Health Information Technology Policy Committee
Final
Summary of the July 6, 2011, Meeting

KEY TOPICS

1. Call to Order

Judy Sparrow, Office of the National Coordinator (ONC), welcomed participants to the 25th meeting of the Health Information Technology Policy Committee (HITPC). She reminded the group that this was a Federal Advisory Committee meeting being conducted with the opportunity for public comment, and that a transcript would be made available on the ONC Web site. She asked Committee members to introduce themselves and then turned the meeting over to National Coordinator for Health Information Technology Farzad Mostashari.

2. Opening Remarks

Mostashari first welcomed the newest member of committee, Patrick Conway, the leading Chief Medical Officer for the Centers for Medicare and Medicaid Services (CMS). Mostashari then reviewed the meaningful use recommendations from the last HITPC meeting, recognizing that they were the result of expert testimony, input from a range of stakeholders, and countless hours of review, analysis, and deliberation by workgroup members.

Mostashari applauded the framework that was used, calling it insightful to focus on the priorities of the National Quality Strategy. Regarding the timing recommendations for meaningful use Stage 2, he noted that the Committee and ONC agree with the conclusion that widespread implementation of Stage 2 systems in 3-6 months may be infeasible and could have a detrimental effect on their goals of increasing adoption. He indicated that he agrees in principle that extra time will help providers and vendors to put together their systems.

In consideration of these points, the ONC agrees with the logic of delaying the start of meaningful use stage 2 for a period of 1 year for those first attesting to meaningful use in 2011. Mostashari noted that it makes sense to maintain standards so that everyone—those attesting to Stage 1 in 2011 and those attesting in 2012—will be attesting to Stage 2 in 2014.

3. Review of the Agenda

HITPC Chair Paul Tang reviewed the agenda, noting that the Committee would be hearing an update from the HIT Standards Committee (HITSC), the Policy Committee's sister group. HITPC members also were to be presented with an update on how submissions have been going for Stage 1 at CMS; Tang suggested that this be a standing item on the agenda for future HITPC meetings.

> **Action Item #1:** Minutes from the June 8, 2011, HITPC meeting were approved by consensus.

Tang offered a brief follow-up comment to Mostashari's opening remarks on the meaningful use recommendations. The Meaningful Use Workgroup is preparing a matrix that will have in one place the final rule from meaningful use Stage 1, recommendations regarding Stage 2, and comments for Stage 3. It is expected that this matrix will be available the week after this HITPC meeting.

4. Privacy and Security Tiger Team Recommendations

Privacy and Security Tiger Team Chair Deven McGraw explained that the group's recommendations being presented at this meeting address amendments and corrections to the electronic health record (EHR). She acknowledged the special assistance provided by Dan Rody from the American Health Information Management Association (AHIMA) in exploring issues related to the legal medical record.

McGraw reminded Committee members that ONC's Nationwide Privacy and Security Framework for Electronic Exchange of Individually Identified Health Information states that people should be given an opportunity to respond to items questioned or changed in their record in a timely manner. That framework reiterates a concept that has been in the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rule since its inception: patients should have a right to request amendments to information in their medical record, and to have disputes documented. If an amendment is made, then the correcting entity must forward it to anyone the patient requests, and anyone to whom the hospital or organization believes the information has been sent. If there is a dispute about whether the amendment needs to be made, then there is a method for documenting the dispute. The entire package of information, including the rebuttal information, is then supposed to remain with the disputed information in the record, and transmitted with the record every time.

It is hoped that the group's recommendations can specify the extent to which a certified EHR can help with this process. The same types of functionalities that would allow an institution's ability to help a patient to honor a dispute functionality is the same set of functionalities would be needed if the entity itself discovered the error and then had to transmit it to other providers. Therefore, the Tiger Team focused on setting priorities for certification, so that those technological capabilities would be present.

