Collaboration of the Health Information Technology Policy and Standards Committees

Final Summary of the January 10, 2017, Joint 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 two opportunities for public comment (limited to 3 minutes per person) and that a transcript will be posted on the ONC website. She told members to identify themselves for the transcript before speaking. Members introduced themselves for the roll call.

Review of Agenda

HITPC Co-chairperson Paul Tang asked for a motion to approve the summary of the December 6, 2016, meeting as circulated with the meeting materials. The motion made by HITPC Co-chairperson Kathleen Blake was seconded. The summary was approved unanimously by voice vote. Tang noted the items on the agenda.

> **Action item #1: The summary of the December 6, 2016, joint meeting was approved unanimously by voice vote.**

Office of Policy Updates

Elise Anthony, ONC, reported on the Model Privacy Notice (MPN), a voluntary, openly available resource designed to help developers provide transparent notice to consumers about what happens to their data. A broad range of consumer health technologies beyond PHRs are now in use, and not all users read the privacy policies. Those who do may not fully understand the content in the policy. To update the MPN, ONC put out a request for information on March 1, 2016, to seek comments on what information practices health technology developers should disclose to consumers and what language should be used to describe those practices. Anthony showed slides to portray the December 1, 2016, version of the MPN. In addition, ONC has issued the Privacy Policy Snapshot Challenge, which calls upon developers, designers, health data privacy experts, and creative, out-of-the-box thinkers to use the MPN template to create an online tool that can generate a user-friendly "snapshot" of a product's privacy practices. The deadline for submission is April 10, 2017. Winners will be announced in mid-2017. For more information visit: https://www.healthit.gov/policy-researchers-implementers/model-privacy-notice-mpn.

Q&A

Anthony assured John Scott that staff will try to be consistent with language used in the Health IT Playbook. Commenting on the importance of using plain language, Chris Lehmann wondered what was being done to move in that direction. He asked about children transitioning to adulthood: What control do they have over their data submitted by parents? Anthony said that staff tried to make the MPN usable to all audiences, while at the same time balancing it with the need for accurate information. ONC Chief Privacy Officer Lucia Savage reminded members that state laws govern how minors obtain control

of their data. The MPN does not deal with state laws. Although patients have the right to change their mind about consent, what is collected cannot be reversed. However, the MPN identifies those data.

Staff announced a January 12 webinar. Join **here** to participate. The language of the Privacy Policy Snapshot Challenge refers to consumer testing prior to submissions.

Patricia Sengstack asked what is being done to educate the public about the MPN. Anthony talked about presentations to trade associations and other stakeholders. Efforts are ongoing. Staff is receptive to suggestions.

Andy Wiesenthal called for a longer discussion about the implications of the variation in state laws: What about those situations in which the state of residency and the state in which care is received are different? Federal hospitals, such as those operated by the military, the Department of Veterans Affairs, and the Indian Health Services, are not subject to state and local laws. The differences between state and federal privacy laws are creating chaos. He referred to a bill that would allow children to be admitted to any children's hospital, regardless of state of residency. The committees should make a recommendation for resolution of the state-federal issue. Savage announced that her presentation scheduled for later in the meeting addressed that issue. Gayle Harrell said that, without federal legislation, state laws cannot be preempted. According to Donna Cryer, there is president to work out these issues.

Tang asked what happens to data when a company ceases to do business. A staff member responded that in that case or when a company is acquired by another organization, there must be notification to the consumer. ONC does not have authority to require more. Savage referred to a briefing at the July meeting. A different set of rules applies to organizations not covered by HIPAAs. Other than notification to customers, nothing is required.

Anthony announced that ONC has contracted for a white paper on patient generated health data. The draft paper will be reviewed by the Consumer Task Force. The contract includes plans for two pilots to inform the final white paper, which is scheduled for release in 2018.

