Collaboration of the Health Information Technology Policy and Standards Committees

Final Summary of the July 27, 2016, Joint Virtual Meeting

KEY TOPICS

Call to Order

Michelle Consolazio, U.S. Department of Health and Human Services (HHS) Office of the National Coordinator for Health Information Technology (ONC), welcomed participants to the Health Information Technology Policy Committee (HITPC) and Health Information Technology Standards Committee (HITSC) joint meeting. She reminded the group that it was a Federal Advisory Committee Act (FACA) meeting being conducted with an opportunity for public comment (limited to 3 minutes per person) and that a transcript will be posted on the ONC website. She called the roll. Consolazio told members to identify themselves for the transcript before speaking. She welcomed new members.

Opening Remarks

Vindell Washington, ONC, thanked the members for their work. He was excited about the agenda items. The staff report on interoperability is in response to members' requests.

Review of Agenda

HITPC Co-chairperson Paul Tang announced a change in the agenda. A co-chairpersons' conference call resulted in a decision to postpone the report from the Interoperability Experience Task Force until the September meeting. The co-chairpersons instructed that task force to focus its report and transmittal letter on the role of the federal government. Tang told the members to disregard the task force's slides distributed in advance of the meeting. Tang asked for a motion to accept the summary of the June 23, 2016, meeting as circulated with the meeting materials. A motion was made and seconded. The summary was approved unanimously by voice vote.

Action item #1: The summary of the June 23, 2016, joint meeting was approved unanimously by voice vote.

HITSC 2017 Interoperability Standards Advisory (ISA) Task Force Recommendations

HITSC Co-chairperson Arien Malec reminded the members that a vote would be taken on the acceptance of the recommendations. Task Force Co-chairperson Kim Nolen reported that the 2017 ISA Task Force is charged to develop recommendations for the HITSC in two phases. Since the task force did not complete the work scheduled for completion in July, that work will continue. Nolen reminded the committees that many of the recommendations had been presented for discussion at the June 23 meeting. Following a 20-minute intermission due to audio failure, Nolen went on with the slides and the presentation of recommendations.

ISA Scope Recommendations

- The ISA document should focus on data, standards and interoperability needs for Certified Health IT and will, when appropriate, include an appendix which references authoritative sources for other standards in healthcare including security, administrative, research/clinical trial etc.

- Secondary data used for ISA purposes will be defined as the reuse of the same data that is collected for clinical care
- ISA TF recommends including standards for interoperability which connect technologies outside the EHR, creating a path where data can be put in once (primary use) but used many times (secondary use)
- ISA TF recommends a section to identify "industry gaps" that exist (per task force/HITSC recommendations) in areas where standards likely would be valuable but are not known to exist. (i.e., data quality in patient matching)
- ISA TF recommends deprecation of listed standards once sufficient experience is gained with newer standards/approaches

Structure Recommendations

- The ISA should evolve to a more dynamic experience for users
- The ISA term "Best Available Standards" should be replaced with "Recognized Standards"
- Recognized Standards will include voluntary consensus standards (see OMB Circular A-119 Revised) and related implementation specifications
- To be listed in the ISA, Recognized Standards should be approved by the governing standards development organization (or equivalent governing body) as either a trial standard for pilot use (or equivalent) or approved for production use (or equivalent)
- Standards that are considered "emerging" may include broader standards that do not meet this criterion
- The ISA should serve as a filter to identify Recognized Standards which may be considered in a future regulatory process
- Recognized Standards should be dynamically linked in the ISA to the applicable standards specifications and governing body statements regarding the individual standard's maturity

Recommendations to Improve Use and Function of Standards

- ISA TF recommends that, in the interests of improving the use and function of existing standards already in regulation, that the following additional implementation references be incorporated into the ISA:
- HL7 Structured Document Examples
- HL7 C-CDA R2.1 and the C-CDA R2.1 Companion Guide (to be balloted in September)
- Direct Trust Recommendations to Improve Direct Exchange
- Argonaut Implementation Guide
- NCPDP/HL7 Pharmacy eCare Plan V1.0 (Guidance on the Use of the HL7 Clinical Notes R2.1 Care Plan Template)

