HIT Policy Committee and Standards Committee
FINAL
Summary of the February 10, 2015 Joint Meeting

ATTENDANCE (see below)

KEY TOPICS

Call to Order

Michelle Consolazio, Office of the National Coordinator (ONC), welcomed participants to the Health Information Technology Policy Committee (HITPC) and Standards Committee (HITSC) joint meeting. She reminded the group that this was a Federal Advisory Committee (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. Members introduced themselves. She instructed members to identify themselves for the transcript before speaking. There are several openings on the committees. Interested persons can apply through the ONC website. HITSC applications are open through March 6, 2015. February 27 is the deadline for HITPC applications via GAO.

Remarks

National Coordinator and HITPC Chairperson Karen DeSalvo welcomed everyone. Acting Deputy National Coordinator and HITSC Chairperson P. Jon White said that many things are happening at ONC.

Review of Agenda

HITPC Vice Chairperson Paul Tang noted the agenda items. The agenda was distributed in advance of the meeting. He referred to the January 26 announcement by the HHS secretary that by the end of 2015 30% of Medicare fee-for-service payments will be in alternative payment models with 50% by the end of 2018. HITSC Vice Chairperson John Halamka participated by telephone. He commented on the importance of the agenda items in framing work over the next few years.

Interoperability Roadmap - Summary and Introduction

Erica Galvez, ONC, described the process for the Roadmap development. The committees had opportunity to comment on the vision paper and a number of recommendations from workgroups have been incorporated. This is the first draft, following a concept paper that was published some time ago. She said that the purpose of her slide presentation was to let members know what is in the Roadmap. Assignments will be made to specific workgroups to comment on different sections. Significant progress in digitizing the care experience has been made. Now there are data to be shared. Consumers increasingly expect and demand real-time access to their electronic health information. Evolving delivery and payment models are driving appropriate data sharing. Best practice models of information exchange and interoperability across the nation indicate it is possible to achieve. Technology is evolving in ways that will greatly simplify the challenge. Opportunities exist to improve care and advance science in a learning health system environment. She delineated 10 principles, which were depicted on a slide. The Roadmap is organized around five building blocks, each of which Galvez briefly presented, beginning with supportive business, clinical, cultural and regulatory environments. She pointed out that not all

action items fall under ONC purview. The federal government will link policy and funding activities beyond meaningful use (MU) to the adoption and use of certified health IT and electronic information sharing according to national standards. State governments are called to use available levers and Medicaid purchasing power to expand upon existing efforts to support interoperability and explore new options. Non-governmental payers and purchasers are called to explore financial incentives and other ways to emphasize the interoperable exchange of health information among provider networks. She paused for questions.

Discussion

Arien Malec observed that in some sections the Roadmap refers to a person-centered approach, but other sections imply being provider- and or HIT-centered. Patient matching is required for a person-centered approach. The Roadmap should clarify whether a person centered, full person record is intended.

David Lansky referred to slide 9 and said that it is important to state connections among federal, state and private sector actors. He suggested describing more specific use cases on which the sectors can align on mid-term objectives. Galvez said that the complete Roadmap contained such details. DeSalvo said that the document did go through clearance with other federal partners. There is opportunity to work with private payers. White said that both person-centered and provider-centered are important. Many times they are the same. Malec talked about bringing records together in a holistic person-centered record.

Gayle Harrell wants the federal government to provide guidance on privacy and security to states. Eric Rose referred to individual data matching (p. 90 on) and wondered about something beyond matching. Galvez indicated that matching devices and other things may be dealt with later.

Charles Kennedy talked about expanding interoperability to include functionality. David McCallie said that person centered may be a cross-cutting theme. He expressed concern that the Roadmap be perceived as a ceiling. Galvez responded that she is looking for a balance. She would appreciate feedback on where the floor may be set too low.

Citing slide 9, Paul Egerman noted that certification requirements are changing over time. What about states having different requirements and incentives for interoperability? Galvez noted the prevalence of the word align throughout the Roadmap.

Wes Rishel noted Galvez's use of the term ultra large systems to refer to those systems too big to manage externally. However, that term or concept is not actually used in the document. Use cases will arise out of economic necessity. Interoperability only happens when a manager's job depends on it and then it becomes a business imperative.