Remarks

Vindell Washington, ONC, thanked the committee members for their work and support throughout his tenure as principal deputy. He noted that hospital capability to view, download and transmit EHR data increased from 10% in 2013 to 70% in 2016. He expressed confidence in the work of the ONC career staff to continue ONC efforts. Going forward, Jon White will serve as acting coordinator, and Lisa Lewis will continue as deputy national coordinator. Steve Posnack and Anthony will remain. Washington thanked the staff political appointees for their work. He observed that the 21st Century Cares Act seeks to protect patients' information. The act passed with unprecedented bipartisan support. The law calls for an "orderly transition" to a new FACA structure. Since the committees are already working together, the transition is expected to be a smooth one. On behalf of the committees, Tang thanked Washington for his work.

2017 Interoperability Standards Advisory (ISA) Review

HITSC Co-chairperson Arien Malec introduced the topic. According to Steve Posnack, ONC, the new online ISA is a significant, positive shift to the delivery of updated content through an interactive web-based platform. It provides a community-wide, centrally accessible resource to standards and

implementation specifications. The ISA incorporates the following mid-year (July 2016) ISA Task Force recommendations to offer a more dynamic experience for users:

- Link to or embed content from websites like the ONC Interoperability Proving Ground demonstrating interoperability use cases
- Enable viewing of public comments and ONC responses in the context of which standards/interoperability needs they pertain
- Link to known profiling entities, which coordinate standards listed in ISA to address specific clinical needs and use cases
- Link to published assessments of a particular standard's maturity
- Link listed value sets to their publication in Value Set Authority Center (VSAC)

Chris Muir, ONC, continued the presentation. The ISA timeline and annual publication cycle were shifted. Now ONC will annually publish a static reference edition of the ISA that can be referenced in contracts, agreements, or as otherwise needed with certainty that the information will not change. A call for public comments is expected to occur annually to ensure the published reference edition is as accurate as possible. The web-based version of the ISA is expected to be updated throughout the year with real-time updates to standards and implementation specifications from standards development organizations. This will allow dialogue, debate, continuous feedback, and correction of errors. The most substantial changes between 2016 and 2017 include:

- The discontinued use of the label "best available" as an overall concept
- Changing the scope of the ISA to include more specific references to research and public health
- Including personal health device, nursing, research, nutritional health, and social determinant interoperability needs within the ISA
- Adding a new section that begins to include functional and data models as well as functional profiles
- Where applicable, the addition of "Applicable Starter Set(s)" alongside appropriate code sets in Section I
- Links to active projects listed in ONC's Interoperability Proving Ground
- Better representation of the pairing of standards for observations (i.e., questions) and standards for observation values (i.e., answers)

Staff expects that future changes will increase functionally. ISA Task Force recommendations will be considered for inclusion. Feedback from users will also be obtained. Interoperability needs for consumer and patient access will be addressed. A continuation of more granular reference to FHIR resources, profiles, and implementation guides is expected, as well as improvements in how privacy and security are addressed.

Posnack reported that the 21st Century Cures Act calls for the transition of the Health IT Policy and Standards Committees to a single advisory committee, the Health IT Advisory Committee (HITAC). The HITAC is charged with performing three duties with respect to setting priorities for standards adoption:

- Identifying "priority uses of health information technology" related to several health care areas
- Identifying "existing standards and implementation specifications that support the use and exchange of electronic health information needed" to meet the identified priorities
- Publishing a report summarizing the findings of the analysis conducted in connection with the above as well as making appropriate recommendations

Q&A

Malec challenged all stakeholders to comment on the ISA. Washington said that the appropriate level of prescription is much debated. He called for discussion of removal of the best available label.

Wanmei Ou asked about better efforts to inform potential stakeholders about the ISA. She reported that it is not used to the extent that it should be. Posnack responded that staff is always seeking new and better ways to inform potential users. The HITAC can consider this question. Posnack referred to the search for a balance of level of prescription. The online version can be updated. Links to experience and research citations can be incorporated.

Referring to the limitations and dependencies section, Jonathan Nebeker called for more forward-looking suggestions for the use of standards. Posnack replied that the committee is responsible for considering more direction. Staff reacted to suggestions. Malec interjected that ONC staff cannot advise without benefit of experience. Users should publish the results of their experiences so that the results can be incorporated into the ISA.

Carolyn Peterson inquired about consumer comment. According to Muir, not a lot of comments were received from consumer groups, most likely because they are not too involved with technology. Staff will work with the Consumer Task Force to elicit more input. Peterson requested more attention to those committee members, such as herself, not previously involved.

