

Health Information Technology Policy Committee

DRAFT

Summary of the October 12, 2011, Meeting

KEY TOPICS

1. Call to Order

Mary Jo Deering, Office of the National Coordinator (ONC), welcomed participants to the 28th meeting of the Health Information Technology Policy Committee (HITPC). She reminded the group that this was a Federal Advisory Committee meeting, with an opportunity for the public to make comments, and that a summary of the meeting would be available online. She conducted roll call, and turned the meeting over to National Coordinator for Health Information Technology Farzad Mostashari.

2. Opening Remarks

Mostashari noted that on his drive in to the meeting, he passed a construction site that had a sign reading “Pardon our appearance, transformation underway.” The site also displayed a picture of what the final project would look like. It prompted him to consider what is taking place with the transformation in health care. He commented that sometimes, not enough is done to apologize for the messiness and difficulty associated with this transformation, and that more could be done to illustrate the future vision with an explanation of why the transformation will be worthwhile.

Mostashari noted that California has traditionally been looked to for obtaining a glimpse of what the future will resemble. Recently, he visited a typical one-doctor office in California, at which the doctor’s wife is the practice manager, there are two receptionists, and three exam rooms. For years, this practice has been conducting 10-minute office visits every day. As is the case with many health care providers, this physician’s livelihood depends on being able to see those patients and charge for the encounters. Three years ago, the physician began a transformation in his office. He received help from his regional extension center (REC) with regard to smart customizations, and he is using hosted solutions to handle payments from California Medicaid, in order to be among the first to get paid.

The RECs have served as a point of convening and trust. The California doctor related that he was in a meeting with other practitioners who are a part of the REC community, at which they discussed sharing records as part of the referral process. The doctor indicated that he did not like the idea of somebody else looking at his records, but part of what made this happen was that they are all part of a group, and there is trust and policies in place. The main thing he realized, though, is that these are not his records, they are his patients’ records.

Mostashari noted that it seems to have gone largely unnoticed to the world that three trends are happening with regard to transformation within practices of how patients are cared for, transformation of how care is paid for, and transformation of patients engaged in their own health. These largely submerged, massive trends will become apparent in a few years. If the

payment system takes advantage of the IT structure, and if the IT structure does what it needs to in terms of increasing patient engagement and performance improvement, then they will vastly exceed anyone's expectation of how much health care can improve.

Charles Kennedy said that he recently had a conversation with the COO of a high-cost delivery system company. The discussion indicated that the transformations Mostashari described at the macro level are also occurring at the micro level.

3. Review of the Agenda

HITPC Chair Paul Tang reviewed the day's agenda, and asked for approval of last month's meeting minutes. Deven McGraw asked whether they could indicate preliminary approval.

Action Item #1: The Committee provisionally approved by consensus the minutes from the September 14, 2011 HITPC meeting.

4. Privacy and Security Tiger Team Recommendations

Research ANPRM regarding secondary uses of EHR data for research purposes

Tiger Team Chair Deven McGraw asked for final approval of the letter of recommendations regarding the use of electronic health record (EHR) data for secondary purposes. The focus was on the questions raised by the Advanced Notice of Proposed Rulemaking (ANPRM). The letter needed to be framed as an approach to these issues, which is consistent with, but improved from, what the Department of Health and Human Services (HHS) has already put on the table in the ANPRM.

Discussion

- Larry Wolf voiced support for the notion that to create a learning health system, knowledge must be generated for the greater good. The historic distinction between research and operations created a line, and they are looking to move that line. Having that reflected in the rule will be helpful.
- Josh Sideman asked for an explanation of how public health is handled in the comments. McGraw indicated that it is not. The Privacy and Security Tiger Team was examining categories of activities that would never fall into public health, at the grey area between operations and research. Sideman said that what tends to happen is that public health lines up as research. McGraw indicated that the Team could add language reflecting the importance of public health to the letter.
- McGraw said that a number of people are still looking for a line in the sand where data analysis crosses into research. The HHS may want to consider exploring this issue, given its importance for a learning health system.

