Health IT Standards Committee
A Public Advisory Body on Health Information Technology to the National Coordinator for Health IT

HIT Standards Committee
DRAFT
Summary of the November 3, 2015, Virtual Meeting

ATTENDANCE (see below)

KEY TOPICS

Call to Order

Michelle Consolazio, Office of the National Coordinator for Health Information Technology (ONC), welcomed participants to the meeting of the Health Information Technology Standards Committee (HITSC). She reminded the group that this was a Federal Advisory Committee Act meeting with an opportunity for public comment (3-minute limit) and that a transcript will be posted on the ONC website. She called the roll and instructed members to identify themselves for the transcript before speaking.

Opening Remarks

Deputy National Coordinator and HITSC Chairperson P. Jon White thanked the members in advance for their attention to the agenda items. He introduced Elise Sweeney Anthony, who is serving as acting director of policy.

Review of Agenda

Vice Chairperson John Halamka referred to articles that have taken his blog comments out of context. He does not feel hostility to the rules. He said that members' comments potentially could affect future revisions of the rules. White said that the 2015 certification rule is final. The EHR incentive program rule is final, pending a 60-day comment period, with comments to be considered in future rulemaking. Halamka referred to the extraordinarily length of the rules and stated that he will not bias the discussion. He asked whether there were corrections or additions to the summary of the October 2015 joint meeting with the Policy Committee. The summary was circulated with the meeting materials. Hearing none, he declared the summary approved.

> **Action Item #1: The summary of the October 2015 meeting was accepted as distributed.**

Meaningful Use Stage 3 and Modification Rule

Robert Anthony, CMS, reported that on October 6, 2015, CMS released a final rule for the Medicare and Medicaid EHR Incentive Programs in 2015 through 2017 and stage 3 in 2018 and beyond. Stages 1 and 2 have been modified to be consistent with stage 3. He showed slides that delineated reporting periods and participation timelines and explained the changes. By 2018, everyone will be on the same objectives and the same calendar reporting period. He showed slides and talked about each of the following

stage 3 objectives and corresponding measures, explaining the changes made due to experience and public comments:

- Protect electronic health information
- Electronic prescribing
- Clinical decision support
- Computerized provider order entry
- Patient electronic access to health information
- Coordination of care through patient engagement
- Health information exchange
- Public health reporting

The rule also restructures stages 1 and 2 objectives and measures to align with stage 3 for 2015–2017. There are 10 objectives for EPs, including 1 consolidated public health reporting objective with measure options, and 9 objectives for EHs and CAHs, including 1 consolidated public health reporting objective with measure options. Starting in 2015, the EHR reporting period aligns with the calendar year for all providers. The rule changes the EHR reporting period in 2015 to 90 days to accommodate modifications to meaningful use. The stage 2 patient engagement objectives that require patient action are changed. Redundant, duplicative, and topped out measures are removed. CQM reporting for both EPs and EHs remains as previously finalized. In conclusion, Anthony said that instead of thinking in terms of stages 1, 2, and 3, one should think of three stages of stage 3. He offered to answer questions, saying that Elizabeth Myers, who heads the policy team, was unable to attend the meeting.

Q&A

Halamka said that he had made a list of controversial items. He referred to the EH requirement for discharge medications, noting that when the committee reviewed the topic several years ago, members concluded that although the standards were there, they were not implemented by pharmacies. Kim Nolan reported that the standards had not been implemented in the EHRs. Halamka said that this concern should be considered in reviewing the certification rule.

Halamka referred to the API requirement and consumer apps, wondering about a consumer who wishes to connect to an app developed by the Chinese government. Anthony responded that a provider is not required to connect to any app, which would not be possible to implement. The requirement is to make it so that any app developer can access the language and standard. Halamka asked about a hospital not wanting to accept a bad developer. Anthony indicated that he was restricted in his response. He suggested that Halamka submit a written comment. Josh Mandel observed that the requirement applies only when the patient and the app developer have agreed on the use of the app. He does not see it as a concern because it is an access issue. Arien Malec said that OCR should clarify the breach issue; responsibility rests with the patient. Halamka emphasized the provider's responsibility for a secure endpoint. Anthony said that OCR will soon clarify responsibilities for hand-offs. Leslie Kelly Hall said that someone must explain to the patient in plain language the risks and responsibilities; education is more important than restrictions. Dixie Baker pointed out that the risks to organizations must be considered. It is not reasonable to expect providers to put themselves at risk. Anthony deferred to the OCR and certification staffs, saying that he can only comment on requirements. Halamka emphasized the need for clarification. Kelly Hall talked about the possibility of a tiered approach, such as provider-approved apps and potentially risky apps. Halamka asked whether a curated app store would meet the requirement. Anthony again suggested making written comments. However, he noted that an uncooperative organization could restrict any listing of approved apps, thereby stemming the flow of information to patients. Halamka replied that dissatisfied patients can always move to other providers.