ISA "Characteristics"

- The *Adoption Level* bubbles should be more qualitative in nature than quantitative when possible and should be referenced/sourced to how the adoption level was determined.
- One consideration could be to have a descriptive field of what is known about *Adoption Level*
- Include reference annotations (and any available public links) associated with adoption level classifications, including source used to quantify adoption level
- The ISA TF recommends linking the maturity assessments to known published criteria about the standards either from the SDO itself to other known evaluation entities (e.g., IHE Standards Matrix Criteria)

- The ISA should add a category under *Standards Process Maturity* to include categories of 'ballot in development' that could reflect emerging standards which may be in rapid development

Overarching Recommendations on Section I Vocabulary and Terminology Standards

- Change "Applicable Value Set(s)" to "Applicable Value Set(s) and Starter Set(s)"
- A brief definition of value sets and starter sets should also be included
- Suggest adding reference to VSAC, PHINVADS or other public repositories where appropriate to address public comments requesting "central repository" of value sets
- Provide direct links (where possible) to value sets
- VSAC should consider permalinks for value sets so they can be more easily accessed

Section I-A: Allergies

- The ISA should clearly differentiate between the allergens (substance causing the reaction) and allergic reactions
- For use of SNOMED-CT, codes should generally be chosen from the Clinical finding axis
- A single value set could be created in VSAC called "Clinical Problem Value Set")
- For allergic reactions, there is an 'Adverse Clinical Reaction' set in VSAC created by FHIMS which can be considered a candidate as a starter set. FHIMS should consider liaising with SDOs to validate this subset

Section I-B: Care Team Member

- The ISA should reflect work occurring in the HL7 Argonaut FHIR Provider Directory Work Group, which could be an emerging standard for this interoperability need as it becomes more mature
- The ISA should list vocabularies that expressly differentiate the credentials vs the role of the care team member (e.g., pharmacist vs family member)
- A gap currently exists for a value set that captures the care team members' role on the care team. ONC should work with appropriate parties to accelerate such a value set's development
- The National Uniform Claim Committee (NUCC) should be evaluated to determine its effectiveness at identifying individual care team member roles in future ISA updates

Section I-C: Encounter Diagnosis

- For use of SNOMED-CT, codes should generally be chosen from three axes: Clinical finding, Situation with explicit context, and Event. A value set could be created in VSAC to cover these, which can be called the "Extended Problem Value Set"
- A precondition should be added for medical diagnoses that systems should be able to handle older code sets, such as ICD-9, as legacy content still exists and may be used for analysis/decision support/quality measurement needs as retroactive analysis is often required
- A link to NLM's SNOMED-CT and ICD-10-CM mapping should be provided
- Add the CORE Problem List Subset as a starter set for SNOMED-CT codes for this interoperability need
- For dental diagnoses, consider including CDT-2 and provide transcoding from CDT-2 to SNODENT

Section I-E: Family Health History

- See recommendations on structure and observation/value pairings so context of meaning is not lost. (e. g. WHO the history pertains to, WHAT history condition is recorded)
- The condition part could be coded with SNOMED CT, referencing the value set "Clinical Problem Value Set" (as in the Allergies slide)

Section I-F: Functional Status & Disability

- A number of survey/assessment instruments and tools exist in this area. CMS should work with stakeholders to choose a preferred set of survey instruments for various settings
- LOINC and SNOMED-CT should be the preferred vocabularies

Section I-G: Gender Identity, Sex, and Sexual Orientation

- This sub-section should be renamed as "Sexual Orientation and Gender Identity" for consistency with most widely accepted terminology
- Precision medicine requires an increased focus to document granular, specific information about the patient that aids in targeted delivery of healthcare to the patient. There are other ways to determine gender outside of traditional approaches. ONC should solicit feedback from the community on appropriate genetic identifiers/gender determinants (e.g., gonadal sex, karyotypic sex, etc.) for potential inclusion in the ISA