Action Item #2: The Committee approved the Privacy and Security Tiger Team's letter on the Research ANPRM regarding secondary uses of EHR data for research purposes, with the addition of a reference to the importance of public health as it relates to the use of EHR data for secondary purposes.

Query Health

Tiger Team Co-chair Paul Egerman then began the discussion about ONC's Query Health project. He reminded the group that Richard Elmore offered a presentation about Query Health during the last HITPC meeting. Query Health is a project the ONC is undertaking at a high level, similar to the Direct project. The Tiger Team's recommendations are related to policies that the ONC is establishing in this area, rather than regulatory recommendations. The Office established a set of baseline policies for a pilot project that will be a means of obtaining information for research projects under a distributed model. The Tiger Team was asked to comment on these policies.

McGraw reminded the group of the fact that this is a distributed network, so questions are brought to the data. The data holder retains control of the raw data, performs the necessary analysis, and reports the answers back. Each data holder decides whether to participate in a particular query.

Egerman presented the Tiger Team's recommendations in the areas of disclosing entities, data exchange, and small cells.

Regarding the second recommendation (on data exchange), McGraw explained that the Team was asked by ONC to delay finalizing the recommendation that the data use agreement restrict the data recipient's use of data to researching query health. The Office is concerned that a hard-and-fast rule stating that people are not allowed to use this for anything but Query Health would be a disincentive for people to participate. Nevertheless, the Tiger Team's consensus recommendation remains. Their concern is that they do not want Query Health to become a pipeline for entities to receive data that they would not otherwise have had access to, and then to use it for a broader range of activities than just Query Health.

McGraw suggested that one approach might be to hold this in abeyance until the pilots have had an opportunity to operate. Another option would be to specify that the data use agreement must specify with particularity how the data can be used, and that any other use not specified in the agreement would be prohibited. There are questions about whether that approach is scalable, but it is another option for accomplishing restrictions on the recipient, which clearly was a priority for the Tiger Team.

Joy Pritts of ONC pointed out that this is aggregate data, some of which is de-identified. These recommendations are restrictions above and beyond what is normally in place for aggregate data. A lot of nuance needs to be explored, and ONC is asking that additional discussion take place before a recommendation is made in this area.

Discussion

- Paul Tang recommended that the recommendations be segmented so that there is broader flexibility in terms of the way summarized information is treated versus de-identified and potentially re-identifiable information.
- Judy Murphy questioned the fact that a researcher would not be able to ask questions beyond the original query. Given that a huge amount of research is iterative, the process of research will become very difficult. McGraw did specify that the data could not be used for any other purpose. Perhaps they could limit the use to queries related to the specific query submitted, but the concern was about using this as a pipeline without any rules.
- Tang suggested that this is more about a larger description of the research question, rather than having every single query approved. He suggested the Team get to a higher level and allow some flexibility in getting those details worked out. The concept is that the disclosing entities decide whether they are going to participate in the query.
- Josh Sideman said that the public health use of data is a very different paradigm than this approach, which he characterized as a reasonable one. Public health agencies receive very specific, identified data about very sensitive topics including sexually transmitted diseases, opiates, etc. There is a level of accountability in place for public health that is not in place for researchers. Sideman's preference would be to rely on the system of accountability that exists in general, rather than trying to replicate it in an entirely new system of accountability.
- Sideman also explained that public health has a very different approach and timeframe. Researchers explore different paths and are unsure of what they will find. In public health, if there is an epidemic, they must move quickly. Sideman commented that it is not a good assumption that they can become that specific in framing queries.
- McGraw said that they are handicapped by the fact that they do not have a set of pilot queries on the table. The Tiger Team did not intend to suggest that these recommendations would relate to public health reporting of cases as authorized by law. They were looking at situations in which the public health authority is more general in nature and is looking at post-market safety and surveillance questions, for example. At the early stage of signal detection, they do not need the data to be identifiable.
- McGraw also pointed out that in discussions in the Tiger Team, there were a number of people who, notwithstanding health care's other sets of regulations, expressed concern about level of identifiable data that occurs in the public health arena.
- Richard Elmore explained that the project is at the stage where several specific user stories have been developed that relate to issues as diabetes, myocardial infarction, and others. In the next month or so, a few user stories will be selected to meet the various needs of the project. By end of the year, user stories will have been selected to serve as the foundation for the pilot. At that time, it will be possible to better assess the policy recommendation.