The Privacy and Security Tiger Team's recommendations were as follows:

- Certified EHR Technology should have the capability in Meaningful Use Stage 2 to support amendments to health information, and in particular to support a provider's compliance with HIPAA obligations to respond to patient requests for amendments. Specifically, the systems should make it technically possible for providers to:
  - Make amendments to a patient's health information in a way that is consistent with the entity's obligations with respect to the legal medical record (i.e., there should be the ability to access/view the original data and to identify any changes to it).
  - Append information from the patient and any rebuttal from the entity regarding disputed data.

- Certified EHR Technology should have the ability by Meaningful Use Stage 3 to transmit amendments, updates or appended information to other

The Tiger Team tried to stay within the policy sphere and leave the technical details of how this could happen in terms of standards, implementation, and certification criteria (including the ability to incorporate amendments from other entities) to the HITSC. The technical capabilities should be kept as simple as possible, and evolve over time to include increasing complexity where necessary, even perhaps automating the process.

The Team specifically did not make recommendations on policy requirements for entities that self-discover errors and the necessity that they transmit those corrections forward to other providers. The group's sense was that it is already part of providers' ethical and legal obligations to make and transmit amendments when they are self-discovered. If the technical capability is in the system to allow the amendments to be made and transmitted, then the providers would use them when they need to (and the patient's right to request them is already in place through HIPAA).

The Tiger Team did not feel it had sufficient information to make a recommendation on the issue of whether to place obligations on health information exchanges (HIEs). There are a plethora of models suggesting that different health information organizations (HIOs) take on different roles with respect to corrections. So recognizing this, the Team recognized that a "one-size-fits-all" recommendation may not be appropriate.

Privacy and Security Tiger Team Co-Chair Paul Egerman explained that meaningful use Stage 2 gives patients the ability to view and download data. As a result, he suspects there will be an increase in instances of patients asking for changes and amendments.

Discussion

- David Lansky said that a partnership with patients is a part of the National Quality Strategy, and these recommendations are a vehicle for that to take place. He suggested that the ONC consider a mechanism for tracking improvements in patient safety as a result of data improvement. If the ONC can demonstrate that this translates concretely to a reduction in harm, it would represent a major achievement.

- Lansky also commented that these recommendations represent the opportunity to open the door for consumer-facing applications of EHRs. Vendors could start thinking about reports specifically intended to be read by consumers, and how to present information to patients on the screen. This would be different from the format relevant to providers giving care.

- Neil Calman emphasized the importance of developing a mechanism for HIOs to pass on additions and corrections. Egerman noted that the Tiger Team limited itself to data integrity issues, to making sure there is mechanism to transmit the information. Records are dynamic, and there are some interesting workflow issues as to who should get notified when changes happen. While not included in the Team's scope, it is a fundamental issue. Calman suggested that there must be a mechanism for amendments and corrections to be passed through the exchanges, because HIOs are the only entities that know who has gotten the

updated information. McGraw explained that the Team's recommendations directly address the ability to transmit.

- Paul Tang commented that the Tiger Team's efforts represent an example of the potency of this work for consumers as well as professionals—yet the market did not deliver this functionality in any of the EHRs to date.

- Gayle Harrell stated that if there is no mechanism for amendments and corrections to be passed through the exchanges until Stage 3, there is a window of time during which incorrect information may be propagated. This sets providers up for significant liability issues, which will create a lot of fear. Once a provider moves to an EHR, they have the ability to propagate information to many users, exponentially increasing their liability. Although this may not fall under the purview of the Privacy and Security Tiger Team, it is an issue that must be addressed.

- One Committee member pointed out that EHRs do allow for corrections with time stamps and marked changes, so that changes made to the record can be viewed. Also, there is a long history of EHRs dealing with updates to earlier reports. Having said that, the Committee member agreed with the notion of communicating these changes better and incorporating them into the workflow.

- Egerman pointed out that many specifications already describe how one is supposed to transmit, but they are not uniformly adhered to. Different systems transmit in different ways, and the lack of compliance and lack of standardization is going to be a problem.