Andy Wiesenthal expressed concern that interoperability is the goal. The goal should be that decisions are based on having the full set of information at hand. That goal should be stated. Tang said that the background section clarifies the ultimate goal.

In response to a question, Galvez said that the vision paper described the role of population and community data to improve clinical decisions in the longer term. But for the 3-year term, staff focused on clinical data as what is realistic. A common clinical data set is described. It will cover a lot of needs, if not all.

David Lansky referred to the interplay between shared platforms and delivery reform. New technology platforms can allow shared functions.

Rules of Engagement and Governance

Galvez said that the proliferation of data sharing arrangements has created many different processes and rules for interoperability that do not facilitate interoperability nationwide. Achieving nationwide interoperability will require a single governance framework and process to facilitate trust and agreement on policy, operation, and standards issues. Governance framework and associated rules of the road should address policy, operations and standards. ONC's role is to establish a common governance framework with rules of the road for interoperability of a common clinical data set and to identify a process for recognizing organizations that comply with the rules of the road as well as to evaluate regulatory and certification options. Public and private stakeholders are called to establish a single coordinated governance process.

Discussion

Harrell talked about the importance of governance: How should bad actors be dealt with? Galvez said at multiple levels. Mechanisms would have to be designed. Jody Daniel, ONC, said that comments are being sought on these governance topics, including how to hold people accountable. Accountability can be tied to other programs.

McCallie said that the rules of the road should be the minimum necessary in order not to inhibit progress. The JASON Task Force discussed this topic. Galvez said that the Roadmap calls for measurement on governance objectives. Daniel talked about setting guard rails.

Malec said that the target of a breach is not necessarily the bad actor. Poorly done governance can have negative consequences. Anne Castro asked that the Roadmap deal with reality. The timeline is not helpful. There is so much going on that it is difficult for organizations to keep up. If reducing the cost curve is still a goal, the field needs to learn from current efforts.

Leslie Kelly Hall said that governance really means protecting consumers. She referred to on-ramp and off-ramp governance. John Derr commented on the absence of any mention of the timeliness of interoperability, which is a problem for LTPAC providers. They often get a patient's record days after admission of the patient herself.

Public Comment

None

Introductions

DeSalvo introduced several new staff members: CHIO Michael James McCoy, MD; Director of Public Affairs Chartése D. Day, MBA; and CMIO Thomas Mason, MD.

Privacy and Security Protections for Health Information

Galvez continued to talk about the Roadmap, saying that this section includes permission to collect, use, and disclose identifiable health information. Legal requirements for health information sharing are philosophically aligned, but differ in content across states. Nationwide interoperability requires a consistent way to represent an individual's permission to collect, share, and use their individually identifiable health information. Software systems need to capture and persist both written individual permission and what is permitted without written individual permission (computable privacy). Near-term actions call for OCR and ONC to educate stakeholders on current federal laws. Federal and state governments should reach consensus on what is permissible to exchange (use and disclosure) for TPO without consent for information that is regulated by HIPAA (referred to as background rules in the roadmap). They should standardize existing laws pertaining to sensitive health information, so that laws

mean the same thing in all U.S. jurisdictions, without undermining the privacy protections individuals have today. Stakeholders are called to align organizational policies for information sharing regulated by HIPAA with HIPAA permitted uses and disclosures for TPO, and actively share health information in accordance with the law.

Discussion

Malec asked about basic choice. He suggested that the first focus be on treatment. Lucia Savage, ONC, said that although HIPAA already supports exchange without consent, a number of organizations have introduced choice, but without standards. Since consumers are being offered choice, we need standards. Consumers want to be asked and to know where their data are going. Malec wondered whether HIPAA is insufficient or organizations need to better explain consent. Savage observed that there are HIPAA and other laws with which to work.

Gayle Harrell recalled that the Privacy and Security Tiger Team had made recommendations on choice. The variation in state laws regarding privacy and security are problematic. She suggested working first with the National Governors Association. Considerable time will be required to change state laws. Galvez talked about stages and forming state academies to bring people together to talk. Savage is working on a policy academy.