Section I-J: Lab Tests

- The interoperability need should be revised to: "Interoperability Need: Representing laboratory tests"
- Remove "numerical" from the need name and instead use the general the paradigm of observations and observation values, with LOINC standard for the question/observation, SNOMED-CT as answer/observation value

Section I-K: Medications

- The ISA TF acknowledges that RxNorm is used for the exchange of information, however, it should be available also for export and import by end users. This should be listed as a limitation or gap in this area

Section I-L: Numerical References & Values

- The task force recommends adding a precondition to help stakeholders better understand that UCUM is a syntax rather than an enumerated set of codes

Section I-M: Patient Clinical "Problems" (i.e., "conditions")

- For this interoperability need, codes should generally be chosen from three axes: Clinical finding, Situation with explicit context, and Event
- A single value set could be created in VSAC to cover these, named the "Extended Problem Value Set" to distinguish it from other value sets
- The CORE Problem List Subset urn:oid: 2.16.840.1.113762.1.4.1018.240 should be added as a recommended as a starter set
- SNOMED CT supports the combination of codes (post-coordination) to generate new meaning. Codes from other axes can be used in post-coordination. The need to pick multiple codes may be seen as a disadvantage. This can be avoided if post-coordination is limited to the backend, exposing a single code for users to pick

Section I-Q: Tobacco Use (Smoking Status)

- Use the observation + observation value pattern
- Include the LOINC code (72166-2) that corresponds with the enumerated SNOMED CT value set
- Develop guidance about using the SNOMED CT codes in the value set
- Recognize that there are other clinically important smoking variables beyond the SNOMED CT value set. May need to add additional data elements to capture more granular smoking-related facts in a format that allows for accurate interpretations (e.g. tobacco type, frequency, amount, etc.)
- ONC should ask stakeholders what surveys, instruments or tools are being used to collect smoking status information.

No Recommendations in the Following Areas

- Section I-D: Race & Ethnicity
- Section I-H: Immunizations
- Section I-I: Industry & Occupation
- Section I-N: Preferred Language

Research

- Limit focus only to data, standards and interoperability needs for Certified Health IT in the ISA
- Different standards for clinical care data and research will create barriers for research efforts
- The following 'projected' interoperability needs should not be included in ISA itself (due to scope limitations). An appendix for additional research standards may be more appropriate: (listed on slides)
- A cautious approach should be used in including vocabularies which differ/conflict with vocabulary standards listed in Section I (or adopted in regulation) as this may obstruct much research dependent on data present in EHRs
- FDA itself has as moved toward adopting LOINC as "part of a larger FDA effort to align the use of data standards for clinical research with ongoing nationwide health information technology initiatives"
- Be aware of (and evaluate for future inclusion) efforts underway using FHIR-based approaches to better support research based interoperability needs (e.g. CDASH, Data Capture, etc.)

Patient Matching

- The ISA should highlight what standards are available and in what manner they should be used. Suggested recognized standards applicable to patient matching should include (at minimum) and should include: (listed on slides)
- When developing criteria for patient matching we should think beyond tradition attributes used today and look for other attributes and to other industries which 'link' people through other attributes and activities
- Commonwell - http://www.commonwellalliance.org/specifications/

API-Based Interoperability Approaches

- ONC should add a section to the ISA which highlights key differences between API-based interoperability standards and previous approaches

- ISA should continue to focus on a use-case driven approach to interoperability guidance, but in so doing will need to maintain clear distinction between the lower-level standards that make up the "building blocks" (e.g., FHIR, OAuth 2) and the higher-level use-cases that leverage the lower-level building blocks
- Higher-level use-cases should produce Implementation Guides that document their use of the core API standards, but which also include additional specifications and constraints

Discussion

Malec declared that the recommendations include the level of detail required for an ISA. He commended the task force for its work to date. Consolazio announced that the time of adjournment would be extended to accommodate the delay caused by the audio failure.

