with one request for an addition.

Action item #4: The comments of the Implementation, Certification and Testing Workgroup were approved without objection.

Action item #5: The letter and recommendations of the Architecture, Services and APIs Workgroup were approved as presented without objection.

Meeting Materials:

- Agenda
- Summary of March 2015 meeting
- Meeting presentation slides and reports

Meeting Attendance							
Name	**04/22/15**	**03/18/15**	**01/27/15**	**12/10/14**	**11/18/14**	**10/15/14**	**09/10/14**
Andrew Wiesenthal	X	X	X	X		X	
Anne Castro		X	X	X	X	X	X
Anne LeMaistre	X	X	X	X	X	X	
Arien Malec	X	X	X	X	X	X	X
C. Martin Harris	X	X	X	X	X		X
Charles H. Romine	X	X	X			X	
Christopher Ross	X	X	X			X	X
David McCallie, Jr.	X	X	X	X	X	X	X
Dixie B. Baker	X	X	X	X	X	X	X
Elizabeth Johnson	X	X	X	X	X	X	X
Eric Rose	X	X	X	X	X	X	X
Floyd Eisenberg		X	X	X	X	X	
James Ferguson	X	X	X	X		X	X
Jeremy Delinsky		X	X		X	X	
John Halamka	X	X	X	X	X	X	X
John F. Derr	X	X	X	X	X	X	X
Jon White	X	X	X	X			
Jonathan B. Perlin		X					

Keith J. Figlioli		X		X		X	X
Kim Nolen	X	X	X	X	X	X	X
Leslie Kelly Hall	X	X	X	X	X	X	X
Lisa Gallagher	X	X	X	X	X	X	X
Lorraine Doo	X	X	X	X	X		X
Nancy J. Orvis	X	X	X			X	X
Rebecca D. Kush			X		X	X	X
Sharon F. Terry	X					X	X
Stanley M. Huff		X	X	X	X	X	X
Steve Brown	X			X			X
Wes Rishel	X	X	X	X	X	X	
Total Attendees	**22**	**26**	**25**	**22**	**20**	**25**	**22**