- Mostashari made a connection between the Team's recommendations and those of the HITSC related to metadata. If there was a single source of truth for a patient's record, if there were a universal record and all modifications and amendments went to that single source of truth, this would not be a problem. Instead, however, the environment is such that there are multiple representations of a patient's record stored in multiple places. He stressed the importance on the standards side of uniquely tracking the provenance of data and its sources, including modifications and amendments. Progress on the metadata work will help in this regard.

- Eva Powell indicated that HIPAA only covers patient requests. If the patient is unaware of a mistake, and there is not a mechanism for correction available to that patient, are current legal and ethical obligations covering that? A tremendous cultural shift that will have to occur to include patients as partners in the care team, and that will occur over time. However, she is not sure that they should trust that legal and ethical obligations would win over when the patient is not the one to find the mistake. McGraw acknowledged that this is an issue, and said noted that the Team did not specifically address how to make sure patients are in the communication loop.

    - Judy Faulkner commented that if every correction immediately has to be addressed, then there will be physicians who do not want to read medical records because they are going to think they have an obligation to correct them.

Action Item #2: The Committee approved the recommendations of the Privacy and Security Tiger Team by consensus.

5. Briefing on HIT Standards Committee

ONC's Doug Fridsma offered an update on some of the work happening with regard to standards and meaningful use criteria and gave Committee members an opportunity to ask questions about HITSC activities. HITSC Co-Chair John Halamka explained that the challenge in developing standards is that standards cannot be legislated or regulated, they are adopted. The measure of success is how many transactions are flowing. The HITSC is guided by the principle that "it will select no standard before its time." The group looks for standards that are well understood, deployed, and tested.

Fridsma explained that in April, HITSC members began moving through the spreadsheets relating to meaningful use Stage 2 policy objectives to find gaps in the standards and to triage some of the standards work. This activity set the stage for many of the Committee's summer camp working groups. Within the HITSC, there are a series of principles that guide how it identifies standards. In many cases, standards require refinement and iteration. They will not be perfect, but hopefully they can be practical in the community. HITSC wants to make sure these standards have real-world experience before promulgation on a national level. Standards must be easy to implement and to test—the HITSC looks for simple standards that can solve a piece of a puzzle and be part of a larger picture.

Fridsma reviewed HITSC's action items related to meaningful use Stage 2 and presented the group's four "buckets" in which every meaningful use item falls:

- Performance measures only—no standards needed.
- Sufficient standard and implementation guide identified.
- Existing standard but no implementation guide identified, or standard and implementation guide exists, but additional public input is needed.
- No standard or implementation guide identified; or they exist but substantial public input is needed.

Fridsma then reviewed all of the meaningful use items that fit into each of these categories. He also presented a list of items that require additional discussion, additional priorities for the HITSC, and a list of meaningful use stage 3 items that are coming up soon. Fridsma also reviewed HITSC's timeline, noting that it takes at least 18 months to get a standard into an EHR and tested, even if the standard already exists. The Committee strives to focus on adoption while letting the market pull towards the standards, rather than to push standards and find out that they do not necessarily fit the market's needs.

Halamka provided an overview of HITSC's summer camp activities, noting that the group has been adhering to aggressive timeframes, moving much faster than would normally be the case

for a standards organization. In April, the Committee examined certification recommendations, or transport from point A to point B. The group discussed how to ensure the identity of the sender and recipient, and how to ensure that this data is not modified or intercepted. In May, they addressed the issue of uniquely identifying patients and discussed how to ensure that a sender's identification and provenance is identified, and that there is the ability to attach privacy flags where necessary. The HITSC also examined additional standards, such as e-prescribing of hospital discharged medications. In June, the group considered a variety of provider directory issues and patient matching strategies. In July, it will look at syndromic surveillance and quality measures and in August, the HITSC will tackle simple lab results.

Halamka then provided an overview of each summer camp Power Team's work, as follows:

Metadata: The President's Council of Advisors on Science and Technology (PCAST) produced a report hypothesizing that a universal exchange language is needed, regardless of what is being sent. It was suggested that there be creation of an envelope to transport that package securely, with information including the patient's identity, the identity of the person sending the information, and perhaps, based on regulations or state or institutional policies, some flags to indicate that the contents of the package may include sensitive information. The Metadata Power Team selected some simple XML constructs to identify patient demographics, and the capacity to use privacy flags. CDA R2, simple XML, has been selected for this use.