Karen van Caulil reported that her consumer organization has been successful in consumer involvement. She offered her services. Terry O'Malley reported that the National Quality Forum is working on interoperability for quality measures.

Blake reported that the American Medical Association is supporting the teaching of EHR systems, which is important because clinicians in training are typically prohibited from EHR input. An all-clinicians model is needed and can be used for testing and development of use cases. People-issues in addition to technical ones must be addressed.

Kevin Johnson referred to his documentary (No Matter Where) on interoperability commissioned by ONC several years ago. Members may contact him for screening.

2017 Interoperability Standards Advisory Task Force Draft Recommendations

Presentation slides with the draft recommendations and a document entitled Understanding Emerging API-based Standards were distributed to committee members on January 9. Noting the recommendations that have already been incorporated into the ISA, Co-chairperson Kim Nolen explained that the task force has yet to complete its work; the draft recommendations are, therefore, incomplete. Complete recommendations will be presented at the February meeting at which time the HITSC is expected to act. The overarching recommendations are:

- Base standards (e.g. CDA, etc.) that are listed for multiple interoperability needs should be re-located into a new section for "base standards" that can be referenced throughout the ISA. These should be removed from individual interoperability needs within the ISA (unless they can be used alone to achieve the interoperability need) to avoid confusion by implementers.
- Standards listed throughout the ISA are and should remain varied by the use case or interoperability need they support (i.e., the "best" standard for one use case may result in loss of critical metadata or other important information for another use case). Continued and expanded use of ONC's Interoperability Proving Ground to showcase actual use of standards and best practices directly from the ISA is encouraged.

- Where interoperability needs align with ONC certification criteria, these should be listed and linked appropriately so that stakeholders know what to certify to as things evolve.
- Security patterns listed for each interoperability need in Sections II and III are duplicative. They should be relocated to an appendix that deals with general security concerns.
- The ISA currently lacks interoperability needs supporting consumer and patient access to their health information. A section should be added to the ISA to address this.
- Final recommendations will include more detailed recommendations and use cases to better represent patient access within the ISA.
- As the ISA grows to become a more robust tool for industry reference, it should also provide educational information about standards issues to support implementers. (E.g. observation/observation value pairings; emerging-API based standards; etc.) Recommended language from the task force in these areas has been provided as a separate document for committee review.

Next, section-specific draft recommendations were presented.

Section II-H: Electronic Prescribing: A number of the SCRIPT V10.6 transaction types have incorrect information about the maturity or adoption level listed. These should be updated to reflect the current state of industry capabilities in support of e-prescribing transactions.

Section II-I: Family Health History (Clinical Genomics): FHIR's Sync for Genes should be mentioned as a project that will test out FHIR's clinical genomics resources.

Section II-J: Images: If mature enough, the ISA should reflect ongoing work within Commonwell and Carequality surrounding narrative text portion of image exchange.

Section II-K: Laboratory: The adoption level for the implementation specifications for receiving electronic lab results should be increased to at least two bubbles to reflect actual adoption and use. The HL7 Version 2 Implementation Guide: Clinical Genomics Coded Reporting, Release 1, U.S. Realm should be monitored and added to the ISA as an emerging standard once released as a balloted draft.

II-L: Medical Device Communication to Other Information Systems and Technologies: A limitation should be added to reflect the variety of approaches and various use cases for medical devices that may be included as part of this interoperability need. Next year's ISA Task Force should include experts in this area to better support enhancing this interoperability need.

II-M: Patient Education Materials: The SOA-based implementation specification has an over-stated adoption level. The adoption level should be reduced to two dots. The context-aware knowledge retrieval (infobutton) release 4 should have an adoption level of four dots. A FHIR-based approach for patient education materials is currently being developed. This should be reflected in the ISA.

II-N: Patient Preference and Consent: BPPC is not executable, just provides documentation of consent. Adoption level should be lowered to one star. A note should also be added that BPPC is being used for SSA disability determination requests, which may impact overall adoption level. A note should be added to reflect that Carequality has created a profile that provides additional information and context for consent and authorization preference that is conveyed through the SAML security header portion of a SOAP message.