- In response to a comment by Paul Tang, McGraw explained that the Team was pushing back against the blanket assumption that public health should always get identifiable data. They still want the practice to entail giving only the information that is actually needed when responding to queries, even to public health agencies. ONC's notion was that if it is public health, by default they receive identifiable data. Instead, the Tiger Team suggests that the data needs to match the needs of the query.
- Sideman said that if the purpose is not to limit the existing legal authority, then this point could be more explicitly stated.
- Egerman commented that the pilot project is wonderful from a privacy and security standpoint. It brings the question to the data—the less data there are moving around, the more trust people have in the system. That is what this project is about: when someone asks for the data, they get only the amount of data that they need. This is not intended to interrupt what public health is doing.
- Sideman suggested that the Tiger Team include the concept of feasibility or time.
- Gayle Harrell noted that there are public health statutes that vary from state to state. The notion of going beyond those statutory regulations could make the public very nervous. Public health is the government. Opening non-statutory authority endeavors will create a significant amount of pushback. A good example is related to prescription drug abuse and getting statutory authority to examine the prescription history of patients. That is crossing a line where the government could data mine into prescription issues and know who takes what medication. That is a scary proposition to the public.
- It was suggested that rather than “re-inventing the wheel” in terms of the pilot, the Centers for Disease Control and Prevention (CDC) and Center for Medicare and Medicaid Services (CMS) could be engaged because these organizations have experience in striking data use and business associate agreements. Data requests come in many forms, and it may be worthwhile to draw on CDC and CMS experiences and resources if possible.
- One Committee member suggested that part of the pilot examine the impact on staff time and dollars required on various organizations. It was also suggested that computer hackers employed to protect security (“white hat” hackers) be tasked with trying to break into the data set during the pilot.
- Regarding governance, Gayle Harrell noted the need for the ONC to identify the decision makers as well as the penalties for misuse.
- Charles Kennedy clarified that recommendation 2 does, in fact, indicate that a data use agreement is required even with de-identified data. This is more stringent than Health Insurance Portability and Accountability Act (HIPAA) requirements.
- The group came to agreement around the Tiger Team's recommendations, with the addition of some clarification around the public health issues discussed, especially relating to emergency situations in public health authority. The Committee also asked that the Team

include reference to the notion of different kinds of queries, especially ones dividing classes like summary versus de-identified line items, having different policy guideposts. Finally, the Committee suggested clarification around a query versus a series of queries, to address the issue that Judy Murphy raised earlier in the discussion.

Action Item #3: The Committee approved the recommendations of the Privacy and Security Tiger Team with clarifications. One Committee member voted against the recommendations.

5. Update on CMS Meaningful Use Activities

Robert Anthony of CMS walked the committee through a series of slide showing an approximately 70% increase in active registrations for Medicare Meaningful Use in the last month, and a 40% increase in the month before. He said they have passed the 100,000 registration mark for people participating in the program. There is also good news on payment side. Medicare paid out roughly \$25 million in incentive payments, representing an increase of 36% over August. The figures from August were double those of July.

Anthony discussed the highlights of attestation data received. He said that he is leery of drawing conclusions from these numbers, given that this is a small sample of the total universe of eligible professionals who could participate. That said, the preliminary findings indicate the following: (1) on average, all thresholds were greatly exceeded, but every threshold had some providers on the borderline; (2) there was little difference between eligible professionals and hospitals; and (3) there were relatively few exclusions claimed on average. The payment year ended for hospitals on September 30, 2011, but hospitals have until November 30 to attest for 2011.