Baker approved of the increased attention to patient engagement and the addition of the integration of patient-provided data. She reported that she is working with patient advocacy groups that want the capability to receive structured EHR data sent as requested to the patients. Regarding secure messaging, many EHRs provide secure messaging within the patient portal using TLS instead of Direct. Will EPs and EHs receive meaningful use credit for secure messaging by means other than Direct? Is it a requirement to send structured data in a CCDA when the patient requests it? Anthony said that, to answer the first question, he will have to review the language of the legislation. Regarding the CCDA, the view-download-transmit objective requires transmission in structured data formats. Malec said that OCR requires that providers offer data in the form requested by the patients when they have the means to do so.

Malec inquired about the relationship between this rule, MARCA, and MIPS. He summarized his understanding. Starting in 2017, providers are on the hook for measurement relating to a 2019 first initiation of MACRA, either fee-for-service increases or decreases per MIPS incentive. The years 2017 and 2018 are an awkward period for providers being measured for a MIPS incentive while the meaningful use incentives and the PQRS incentives go away. What is the connection between this rule and MIPS? Anthony responded that there is likely to be a 2017 performance period with a 2019 associated payment adjustment period that is positive or negative. If a provider is participating in an eligible alternate payments model, the provider would go down that route. Relevant regulation will be proposed. In 2017, meaningful use requirements will become part of the overall scoring for MIPS. CMS is seeking comment on the MIPS RFI. A variable scale may be used, which would roll up into the composite score. This pertains to EPs only.

John Derr declared his disappointment that the work to include long-term post-acute care (LTPAC) providers and other levels of care was left out of the rule. Communication across the entire spectrum of care is essential. Anthony reminded him that the issue of eligibility is entirely out of CMS' hands. Eligibility is defined by the HITECH Act. Nevertheless, CMS staff has ongoing conversations about the standardization of long-term care measures and data elements. CMS does not have authority to require LTPAC organizations to use EHRs. Derr referred to an agreement on voluntary compliance, which was not included in the rule. He expressed concerns about edicts instead of voluntary compliance. Anthony repeated his statement about the lack of authority. He suggested that Derr discuss the certification implications with ONC staff. He pointed out that one of the measures pertains to transmittal of summary of care, saying that a transition to an LTPAC facility counts toward the threshold. Derr requested some reference to that point in the rule.

Consolazio announced that the Q&A had exceeded the allocated time. She asked the members to be brief. Patricia Sengstack mentioned alert fatigue and wondered whether the CDS requirement includes measuring the effectiveness of the CDS alerts. Anthony responded that CMS has allowed very broad interpretation of CDS. There is not a well-defined CDS for every specialty. The purpose is to encourage organizations to use CDS in a meaningful way. MIPS may give an opportunity to use CDS as a part of a suite of HIT tools to improve outcomes. Citing slide 17, Sengstack went on to ask whether actively engaged and patient-generated health data are defined. Anthony told her to look at the specific language of the rule and to comment if the meaning is not clear.

Wes Rishel commented on the API. Four parties are involved: EHR vendor, app vendor, provider, and patient. In the debate about third-party apps, only the provider and the patient were considered. As a practical matter, the third-party app developer is going to have a hard time without some sort of trust relationship with at least one vendor. Marketing and distribution will require testing with several EHR vendors in an environment in which there are no secure patient data. Ideally, the magic will happen with FHIR, and it will become unnecessary to test, but that is not likely. Members have talked about security

and privacy in the trade-off between encouraging responsible use and allowing providers to block data. What happens with the use of the app relates to privacy and perhaps the security of the patient's own devices. Regarding security, experience shows the difficulty of predicting where exploits will turn up. Simply offering the service creates substantial vulnerabilities that are unrelated to the specific service. Requiring providers to open up access without the due process of identifying the potential security risks would create a substantial nightmare. Balance is critical.