II-O: Public Health Reporting: For antimicrobial reporting, the CDA R2 HAI Reports Implementation Guide should have a higher adoption level as it is federally required. Increase to two bubbles. For Electronic Transmission of Reportable Lab Results, the adoption level for the ELR Implementation Specification should be increased to five bubbles.

II-P: Representing Clinical Health Information as a Resource: A specific definition should be provided to distinguish between the uses of FHIR as a clinical resource vs. as an API based approach to interoperability. Draft text to reflect this information has been provided in a separate document for the committee's review.

II-Q: Research: Recommendations are still being discussed by the task force.

II-R: Segmentation of Sensitive Information: There is a federal send and receive requirement (partial data segmentation), which should be noted in limitations and may be difficult for providers to accomplish. This has largely only been used in pilot settings with low adoption. In addition, the second standard (full data segmentation for privacy) is in pilot with very low adoption.

II-S: Summary Care Record: Resources for implementers should be provided, such as lists of examples that are accessible from directly within the ISA (e.g. EDGE testing tool). Identifying and providing links within the ISA to CCDA example libraries that vendors and developers can use to ensure consistent adoption of CCDA and consistent representation of the clinical data within the CCDA would be a helpful addition.

Many detailed nursing recommendations, written by Susan Matney, were presented, including to use consistent terminology throughout the document when referring to mapping, translating, or converting from one terminology to another. A forthcoming report on nursing terminology from ONC may help influence population of the adoption level fields for nursing standards. Regarding nursing assessments, it was recommended to change the title to Representing Clinical/Nursing Assessments. LOINC should be used to represent the questions and SNOMED CT should be used to represent the answers (except when using validated scales). Adoption level should be listed as low for both LOINC and SNOMED CT for this interoperability need. LOINC assessment panels should be added as starter sets. A note should be added to reflect that definitions of the panels are in LOINC. The procedure axis of SNOMED CT is the terminology used for nursing interventions.

With regard to nursing interventions:

- LOINC is not used and should be removed as a standard for this interoperability need.
- A resource for nursing intervention value set is the map set from ICNP to SNOMED CT can be found at http://www.icn.ch/images/stories/documents/pillars/Practice/icnp/ICNP_to_SNOMED_CT_Equivalency_Table_for_Intervention_Statements.pdf.
- SNOMED CT should be added as a standard for this interoperability need.

Regarding representing nursing outcomes:

- Terminologies listed should follow recommendations in the previous section of the observation and observation value pairing.
- We agree for most circumstances that LOINC should represent the observations/questions and SNOMED CT should be used to represent the observation values/answers. However, when the outcomes are recorded as an assertion (e.g., normotensive, afebrile, etc.), the terminology to be used is SNOMED CT.
- We agree with SNOMED CT being used for this interoperability need.

The Limitations/Dependencies/Preconditions should be modified as follows:

- Add "The use of SNOMED CT® for this interoperability need, codes should generally be chosen from two axes: Clinical finding and Situation with explicit context."

- Add “Local and” to the beginning of the statement “Other ANA-recognized terminologies should be…”

It was recommended to add Nursing Problem List Subset of SNOMED CT as a starter set in the Applicable Value Set and Starter Set section https://www.nlm.nih.gov/research/umls/Snomed/nursing_problemlist_subset.html.

The task force will continue to deliberate on recommendations for Section III Content (Services/Exchange), research standards, and consumer access standards. Task Force Co-chairperson Richard Elmore noted that many current and future use cases and needs, such as new payment methods, are not covered in the ISA. Attention must be given to this issue in the future. He thanked the staff and task force.

Q&A

Floyd Eisenberg commented on the need to use common, validated assessment tools. Leslie Kelly Hall, a member of the ISA Task Force, talked about the need for a gap area. Elmore said that the task force considered emerging standards that could be linked back to an existing standard. An expanded focus could be considered by the committee.

Referring to page 13, Jamie Ferguson inquired about the difference between translation and mapping. Nolen explained that the point is to use consistent terms. The task force was silent on which term to use. Several members advised that mapping is the correct term.