Andrey Ostrovsky asked whether use cases and implementation guides should consider and align with the business cases as the next step. Task Force Co-chairperson Richard Elmore responded that a standard in itself may not provide sufficient specificity for implementation. Reference to implementation guides in the ISA is recommended. Use cases are the framework for moving forward. Business case discussions are out of scope. Ostrovsky observed that many under resourced providers want to leverage this technical information but do not have the resources to do so.

Eric Rose expressed approval of the linkage with the interoperability proving ground. However, the boundary between regulation and the ISA is murky. If something is covered in regulation, it should not be included in the ISA. Elmore suggested that the distinction be tightened. He explained that the task force understands that the ISA is intended to look at all standards; some are possibly on the on-ramp for future regulations, but inclusion does not necessarily indicate that regulation is forthcoming. According to Rose, the ISA should make it very clear what is and is not regulation.

Leslie Kelly Hall said that the Precision Medicine Task Force had recommended an addendum for precision medicine. Also, Direct Trust and consumer mediated exchange should be clarified. The ISA should give more guidance on patient-generated health data and consumer vocabularies. Kelly Hall went on to voice concern with the evolution of standards, in particular FHIR. When compatible or equivalent standards are available in a new technology, advice is needed. Elmore acknowledged that her reference to precision medicine should have been included. Elmore agreed to take the suggestion for consumer vocabulary back to the task force for deliberation. Regarding FHIR, he yielded to Malec, who clarified that recommendations can be approved with clear additions or amendments. Malec said that the ISA historically serves as a means of introducing new and emerging standards. Consolazio noted that the discussion was falling behind schedule. She asked members to restrict their questions to those that materially affected their action on the recommendations.

Rajesh Dash wondered about a broader focus on interoperability, saying that standards are not sufficient. The important of building an infrastructure to work in conjunction with standards should be recognized. Many of the standards do not affect patient care. Data registries are needed. Elmore responded that infrastructure is out of scope for the task force. Everyone understands that standards are only one factor in interoperability.

Floyd Eisenberg referred to slide 21, saying that although examples of what works are appropriate, defining functional forms and tests is out of place. Regarding problem lists, a way to ensure correctness of the data is needed. Eisenberg requested an amendment to ask CMS to provide examples of preferred survey instruments. CMS should not be in charge of selection. Additionally, these instruments will change over time. Larry Wolf interjected that CMS is reviewing its mandated assessments, and the ISA can be a back reference for the use of these assessments. Nolen approved of Eisenberg's amendment.

Steve Brown pointed out that the U.S. Department of Veterans Affairs has specific authority for its own assessments, not to be confused with CMS authority. He does not want information that cannot be received to be sent to his facilities. When a member noted that it would be beneficial for federal agencies to align standards, Malec called a point of order, saying that the suggestion was out of scope for the charge.

Jamie Ferguson, a member of the HITPC, referred to the approved summary of the June 23 meeting, which documented his request that page 8 of the task force's presentation should refer to use of the eHealth Exchange. He observed that the request was not reflected in the transmittal letter. Elmore assured Ferguson that the suggestion was consistent with the intent of the task force and that a correction will be made.

Malec called for a vote on the recommendations as amended: (1) change slide 21 to say, "CMS to give examples," instead of "CMS to select preferred surveys"; (2) add a reference to the eHealth Exchange as an example of an implementer; and (3) add a reference to precision medicine. Consolazio said that only HITSC members are allowed to vote. Ex officio members are not allowed to vote. Consolazio instructed members to vote via the website, email, or telephone.