Discussion

- Gayle Harrell suggested that it would be helpful to have these numbers expressed in percentages, so that they could know what the percentages of participants is compared to the total number of possible eligible providers.
- In response to a Committee member's comment, Mostashari pointed to the need to hear from the RECs regarding details about participant experiences. The RECs represent an important source for a more qualitative understanding of activities within critical access centers, health clinics, consortia, and small practices. He also noted that surveys, such as the National Ambulatory Medical Care survey, ask about the intent to apply for Meaningful Use. The ONC has supplemented the sample size and the timing of some of those surveys, and he hopes they will have the ability to look at 2011 survey information when creating the final rule.
- David Bates asked whether they are making public the list of people who have been successful so that others could contact them. It would be helpful to have a sense of how many hospitals are big versus small, what regions are they from, etc., to assist in identifying who is struggling and how best to address their challenges.

- Anthony noted that a quarterly list of successful attested providers is being published. CMS intends to engage in the type of data breakdown that Bates referred to, and CMS plans to work with the REC data as well to examine stratification.
- Christine Bechtel noted that the areas with the biggest number of exclusions are patient and family care engagement. She said she knows that people had trouble with transition of care summary because it was so undefined. She asked whether there might be easier fixes that they should know about. Anthony explained that CMS hears from providers that there is a lack of specificity, and CMS is creating lists of frequently asked questions (FAQs) to provide guidance. As they look at the published FAQs it seems that they have gotten past the early hurdles of “what do you mean by this?” Now, they are receiving and addressing more program and operational-related questions.

6. HIT Standards Committee Update – Report on Summer Camp Activities

HITSC Co-Chair John Halamka presented an update to the Committee on the standards work that six Power Teams completed between April and September, when they averaged a meeting every 3 days. He reviewed the charges of each of the six teams.

The Power Teams examined Meaningful Use Stage 2 recommendations to identify the updates to Stage 1, where the gaps are, and where there are new standards that were not previously available. They also looked at donations, like Kaiser’s set of medical terminology, which is now available through the National Library of Medicine (NLM). The goal was to identify those standards that are good enough, mature enough, and tested enough to be nationally deployed.

Halamka presented the HITSC Action Items for Meaningful Use Stage 2, which include: (1) recommending revisions to adopted certification criteria and new standards/implementation specifications to associate with adopted certification criteria, and (2) analyzing Meaningful Use Workgroup draft recommendations (identifying and drafting new certification criteria and associating standards/implementation specifications where available).

He presented the Summer Camp timeline, which included the HITPC needs and also work suggested by the President’s Council of Advisors on Science and Technology (PCAST). The timeline was complete on September 28, with formal recommendations complete for every standard, deliverable to ONC thanks to the Summer Camp Power Teams and Standards and Interoperability Framework (S&I) project activities.

Halamka reviewed the completed work from each team, and invited questions from the committee.

Discussion

- Marc Probst asked about the criteria used to reach decisions. Was it the path of least resistance, the most technically feasible approach, or some other set of guidelines? Halamka commented that the “path of least regret” was used. The Power Teams tried in each case to identify a standard that is appropriate for its purpose and well tested enough to be known as

implementable, with widely available implementation guidance, maintained by a standards development organization, and able to fit in the constellation of other standards.

- Regarding metadata, Larry Wolf asked whether other identifiers, such as phone numbers or e-mail addresses, were considered in the identity component. Halamka explained that all possible identifiers were considered in terms of accuracy, specificity, sensitivity, and the static nature of such data. Doug Fridsma added that the ONC has received a number of comments on this topic, and will be reviewing this feedback to determine whether other identifiers should be suggested for consideration.
- In response to a comment from Deven McGraw, Halamka confirmed that the Power Teams were striving to recommend standards to reach the levels of sensitivity and specificity that organizations are probably striving for; they are not making a recommendation on those levels per se. He said that the desire is always to combine information accurately, even at the cost of missing a match. They did not dictate specific items to be collected.
- In response to a question by Gayle Harrell, Jodi Daniel of ONC explained that the Office is scheduled to inform the Committee about the results of the ANPRM. The ONC is working on the standards and certification rule associated with Meaningful Use Stage 2, with a target of December or January. Anything from the ANPRM would be included in that NPRM. The only component from today's presentation that will be put forward for ONC is the advanced notice on the metadata standards.
- Harrell followed up by asking what the impact will be on health information exchanges (HIEs), and whether the HIEs will be able to get up and running by Meaningful Use Stage 2. Halamka said that Massachusetts examined the Summer Camp work and decided to create a backbone connecting every provider and patient in the state in the format as dictated by the Summer Camp activities. This has impacted the entire HIE strategy for the state.