Another member referred to slide seven and wondered about adding references to standards for CMS measures. Nolen agreed that it was an interesting question. Although it has not been discussed by the task force, she agreed to raise the question. Elmore said that there could be linkage between the 2015 Edition and CMS payment programs. Posnack reminded the members that the regulatory side is more restrictive than advisories. There is coordination with CMS behind the scenes. Elmore opined that the topic is probably not in scope for the current task force.

Aaron Miri recommended that the January 2014 SAFER Guide be referenced in the ISA. Savage reported that work has been done with PCORE to electronically document patient’s choices. State privacy laws must be taken into account. The PCORE work has a wiki. Malec observed that this is an area in which standards alone are not sufficient for interoperability. They do not inform what to do with the data.

Nancy Orvis asked about the maturity and mapping of nursing standards referenced in slides 13, 14 and 15. Nolen said that she will seek Matney’s input and add to the recommendations as necessary. Although more work is probably needed, Nolen did not know what additional effort may be required. Orvis asked for clarification regarding the amount of work yet to be done. A recommendation for ONC assistance should be added.

Office of the Chief Privacy Officer Updates

Lucia Savage, ONC, reported. The President’s Commission on Enhancing National Cybersecurity Report was issued December 1, 2016. A number of the recommendations are related to HHS efforts:

- Incent the sharing of threat information, and how to act on such information, through public/private collaboration, including pathways for businesses to share threat information without fear of inappropriate legal liability
- Strong identity authentication
    - HHS staff already should be using two factors.

    - ONC has accepted a FACA recommendation to move to require multifactor capability for system users in EHRs it certifies.
    - ONC committed to policy guidance on the identity proofing and authentication rigor for consumers to access their own information.

- Develop concrete efforts to support small and medium sized businesses
- Private and public efforts to rapidly improve security in Iota, including through rule-making where appropriate and authorized

Savage described the Department of Homeland Security (DHS) FBI Cybersecurity Briefing of December 30, 2016. Although in the context of nation-state cyber hacking, the following techniques are recommended to improve cybersecurity prophylaxis:

- Data backups
- Risk analysis and remediation
- Staff training
- Vulnerability scanning and patching
- Application whitelisting
- Incident response
- Business continuity planning
- Penetration testing

Savage said that ONC applies these techniques in its various efforts. The Assistant Secretary for Preparedness and Response is leading the charge and is the main point of contact for the Healthcare Industry Cybersecurity Task Force.

Next, Savage talked about privacy. She referred to an important recent NIST publication on privacy engineering: http://nvlpubs.nist.gov/nistpubs/ir/2017/NIST.IR.8062.pdf. The paper explains the difference between privacy engineering and security engineering and their applications.

Publications in the ONC/OCR series on the "permitted uses" of HIPAA describing the circumstances in which PHI and ePHI can be shared identifiably without first obtaining the individual's written consent were released. Treatment and Health Care Operations was released February 2016. Public Health Oversight was released December 8, 2016.

Regarding the 2015 grant to the National Governors Association (NGA), a road map https://www.nga.org/files/live/sites/NGA/files/pdf/2016/1612HealthCareRightInformation.pdf was produced to assist states to evaluate their own legal and regulatory privacy landscapes, and to take decisive steps to improve the availability of electronic health information while simultaneously protecting patient privacy. NGA found that, in addition to confusion resulting from variation across state privacy laws, key market issues are negatively affecting health information exchange. In the third phase of the project, NGA will provide technical assistance to Michigan, Illinois and Louisiana to apply the roadmap in their own environments.

Savage concluded by showing a slide that delineated a month-by-month list of accomplishments of her office since October 2014.

Q&A

Malec thanked Savage for her work during her tenure at ONC.

Eric Rose asked about a disconnect with the API regulation and what hospitals are prepared to do. Hospitals need to protect the security of patients' data. Hospital executives to not want to lower the firewalls. Savage pointed out that this topic was discussed at length and acted on at a previous meeting. Hospitals have no responsibility or right regarding what patients do with their data in their own hands. This is similar to the protection of banking information. ONC and OCR are prepared to assist organizations with implementation. Educational materials are forthcoming. Savage suggested that Rose review the proceeding of that HITSC meeting and contact the API Task Force for more information.