McGraw asked whether the Roadmap is calling for basic choice. Galvez responded that the Roadmap says if an organization does basic choice, do it in a standard way.

McCallie suggested identifying simple, straightforward use cases and developing guidance on exchange for those use cases. The discussion in the document is confusing.

Dixie Baker observed that in moving to a learning system, data for research and data for treatment will converge. She called for regulation to harmonize HIPAA and the Common Rule. She suggested thinking about consent as on-going process not just a signed piece of paper. In the future computable consent will be the standard. Savage reminded them that an RFI on the Common Rule was issued some time ago. Rishel asked about computational privacy. Savage said that it refers to being able to undo an individual's privacy preferences; it is the opposite of what we want. Rishel said that rationalizing and normalizing views on consent is required for lesser goals. However, the notion of a national arbiter and releasing every bit of information based on an individual's preferences is unthinkable in an ultra large system. Galvez said that more work needs to be done on granular privacy. McCallie added that going from enterprise to national scale is complex in the pre-coordination required.

Floyd Eisenberg observed that doing these things would be very difficult. He wondered how much advancement can be made within the context of the background rules. McCallie said that the background rules are hard to code.

Andy Wiesenthal wondered about attesting that rules have been followed prior to exchange. McCallie said that that would be a straight-forward use case. Kelly Hall talked about starting with what the patient wants. The patient should be at the center. David Kotz wondered whether the Roadmap took into account the many new kinds of information that will likely be available in 10 years. Galvez indicated that ONC has various efforts underway, such working on mHealth and big data.

Core Technical Standards and Functions and Certification and Testing to Support Adoption and Optimization of Health IT Products and Services

Halamka said that members should keep in mind the maturity of standards. Galvez continued. Health Information must be properly standardized, packaged, and securely transported in order for meaning to

be retained across systems and to be parsed and displayed in useful ways. Topics addressed in this section of the roadmap are consistent data formats and semantics; consistent, secure transport techniques; secure, standard services; accurate individual data matching; and reliable resource location. Regarding technical standards, the Roadmap calls for ONC to publish an annual list of best available technical standards for core interoperability functions. Stakeholders are asked to tightly define a common clinical data set to include C-CDA, data provenance and RESTful APIs. Regarding individual data matching, SDOs and stakeholders are called to standardize the minimum individual attributes to be used for matching. Stakeholders that purchase and use health IT need reasonable assurance that what they are purchasing is interoperable with other systems. Certification is designed to provide confidence to stakeholders without the expertise to individually evaluate whether a product meets specific requirements.

Discussion

McCallie said that the list is a good start. However, these are standards of the recent past. The C-CDA has not been adequate. (Audio lost) Referring to deep provenance, Rishel talked about shredding and re-shredding and questioned what can realistically be expected in storing and retrieving provenance. Deep provenance is not realistic. The Roadmap assumes patient matching on demographic data because a national ID is prohibited and also assumes an excellent process, which is not a valid assumption. However, industry may eventually find a better way than matching on demographic characteristics. Galvez said that data quality may be added to the section on matching.

Marc Probst suggested prioritizing what is important for provenance. Galvez referred him to the prioritized list in the Roadmap, saying that she would be happy to have feedback. Halamka added that the MU common data set is useful and a RESTful API could be designed around that set and documents. The priorities are to clean up C-CDAs, include the smallest possible number of RESTful APIs and think about provenance.

Certification and Testing to Support Adoption

Galvez said that stakeholders who purchase and use health IT need reasonable assurance that what they are purchasing is interoperable with other systems. Certification is designed to provide confidence to stakeholders without the expertise to individually evaluate whether a product meets specific requirements. ONC will improve the rigor of the certification program and reach to health IT used in additional care settings. ONC and federal partners will continue to develop and provide testing tools for the ONC HIT certification program. Stakeholders are asked to accelerate a suite of testing tools that can be used pre- and post-implementation and help identify gaps and provide feedback to ONC regarding certification criteria.