7. Enrollment Workgroup Update

ONC's Kristin Radcliffe updated the Committee on the activities of the Enrollment Workgroup, which was convened in response to section 1561 of the Affordable Care Act, which charged the HIT Policy and Standards Committees with developing secure standards and protocols for streamlining eligibility and enrollment in human services programs. The Workgroup made preliminary initial recommendations last September.

The Workgroup held a hearing at which various vendors and states reflected on the initial recommendations and identified implementation challenges that they foresaw as a result of those recommendations. The group continues to work on National Information Exchange Model (NIEM) standard to exchange data elements needed for verification of every piece of information in a consistent way, so that information can be more easily shared between programs and systems in order to implement health insurance exchanges.

The CMS asked the Workgroup to evaluate some potential scenarios involving data exchange between systems, between one state and another, between Exchange and Medicaid, and so on.

The recommendations they provided were passed through this group and then integrated into the CMS guidance that was released.

Over the summer, a significant amount of guidance and proposed regulation was generated by the CMS, which the Workgroup is now refining. Radcliffe anticipates that the work ahead will be more technical in nature. The Workgroup has examined and standards and protocols and identified some implications for technical implementation.

She identified five areas in which the Workgroup can continue to provide guidance: (1) state and federal hybrid approaches for establishing and operating the HIEs; (2) cost allocations for upgrading human services programs, given that the guidance has been newly expanded; (3) NIEM standards; (4) application programming interfaces (APIs) and applications for third parties to connect to state Internet exchanges; and (5) data exchange specifications, and standards work related to the interface specifications.

This Workgroup plans to propose that the HIT Standards Committee (HITSC) develop a sister workgroup. In that way, this group will continue to provide policy guidance on the above five areas, while the HITSC group can take on the fairly detailed standards work. The ONC is in the early stages of identifying what the HITSC charge would look like, and is identifying potential members for such a workgroup. Radcliffe emphasized that the flow of information between the Policy and Standards committees will continue.

Discussion

- Josh Sideman noted that states interested in pursuing exchanges must be ready by January 1, 2013, so they are building their systems now. He asked how Radcliffe envisions standards settings will work, given the fact that eligibility systems have to be built in the next few months. Radcliffe said that they have heard from CMS, vendors, and states that the states are moving forward with requests for proposals (RFPs) and technical architecture, but they are essentially putting in placeholders for the 1561 standards. She understands that the states are waiting on guidance. The CMS expects to move within the next 6-8 months to develop a product that could be tested or piloted.
- In response to a question from Gayle Harrell about the Supplemental Nutrition Assistance Program (SNAP) and states being required to update their internal systems in order to update eligibility, Radcliffe said that the CMS proposed rulemaking distinguishes between vertical and horizontal integration. There will need to be integration between the Medicaid Children's Health Insurance Program (CHIP) and the exchanges. Horizontal integration to other human services is encouraged, but not required for exchange. She said that the CMS is offering a series of early innovator grants to target a set of states that will do the IT prototyping for exchanges. There are also establishment grants and planning grants available. At this point, all of the funding opportunities exist within CMS, which is responsible for determining what is attached to those opportunities.

8. Update on ONC's Regional Extension Program

ONC's Matt Kendall said that providers need an entire network of supporting assistance to carry out all of the activities to implement Meaningful Use well, electronic and otherwise. RECs are there to help providers address these issues and offer a host of services to support providers. Their overarching goal is to get people to Meaningful Use and beyond. The program is focused on improving population health, health outcomes, and efficiencies.