Patient Matching: Because there is no health care identifier number, and it is not likely that there will be one any time soon, how can data be matched to the correct patient? The Patient Matching Power Team examined a number of studies on sensitivity and specificity. The Team prefers the notion that specificity—getting the right patient's data, even if it is possibly incomplete—is preferable to getting the wrong patient. Team members reviewed all of the experience and papers to date, and will not determine a specific algorithm, but rather the data elements used to achieve specificity.

E-Prescribing: The E-Prescribing Power Team is considering where to use HL7 versus the more commercial standard.

Syndromic Surveillance: Incorrect implementation guides were included in the original recommendations. The ONC is now clarifying this issue, through a new regulation to indicate that there is not an implementation guide yet. One of the challenges the Syndromic Surveillance Power Team has given to the ONC is to get one implementation guide to address syndromic surveillance, immunization, and reportable labs. These are very different domains, but perhaps it is reasonable to have one guide describing all of it with HL7 251.

Nationwide Health Information Network (NWHIN): The NWHIN Power Team recognizes that standards for vocabulary and content are important, as are those for transport. There are many different approaches, including queries, responses, and e-mail push kinds of transactions. The Team is considering all of the ways transport may occur and is trying to develop building blocks to address each different approach to sharing information, inclusive of the many different kinds of architectures.

Halamka explained that in parallel to HITSC activities are Standards and Interoperability (S&I) Framework initiatives. Fridsma noted that the S&I Framework is a way of taking what was done with the Direct Project and applying it to other standards that need to be identified, developed, and refined. In a continuation of the work of the NWHIN Power Team, standards that already exist are being reviewed—in some cases, people are using something widely but there is no standards review behind it. In other instances, there is a standard that is already highly mature and widely used, and it may be ready for a national standard. Other standards might be mature but not highly adopted. Therefore, categories for the various standards have been developed to differentiated between those that have a high adoption rate and those that still require some work.

In the Direct Project, the way that NHIN specifications could be used to exchange information was created and expanded. The purpose was to create a simple, directed specification that would allow exchange between known parties in a secure way. The project was announced in March 2010, and within 90 days there was an initial set of specifications and a working proof of concept. Ninety days after that there were working implementations, flowed 10 months later by the exchange of vaccine and immunization information between an EHR and a public health reporting agency in Minnesota.

Discussion

- Tang asked about drug-drug interaction. When the HITPC asked the HITSC to review this issue, the impetus behind it was that even though the function exists in all EHRs, the high false-positive rates make it almost useless. Better positive predictive value is needed so that most people will react on it most of the time. How can the true positive rate of these drug-drug interaction alerts be raised, so that more of them will be appropriate and acted upon? Is that something the HITSC would be addressing? Halamka pointed out that the standards work on vocabularies will help with this issue. Medications must be described using a consistent vocabulary and with consistent categories of medications, so that when rules are written they are based on unambiguous data.

- Fridsma pointed out that there are many standards to choose from. RxNorm is a good vocabulary to identify what the drug is, but there are many different formularies and classifications within the taxonomies that organize drugs. There are also drugs that include a combination of medications, so how are those classified? There is a whole host of those challenges. A “top 10” or “top 100” list of drug interactions has not yet been developed. He pointed to the work being done with the Agency for Healthcare Research and Quality (AHRQ) and Sharp Grants on decision support activities, and suggested that perhaps they could create functional characteristics and work on the building blocks of vocabularies and terms as a way of moving towards those goals.

- Halamka asked if there is an opportunity to evolve a best practices set using the 98 percent of most likely ordered labs and a compendium of LOINC codes. If one organization creates a set of good rules, perhaps the community could pool resources and make those available as a starter set.