Discussion

Halamka talked about the importance of robust testing tools. He suggested adding a column to the Standards Advisory for testing scripts. Rishel said that it appears to many that certification is being substituted for compliance. Certification is expensive. Developers do it because it is necessary for them to sell their products. Interoperability problems go beyond the product to its implementation. Certification bodies are limited to what they can charge and, therefore, to what can be tested. Someone needs to make the buyer want certification.

Castro added that currently nothing guarantees that certified systems can interoperate or even operate internally. Nothing here will help in selecting a product. Certification gives a false sense of security. Halamka agreed.

Malec said that the most recent round of certification did not test whether a product worked. It was just compliance. The tests were unhelpful. There was a disconnect between the tools and the outcomes. He called for ONC to review all aspects of certification.

Steve Posnack, ONC, pointed out that ONC is only one player. Wi-Fi was referred to but it is not government-run. Feedback from the FACA is not feedback from a user community, which is what is needed. Not every problem is a standards issue. For instance, regarding the C-CDA, sometimes too much is pushed into the document. ONC and the government in general have limited resources. If more is wanted, who will step up? ONC should not be relied on as the only tester. Malec said that the time frames for certification caused the situation. Direct Trust works well, but there is no regulatory mechanism for using it. The timeframe for Stage 3 is already very tight.

Rishel observed that problems with interoperability are due in part to a lack of incentives for SDOs to produce standards that work. The incentive is to produce standards rather than to make them work. Theoretically, the volume of use of standards could be taxed. Halamka observed that per Baker's paper maturity and adoption criteria should be applied to standards. McCallie referred to the JASON Task Force and said that even the best standards need constraints to make them useful. Data sharing networks should also test and certify. That certification will be more meaningful than certification to an abstract standard.

Summary and Next Steps

Finally, Galvez referred to a section on measurement and proposed a measurement framework based on capability, use and impact. Staff is working with subject matter experts on its development. The public comment period is January 30, 2015 through April 3, 2015. Public comments can be submitted at http://www.healthit.gov/policy-researchers-implementers/interoperability-roadmap-public-comments.

She announced the following assignments for commenting on the Plan.

Advanced Health Models and Meaningful Use Workgroup – Appendix H – Use Case Prioritization

Consumer Workgroup – C. Individuals are empowered to be active managers of their health and D. Care providers partner with individuals to deliver high value care

Interoperability and HIE Workgroup – M. Accurate Identity Management and N. Reliable Resource Location (including provider directory)

Privacy and Security Workgroup – G. Consistent representation of permission to collect, share, and use identifiable health information and H. Consistent representation of authorization to access health information

Architecture, Services and APIs Workgroup – K. Standard, secure services and L. Consistent, secure transport technique(s)

Implementation, Certification and Testing Workgroup – I. Stakeholder assurance that technology can interoperate (testing semantic interoperability)

Content Standards Workgroup – J. Consistent Data Formats and Semantics

Semantic Standards Workgroup – J. Consistent Data Formats and Semantics

Transport and Security Standards Workgroup – E. Ubiquitous, secure network infrastructure, F. Verifiable identity and authentication of all participants, G. Consistent representation of permission to collect, share, and use identifiable health information

Discussion

McGraw asked whether the workgroups are limited to the assigned topics. Galvez indicated that they would most likely not have time to take on additional topics. Each workgroup will be given specific questions in addition to a core set of questions for all. DeSalvo told them to keep the guiding principles in mind when working on their comments. The goal is a floor, not a ceiling. They should be flexible and parsimonious. They can note where states or the private sector should lead or do more.

Kelly Hall pointed out that ONC's definition of interoperability can guide measurement. The definition states five outcomes of interoperability. DeSalvo responded that interoperability is a means to an end. Information is one influence on quality.

The workgroups will report on the Roadmap at the April committee meetings.