> **Action item #2: Consolazio announced that 19 HITSC members were present. The amended recommendations of the 2017 ISA Task Force were approved by a vote of 17 in favor, with two abstentions.**

Office of the Chief Privacy Officer Updates

Lisa Savage, ONC, showed slides to inform the members of a recent report titled *Examining Oversight of the Privacy & Security of Health Data Collected by Entities Not Regulated by HIPAA* and released on July 19, 2016 (https://www.healthit.gov/sites/default/files/non-covered_entities_report_june_17_2016.pdf). Savage thanked the many people who worked on the report. The report describes continued gaps in policies on access, security and privacy. Confusion persists between HIPAA regulated entities and those not regulated by HIPAA. Non-covered entities (NCEs) are technologies managed by businesses that collect electronic heath information on individuals and are not covered by HIPAA as a covered entity (CE) or business associate (BA). They include: mHealth technology, health social media, and PHRs not hosted by CEs. HIPAA protection does not apply to all health information everywhere it is collected, accessed, used, or stored. HIPAA has specific prohibitions against the use of identifiable data for marketing; this rule does not apply to NCEs. NCEs are not required by law to adhere to minimum security practices, whereas HIPAA provides minimum security standards. NCEs are not required by law to give consumers access to their health information or to send it (disclose it) as the consumers wish, whereas HIPAA guarantees this right. The lack of clear rules may be delaying economic growth. HIPAA, which is enforced by OCR and state attorneys general, provides nationwide privacy, security, and breach notifications for health information accessed, used, disclosed, or held by CEs and their BAs. The Federal Trade Commission (FTC) has a well-developed body of law enforcing the prohibition of unfair or deceptive privacy and security practices, including taking action against an organization that adopts a code of conduct but does not adhere to that code. The FTC uses its authority to bring enforcement actions against companies that fail to have reasonable and appropriate security practices regarding consumer data, including health data. The FTC has also used its authority under Section 5 in cases where, for example, the Commission has reason to believe that a business made false or misleading claims about its privacy or data security procedures. The U.S. Food and Drug Administration (FDA) oversees the safety of medical devices, including those that act through apps that are within the FDA authority.

Savage described several ONC efforts, saying that the report supports the recommendations from the API Task Force and identifies legal gaps that are important to understand if consumers are to take advantage of 2015 Edition provisions, such as open read-only API access, transmission via unsecured email, and the focus on consumer rights of access.

The Health Care Industry Cybersecurity Task Force is scheduled to convene its next in-person meeting October 26. For more information, visit http://www.phe.gov/preparedness/Pages/default.aspx. ONC recently published a funding opportunity to improve cyber threat sharing. The Assistant Secretary for Preparedness and Response (ASPR) published a funding opportunity for a sector Information Sharing and Analysis Organization (ISAO).

Q&A

HITSC Co-chairperson Lisa Gallagher asked about the difference or relationship between the two grant announcements. Savage said that each is based on the respective agency's granting authority. The ONC grant is intended to increase the number of organizations that use information on threats and to assist them in doing so. The ASPR grant focuses on development of infrastructure for threat information. Savage did not know whether applicants are limited to nonprofit organizations. A qualified organization may apply for both grants.

Ferguson was concerned that the NCE report excludes entities that use geo-location data. These organizations are often within the authority of the FCC. Ferguson reported that the FCC has issued a NPRM on privacy and broadband service providers. He recommended that ONC coordinate with the FCC, because many of the provisions appear to be inconsistent with or at least different from HIPAA's and will likely be confusing for consumers. Savage said that the FCC had the opportunity to review and comment on the NCE report.

Paul Tang asked whether recommendations were made on how to address the gaps in NCEs. Savage replied that no specific recommendations were made. Stakeholders are expected to collaborate on moving forward. There may be a role for ONC and the FACAs in helping consumers understand these issues.

Wanmei Ou wondered whether NCEs include pharmaceutical companies that have devices to communicate with patients for disease management. Savage confirmed that pharmaceutical companies are not regulated under HIPAA, but FTC regulations may apply.