Kendall reported that there are 62 RECs, and their goal is to help 100,000 providers reach Meaningful Use by 2014. Each REC has a defined service area as well as a defined number of providers they are charged with recruiting, going live, and getting to Meaningful Use. They recognize that the RECs do not have enough money to carry out the entire scope of work, so they are trying to involve other organizations and identify ways to scale the work.

He reviewed their core set of services, from implementation support to designing workflow, handling privacy and security, and more. How those services are provided is up to the RECs, and the different models that they support. They recognize that different activities and approaches are more effective in different parts of the country.

Kendall presented some specific examples of RECs and their strategies. He offered case studies and program highlights from various parts of the country, including Nebraska, South Florida, Los Angeles, and others, noting that they are leveraging best practices by using the Health Information Technology Research Center (HITRC).

Regarding workforce training, Kendall pointed to the various workforce roles in community college programs, including management, medical, and technical roles. They are seeing an older demographic, with an average age of 45 years. Many incumbent workers are using this training to move up the ladder, and there are many opportunities to create internships for training.

Discussion

- One Committee member referenced last week's Meaningful Use Workgroup hearing. She said that testimony indicates that workflow issues are significant. Many changes are needed related to workflows, and in some cases solutions need to be created from scratch. Given that, and the fact that the ONC has recently launched a consumer campaign, she asked about opportunities for those two pieces to work together. She thought that would be an important partnership, especially in areas of helping providers get to Meaningful Use, and also vendor selection. Kendall commented that workflow redesign is a continuous process. They want to promote the philosophy of a continuous quality improvement ethos. He is very supportive of community engagement efforts. He said that RECs can help with this, particularly in terms of the concrete Meaningful Use objectives.
- Gayle Harrell reported that the South Florida REC is building in an HIE component. She asked how other RECs are considering doing this. Kendall said that about 12 of the RECs are also state HIE affiliates, so those are natural alliances. All of the RECs are looking at how to align their work directly with the HIE, whether they are doing it themselves or as partners.

- Harrell also noted that she is hearing from individuals who are taking part in workforce training online, and they are indicating that it is not practical. There is no hands-on contact, and this is becoming a major problem. Kendall acknowledged that they need to get more internships lined up in order for people to apply the knowledge that they learning. They are reaching out to health care organizations in an effort to push them to offer internship opportunities. Harrell warned that they are getting quasi-trained people who do not have the answers. They need mentorships, not just internships. She urged a rethinking of how they are doing this, because she is hearing that it is not working.
- Kim Lynch, REC program Director, explained that each REC has approached the training issue at a different level. The workforce is assessed in each setting so that they can make specific suggestions. Being the connector between people, RECs are helping organizations in-house to use their skills in the transition, and to encourage them to get further training.
- Harrell asked if the RECs are working with places other than community colleges. She pointed out that those grants are running out and asked whether the vision includes getting the message out to universities about the importance of integrating this material into the core curriculum, so that it becomes a part of the pipeline. Kendall noted that many community colleges are already hearing this message. He pointed to Cuyahoga Community College in Cleveland, which is thinking strategically with university programs to determine how to make this transition.
- Kendall also noted that the REC program is engaging many of the medical schools and certifying bodies and working with CMS to look at continuing education programs for providers. The ONC is working with various medical education boards to think about not just the certification of providers, but also maintenance certifications. Maintenance certifications must take into account the expectation that part of being a provider in the 21st century includes knowing how to use technology meaningfully.

9. Public Comment

Carol Bickford of the American Nursing Association said that, with regard to the preparation of clinicians to use information systems solutions, the nursing community has established competencies and these are a part of their accrediting program requirements. They are beginning to see practical examples and emerging input, and she asked whether the ONC has thought about capturing these pieces of evidence in a formal way. Kendall said that this is one of their key goals, to process and share such information. He said he would like to pursue this discussion with Bickford outside of the Committee meeting.

SUMMARY OF ACTION ITEMS:

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Action Item #2: The Committee approved the Privacy and Security Tiger Team's letter on the Research ANPRM regarding secondary uses of EHR data for research purposes, with the addition of a reference to the importance of public health as it relates to the use of EHR data for secondary purposes.

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