Standards Advisory

Steve Posnack, ONC, said that the advisory is a non-regulatory, straight-forward approach with an interactive, predictable process for updates. It was published for comment with the Roadmap. It reflects the best available standards and implementation specifications as of December 2014 and stems from discussions about the Roadmap. The purpose is to provide a single, public list of the standards and implementation specifications for specific clinical health information technology interoperability purposes as well as to prompt dialogue, debate, and consensus. It should be used as a widely vetted resource for standards in one place. Regarding its scope of clinical health IT interoperability, it is electronic health information created in the context of treatment and subsequently used to accomplish a purpose for which interoperability is needed. It is not yet exhaustive. The structure is three columns with purpose, standards and implementation specifications associated with those columns. The Advisory categorizes standards and implementation specifications in four sections: vocabulary/code sets/terminology; content/structure; transport; and services. In most cases standards use will need to be cumulative to achieve a desired interoperability outcome. The 90-day comment period ends May 1, 2015, after which the HITSC will comment. Then The HITSC will submit recommendations to the National Coordinator concerning updates to the following year's Interoperability Standards Advisory and a second round 60-day public comment will open on the HITSC's recommendations. This will occur on an annual basis and the Interoperability Standards Advisory will be issued annually.

Discussion

Halamka recommended having another column for readiness for implementation. Nancy Orvis wondered about adding something on how and when to use a standard. Harrell asked about the long term goal: What are the implications in the policy framework? DeSalvo said than an advisory was something used under the previous administration. It provides a foundation that can be used across federal agencies for certification, procurements and grants. It has sub-regulatory value and could be used in the private sector, but could also be used in rule making. Harrell said that such a mechanism could be used to guide states on privacy and security.

McCallie cautioned about the use of the term service-intended architecture. Also, architectural patterns and use cases will be more important references that the standards themselves. The next iteration may need a higher level construct. The APA Workgroup will attempt to enumerate relevant use cases. Halamka agreed with McCallie.

Baker expressed concern about the lack of mention of security standards. Posnack responded that a section in the document explains that security standards are not included because security standards

are not specific to health care. He said that transport security standards were called out. Others could be called out if members so advise. ONC leadership is not needed everywhere. Halamka referred to Baker's paper on standards maturity, which will be circulated by staff.

Rishel said that the cross references are very helpful. Who is the consensus group for this document? When the membership of a group changes, the consensus changes. Who will take the time to comment on these documents? Posnack requested any comments on making the document more impactful.

Certification Program Update

Posnack described administrative actions being undertaken, many of which are based upon FACA recommendations. The CHPL has been cleaned. A new UI will be released this spring. Test tools are being piloted. A pilot for edge transport testing is open now. Testing jamborees will be held during NPRM development. Future test procedures will be streamlined. Draft test procedures will be released at near same-time as the 2015 Edition NPRM. Regarding transparency, an open test method development pilot was completed. Staff continues to publish FAQs and guidance on ONC's website. Staff is exploring migration to open data CHPL and identifying methods to share program policy guidance given to accredited testing labs and authorized certification bodies with developer community (post-Kaizen). He went on to list other activities:

- Establishing ONC Health IT Certification Program Federal "Collaboratory"
- Working closely with Accreditors (ANSI and NVLAP) to strengthen programs rigor in accordance with ISO standards and program and scheme objectives
- Witnessing and shadowing testing by staff
- Serving customers with a dedicated email box (ONC.Certification@hhs.gov)

Questions about a product's compliance with program requirements should be directed to the ONC-ACB that certified the product.

Discussion

Tang said that the changes respond to the HITPC recommendations on certification. He asked about the CHPL work flow. He said that the recommendation was to give users information on the work flow used by developers as they tested for certification. Posnack said the test procedures are interpreted as the way and work flows develop to meet the way. Going forward, the focus will be on expected outcomes. Not every step and detail will be specified.

Data Updates

Dawn Heisey-Grove, ONC, reported. Through December 2014, 90% of EPs had attested to meaningful use of certified technology. The CAH achievement rate of 89% was slightly lower than non-CAH hospitals (91%). The achievement rate of other small rural hospitals at 95% was similar to large hospitals at 96%. Children's hospitals started later in the process, had a higher proportion paid for through AIU (26%), and fewer attested to MU (55%). Small urban hospitals had lower attainment (80%) and higher non-participation rates (15%) than other hospital types. Providers must complete 2 years of Stage 1 before progressing to Stage 2. The vast majority of hospitals return to attest across multiple years of the program. The 2014 return rates were similar between Stage 1- and Stage 2-scheduled hospitals. More than 90% of hospitals that attested between 2011 and 2013 returned to the Incentive Program in subsequent years. 98% of 2011 cohort hospitals attested in subsequent years and 97% of 2012 cohort hospitals attested in subsequent years. Typically, if a hospital skips a year, it returns the following year. The FY2014 return rate was similar across the two stages. 91% of hospitals scheduled for Stage 1 returned and 89% of hospitals scheduled for Stage 2 returned. 90% of EHs attested using 2014 certified