Aaron Miri referred to ISAOs and asked about the possibility of safe harbor as well as concerns about information blocking. Savage responded that the U.S. Department of Homeland Security is charged with guidance on sharing information on cyber threats and liability. ONC will gather and present more information for the March report. Regarding information blocking, the HHS task force is working on allowing sharing. ONC staff did not examine state laws on NCEs. There are state-specific breach laws. Gallagher added that the cyber threat statute contains information on the types of information that can be shared, protections, and liabilities. She offered to send information to Miri. Savage reminded the group that the issue is the sharing of threat information, not the sharing of health information.

Gayle Harrell was concerned about the opportunities for abuse of devices. NCEs may not want to participate because of perceived liability. What is the role of ONC is clarifying NCE and CE responsibilities? Savage pointed out that liability between two private entities is not within ONC's or any other federal agency's authority. The API Task Force deliberated some of these issues affected by consumer choice. Harrell emphasized the need for education. Savage said that many tools are available via the FTC.

Kelly Hall talked about precision medicine. Many of the new actors are not CEs. Savage said that the report is relevant for precision medicine. ONC is working with the other federal agencies. Many NCEs have been waiting for this report.

Dale Nordenberg inquired about the role of the FACAs in recommending standards for sharing information. Savage said that the HHS task force is concerned with data integrity and ensuring that people are not harmed by sharing. After the task force submits its report, a role may be recommended.

ONC Data Update

Vaishali Patel, ONC, reported on findings from the ONC-American Hospital Association 2015 Annual Survey Information Technology Supplement. Since 2011, all hospitals have dramatically increased EHR adoption. Rural, small, and CAHs are closing the gap with other hospitals. The percentage of hospitals electronically sending, receiving, and finding key clinical information increased significantly between 2014 and 2015, although use or integration of information declined from 40% to 38%. Only 26% of respondents reported doing all four processes in 2015. Electronic availability of outside information at the point of care and use of that information for clinical decisions were lower among rural hospitals, small hospitals, and CAHs compared to all hospitals. Lack of exchange partners' capabilities to receive data was the most frequently identified barrier to interoperability in 2015, although its prevalence had declined since 2014. The percentage of hospitals using only nonelectronic means of exchanging summary-of-care records with outside sources significantly declined. Secure messaging using EHRs was the most common means to send and receive summary-of-care records electronically. For more information, see Data Briefs #35, #36, and #37 at http://dashboard.healthit.gov/.

Q&A

Dash hypothesized that exchange is often directly related to market penetration, regardless of the EHR system. Patel acknowledged that no data were collected on market penetration. Dash went on to observe that the emphasis on interoperability is more frequently due to government reporting requirements than to patient care. Patel said that the questions pertaining to sending summary-of-care documents assume the primary importance of patient care.

Terrence O'Malley referred to slide 9 and care community infrastructure factors: Are there opportunities to develop the infrastructure first and then the means to exchange across platforms? Patel agreed that there are many types of barriers to interoperability. She demurred, saying that she is not the right person to speculate about what comes first for a solution. The *Interoperability Roadmap* considers all of these factors.

Consolazio thanked the members for their patience and told the new members that, typically, meetings are conducted with fewer last-minutes changes to the agenda and without communication system problems.

Public Comment

Shelly Spiro, Pharmacy e-Health Information Technology Collaborative, stated her appreciation for the work on standards. She asked that slide 13 be corrected to "Pharmacist [not Pharmacy] eCare Plan V1."

Tom Bizzaro, FDB, wrote via the chat function, "I don't understand the comment on RxNorm not being available for higher functions likes Clinical Decision Support. Behind the scenes in an EHR are numerous codes that are not visible to the end user that can be used for CDS and other functions. RxNorm codes would be no different."

Next Meeting: The joint committee will meet virtually September 13.

SUMMARY OF ACTION ITEMS

Action item #1: The summary of the June 23, 2016, joint meeting was approved unanimously by voice vote.

Action item #2: Consolazio announced that 19 HITSC members were present. The amended recommendations of the 2017 ISA Task Force were approved by a vote of 17 in favor, with two abstentions.

Meeting Materials

- Agenda
- Summary of the June 23, 2016, joint meeting
- Presentations and reports slides