- Fridsma commented that the standards community and the industry needs as much lead time as possible to get things right. The risk is that creating a policy objective with a 6-9 month

timeline means that big, transformational changes may not be possible because those take clarity and lead time. Laudable policy goals can be created, but if the technology to operationalize them does not exist, then consideration must be given to how to create something that sets them in the direction they want to go and offers incremental steps along the way.

- With respect timely electronic access by patients and whether there needs to be some warning to them about the security of data once it has been downloaded, Deven McGraw noted that this will be discussed at the next HITPC meeting, so there will soon be more information available.

- McGraw also addressed the issue of patient matching. The HITPC Privacy and Security Tiger Team hosted a day-long hearing on that subject and reported on it during last December's Committee meeting. She commented that some of the work done by the HITSC appears to be in conflict with the recommendations made by the HITPC. For example, the Policy Committee recommendations reflected that there is no "one-size-fits-all" algorithm. Whether to err on the side of sensitivity or specificity depends on the purpose for which the data is accessed. Also, the use of any particular data field should not be required for matching, so she does not understand the statement that the Standards Committee Power Team is discussing regarding which patient attributes to require. Halamka suggested that there be a conversation between McGraw and Marc Overhage, who oversees the Standards Committee Power Team dealing with this.

- Charles Kennedy suggested that there may be a series of issues falling through the cracks between the two Committees. Farzad Mostashari raised one example: they are creating an infrastructure in which there will be 10 records of a particular patient rather than one shared across 10 providers. There are both policy and technical implications to this, and somehow these types of issues are not being addressed. He voiced support for a visioning session to discuss where the Committees are heading, and how to ensure they are getting to the right place.

- Judy Faulkner suggested that it will be an enormous challenge to adhere to both principles of keeping it simple and not creating a one-size-fits-all standard, because generally, these two compete with one another.

- Doug Fridsma said that they are working with ONC Chief Privacy Officer Joy Pritts on doing pilots to understand problems better in terms of standards and approaches. Pritts has been taking the lead in this regard as she would like to use a process similar to that of the S&I Framework and the Direct Project.

- Paul Egerman asked whether there were specific parameters defining what constitutes a mature standard or a high adoption rate. Fridsma indicated that there is not, but the NWHIN Power Team is working to help create an understanding at the ONC of how to decide when something is ready to be adopted on a national basis.

- In response to a question by Egerman, Halamka explained that the HITSC has specified a universal language for all enveloping functions: one set of XML standards for patients,

provenance, and privacy. Within that, there are many possible packages, recognizing that there are already standards that work exceptionally well for labs, administrative functions, and so on. Egerman characterized this as an important step forward.

- Larry Wolf commented that a large amount of time has been spent looking at specific quality measures, and it may be a stretch to have the HITPC looking at individual measures. Instead, should the Committee be looking at systems that can support whatever measures become available and looking to standardize how those measures get defined and reported?

- Fridsma pointed out that without standards there tends to be a centralizing effect (e.g., send in the information, it will be figured out centrally, and 9 months later a report will come back). Instead, information needs to be tracked in such a way that people can use it to change what they do, use it for improvement of patient care in almost real time. The results, then, need to stay as close to the decision makers as possible. If what the quality measure should look like is defined in a computable way, then a clinical decision support rule could identify those patients who are potentially at risk for a fall or other quality measure. That would spur the system to provide the feedback necessary to make demonstrable improvements in care.

6. Review of Meaningful Use Stage 1 Submissions

CMS's Robert Tagalicod presented statistics on Medicare and Medicaid registrants for the meaningful use incentive programs, reporting that there are 68,000 registrants to date. The CMS is urging providers to register so that their eligibility can be verified. Seventeen states are now open for registration. Information on adoption, implementation, and upgrade of technology for Medicare and Medicaid members are being collected. He discussed a number of incentives that have been paid so far for successful demonstration of meaningful use, and noted that the CMS has issued more $273 million in payments so far.