Blake referred to slide six, saying that the recommendations regarding small and medium sized businesses should include physician practices. New forms of authentication are needed. She called for NGA to report on best practices at an upcoming meeting. Savage told her to look at the report, which is quite complete.

Miri wondered why other agencies do not use plain language and if there are better ways to present information. Savage said that every agency has its own way to present information. She told Miri to show agency officials what presentation and communication modes work best.

David Kotz raised a concern with security, saying that health facility CIOs are concerned about their organizations bearing the burdens of developers' insecure devices. He wondered about recommendation to strengthen the security of devices. Savage referred him to the EHR Contractor's Guide, saying that the power of the purse matters.

Kelly Hall asked that the last slide show the links for all items. Dale Nordenberg talked about medical devise security efforts with which he is involved. Savage said that the FDA works with stakeholders to increase security. She agreed that considerable progress has been made by DHS, HHS and NIST. FDA uses incentives in the form of extra points to enhance security.

Public Comment

Anthony said that the draft white paper on patient generated health data is open for public comment.

Office of Standards and Technology Updates

This item was removed from the agenda.

Consumer Task Force Update Health IT Playbook Feedback

Task Force Co-chairpersons Cryer and Sengstack reported that the task force members reviewed and expressed opinions on these sections of the playbook:

- Introduction
- Certified Health IT-Information Blocking
- Health Information Exchange: ADT and Transitions of Care
- Value Based Care
- Privacy and Security
- Quality and Patient Safety
- Care Settings

The co-chairpersons showed slides that summarized opinions on each section. The co-chairs also reported that, in addition to the section-specific feedback, task force members gave their overall impressions. They thought the playbook was a great, centralized resource that covers a wide range of topics all in one place. Members liked the tools, links, and resources in the playbook. They felt that the playbook was appropriate for the audience of small to medium size providers. However, members also

felt that the playbook could benefit a broader audience such as health IT implementers, organizational leadership, technology developers, administrators, and others. Members suggested organizing or streamlining the content further to make it easier for providers to skim and digest. Members suggested indexes or using symbols to make it easier for readers to navigate the content and pull out the key points. Members suggested improving the readability and usability of the playbook through the use of plain language. Members also suggested that a PDF version of the playbook may make it easier for providers to share. Members recommended the following to improve the playbook:

- Include more examples from the field
- Highlight the role that patients play in interacting with the clinical workflows of EHR systems
- Add more information for chronic, longitudinal care vs. episodic care

Members suggested updating the playbook in a timely manner to reflect the shifts that are occurring in health care, such as the shift from the 2014 Edition to the 2015 Edition, the new overlay of MACRA's Quality Payment Program using CEHRT, and the emergence of new technologies like APIs and apps. Finally, task force members made suggestions for dissemination.

Q&A

Blake added that the more the inclusion of use cases, the better. Clinicians' move from MIPS to APM should be anticipated and incorporated into the playbook.

A member voiced his appreciation for the inclusion of post-acute care, which he said is actually acute care in non-acute settings. Data needs in non-acute settings are as great or greater as in acute settings. Post-acute care involves a range of providers, such as home care workers. In response to a question about the correct label, he acknowledged that providers have yet to agree.

Johnson referred to a variety of learning styles and asked about the use of pod casts. According to Anthony, ONC is expanding its modes of communication. Different mechanisms should be used for different stakeholders.

White thanked everyone. Chief Medical Officer Thomas Mason thanked everyone. The playbook will be updated this month. Feedback from the Consumer Task Force will be used. The landing page has been modified to be more usable. The task force recommended at least quarterly updates.

Public Comment

A comment was submitted via the web meeting chat. Thompson Boyd wrote, "HIMSS has also submitted valuable comments to the ISA. The comments, submitted, have been on a regular cycle, as requested by the ONC. The ONC may wish to continue to request comments from Health IT (and Standards) Organizations for comments representing the large stakeholder group."

Next Meeting: A virtual meeting is scheduled for February 7, 2017.

SUMMARY OF ACTION ITEMS

Action item #1: The summary of the December 6, 2016, joint meeting was approved unanimously by voice vote.

Meeting Materials

- Agenda
- Summary of the December 6, 2016, joint meeting
- Presentations and reports slides