EHR technology. The proportion that attested using 2014 CEHRT did not vary across the attestation cohorts. Approximately 4,200 hospitals are scheduled to attest to Stage 2 in FY2015. Of those, the vast majority were using 2014 certified technology in FY2014.

Elisabeth Myers, CMS, reported on the January 29 Rulemaking Intent Announcement. CMS is considering the following changes: shortening the 2015 reporting period to 90 days; realigning hospital reporting to the calendar year; and modifying other aspects of programs to match goals, reduce complexity, and lessen reporting burden. In response to a previous request for information, she reported that 2015 EP payment adjustments are not a flat amount but rather are based on a percentage of claims in 2015. Since it is very early in the year, the estimates shown on the slide are imprecise. Adjustments are expected to total 200 million in 2015. 127,815 EPs successfully attested for 2014. New participants (Program Year 1) equaled 25,312. 91,033 EPs attested to Stage 1 and 36,782 to Stage 2. 71,519 EPs are s*cheduled* to attest to Stage 2 in program year 3 and beyond. 4,090 EHs successfully attested for 2014; 304 were new participants. 2,275 attested to Stage 1 and 1,815 to Stage 2. 2,389 are scheduled to attest to Stage 2. Myers also showed slides that contained findings from normal distribution analysis of self-reported performance data.

Q and A

None

Public Comment

Marc Hirsh, a consultant, referred to the attributes for patient matching, saying that since algorithms vary by vendors, perhaps there should be a recommended common framework.

SUMMARY OF ACTION ITEMS

None taken

Meeting Materials

- Agenda
- Presentations and reports slides

HITPC Meeting Attendance					
Name	02/10/15	02/10/15	01/13/15	12/09/14	11/04/14
Alicia Staley				X	
Anjum Khurshid	X	X	X	X	
Aury Nagy				X	
Charles Kennedy	X	X	X		
Chesley Richards			X		
Christine Bechtel	X	X	X	X	
Christoph U. Lehmann			X		
David Kotz	X	X	X		

David Lansky	X	X	X	X	
David W Bates	X	X			
Deven McGraw	X	X	X	X	
Devin Mann	X	X	X	X	
Gayle B. Harrell	X	X	X	X	
Karen Desalvo	X	X	X	X	
Kim Schofield	X	X	X	X	
Madhulika Agarwal					
Marc Probst	X	X	X	X	
Neal Patterson	X	X		X	
Patrick Conway					
Paul Egerman	X	X	X		
Paul Tang	X	X	X	X	
Scott Gottlieb	X	X			
Thomas W. Greig			X		
Troy Seagondollar	X	X	X	X	
Total Attendees	**17**	**17**	**17**	**14**	**0**

HITSC Meeting Attendance							
Name	**2/10/15**	**01/27/15**	**12/10/14**	**11/18/14**	**10/15/14**	**09/10/14**	**08/20/14**
Andrew Wiesenthal	X	X	X		X		X
Anne Castro	X	X	X	X	X	X	
Anne LeMaistre	X	X	X	X			X
Arien Malec	X	X	X	X	X	X	X
C. Martin Harris		X	X	X		X	
Charles H. Romine	Alternate	X			X		
Christopher Ross		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		
James Ferguson	X	X	X		X	X	X
Jeremy Delinsky	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				
Jonathan B. Perlin							X
Keith J. Figlioli	X		X		X	X	
Kim Nolen	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	
Rebecca D. Kush		X		X	X	X	X
Sharon F. Terry					X	X	X
Stanley M. Huff	X	X	X	X	X	X	X
Steve Brown			X		X	X	
Wes Rishel	X	X	X	X	X		X
Total Attendees	**21**	**25**	**22**	**20**	**22**	**22**	**21**