ONC's Josh Sideman offered some qualitative reporting from the Regional Extension Center (REC) programs. In August, the ONC will begin to collect some empirical data from the RECs. They have identified a number of "movers" in meaningful use, who are leading the way in their areas. Forty-two RECs have now identified 1,330 movers around the country, and they are thinking about how to leverage this provider experience. Most are either small practices or safety net providers. Nine events celebrating these providers have already taken place; nine more are planned over the next quarter.

Sideman attended one such event in Delaware, and offered the following take-away messages:

- The meaningful use program has pushed many providers over the hump. Many were sitting on the fence, and these incentives helped them to make the decision to purchase an EHR and move to a paperless practice.

- The meaningful use program has given practices some focus, and given them specific ends to aim for. It is clear that this is about trying to improve patient care.

- The movers are leaders. Some are solo practice doctors, some just came online with an EHR in 2010. These individuals span the whole gamut of providers, and not all of them have historically been leaders in EHR adoption.

- These ceremonies include patient presentations. Patients discussed what it means to be able to get the information they need, when they need it. This also applies to family members and caregivers.

- With everything that every mover has discussed about meaningful use, they are not talking about the incentive money. The incentives did help get people over the hump, but what people are talking about is the real-world, tangible improvements in patient experience, and specific, demonstrative improvements in clinical quality measures.

Discussion

- Neil Calman asked whether, as the CMS starts to get reports of numbers of adopters, they have something to compare to in order to understand whether their trajectory is accurate for the next 3-5. Will we be able to know if we are undershooting or overshooting in terms of making requirements too stringent or not stringent enough? Will the CMS know where it is compared to where it wants to be in terms of adoption rates and numbers of people achieving meaningful use? Elizabeth Holland explained that projects were done in an impact analysis of the July 28 final rule. As people continue to attest, they will be looking at performance on attestation as they formulate plans for meaningful use Stage 2. They are trying to get as many people on the bus as they can.

- Paul Tang said that he has heard a lot in the field about people intentionally delaying because of the catch-22 that early adopters are caught in with regard to Stage 2.

- In response to a question by Eva Powell, Sideman said that RECs are starting to track areas in which people are having difficulties in attesting, and items that people are not dealing with at all. Sideman also said that the RECs will collect data on which measures people are selecting to report on.

7. Public Comment

Carol Bickford from the American Nursing Association commented that it is very helpful to have the Federal Advisory Committee calendar present on the ONC Web site. However, there does not appear to be online information available regarding the summer camp activities. She asked if there was a mechanism for the ONC to publish the calendar of summer camp meetings that are scheduled, so that the public can keep up with all that is happening.

Tom Bizzaro from First DataBank noted that the subject of over-alerting has been much discussed. As far as he knows, there are no best practices defined, and no critical list of alerts that have been made publically known. This is critically needed, and now the Committee is in a position to address it. He would welcome additional discussions of the subject on a national level.

Robin Raiford spoke as a messenger from some of the CIOs of a health care association for New York State. They are concerned and frustrated with the issue of aggregating data. They talked about how some of their eligible professionals who are in multiple locations have no way to aggregate and determine unique patients. Also, there is the issue of the Medicare Advantage program that is addressed in 3 pages of the final rule, and the exemption they have from quality measures other than a "yes" or a "no."

Chantal Worzala from the American Hospital Association (AHA) explained that in proposed CMS rules for physicians and hospital outpatient payment, they reference the meaningful use incentive program and the standards used to automatically report quality data to CMS. In those rules, CMS indicates that since the publication of final rules, it has determined that it is not feasible to electronically receive the information necessary for clinical quality measure reporting based solely on the PQRI XML standard, which is currently required for certification. Now there is an ONC regulation requiring a standard for reporting of data to CMS that CMS has concluded is not feasible to use for that purpose. She looks forward to hearing from ONC how that conclusion might flow into standards and certification rules.

SUMMARY OF ACTION ITEMS:

Action Item #1: Minutes from the June 8, 2011, HITPC meeting were approved by consensus.

Action Item #2: The Committee accepted by consensus the recommendations of the Privacy and Security Tiger Team.