Richard Elmore observed that a heavy lift will be required to meet the 2017 timeline. New measures must be developed, and many of the measure and registry developers lack experience. He wondered whether CMS can leverage what has been learned in stage 2. Anthony assured him that CMS staff is working to leverage learnings from all of its programs. There is no other option since quality measure development takes 3 to 5 years. Elmore suggested that this topic be placed on the HITSC agenda.

Andrew Wiesenthal referred to public health reporting and asked about a definition of target state. Providers encounter multiple jurisdictions with different data definitions and reporting requirements. Anthony responded that the lack of detail in the regulations is due to CMS' attempt at flexibility. It all depends on providers' options. CMS does not want to exclude specific registries. Wiesenthal wondered about requiring public health agencies and registries to be consistent. Anthony pointed out that CMS does not have authority to regulate public health agencies or registries.

Halamka summarized that members had concerns about the alignment of different programs, discharge medications, APIs and patient access, and inconsistencies in requirements for public health reporting. He noted that in stage 3, the thresholds for patient engagement will increase.

2015 Certification Rule

Elise Sweeney Anthony and Mike Lipinski, ONC, showed slides and reported on the 2015 final rule. Sweeney Anthony said that the rule is part of the HHS-wide effort to achieve better care, smarter spending, and healthier people. It builds on the foundation established by the 2011 and 2014 editions and addresses stakeholder feedback by reducing burden as compared to the 2015 edition proposed rule. It focuses on HIT components necessary to establish an interoperable nationwide health information infrastructure and incorporates changes designed to foster innovation, open new market opportunities, and provide more provider and patient choices in electronic health information access and exchange. In addition, it addresses information blocking and the continued reliability of certified HIT. The 2015 edition supports HIT more broadly and is not limited to EHR technology. There is no "Complete EHR" certification in the 2015 edition or future editions. The rule is intended to support HIT across the care continuum and includes LTPAC settings. The certification program will be agnostic to settings and programs and not limited to meaningful use.

Sweeney Anthony went on to describe specific components of the final rule. Regarding enhancement of transparency, ONC-ACBs must ensure that HIT developers conspicuously disclose in plain language — on their website and in all marketing materials, communication statements, and other assertions related to certified HIT — any additional types of costs and limitations on use. Developers will be required to provide a hyperlink for all disclosures and make a transparency attestation. Another requirement pertains to open data. The CHPL will be converted to an open data file to make the reported product data more accessible for product analysis. The ABCs will be required to report an expanded set of information about HIT products. Regarding privacy and security, a HIT module will have to meet applicable privacy and security certification criteria, which are based on the other capabilities included in the HIT module. The final rule removes the responsibility from the providers to ensure that they possess technology certified to all the necessary privacy and security criteria. The final rule establishes requirements for in-the-field surveillance consisting of reactive surveillance (e.g., complaints) and

randomized surveillance of at least 2% of annually certified HIT at one or more locations with non-conformity and corrective action reported to the CHPL beginning in 2016.

Lipinski continued by explaining the base EHR definition and described changes from the 2014 edition. He showed a slide that delineated components of the common clinical data set, previously named the common meaningful use clinical data set. New components are immunizations, unique device identifiers for implantable devices, assessment and plan of treatment, goals, and health concerns. He went on to describe changes from 2014 to 2015 and changes from the proposed 2015 rule to the final rule. Of the 68 proposed criteria, 14 were not adopted, and 6 were added. Compared to the 2014 criteria, 19 are new, 24 are revised, and 16 are the same. Lipinski reviewed slides that described each criterion in detail. New criteria are:

- Patient selection
- Data category request
- All data request
- Trusted connection
- Auditing actions on health information
- Implantable device list
- Patient health information capture
- Case reporting
- Antimicrobial use and resistance reporting
- Health care surveys
- Accessibility-centered design
- CCDA creation performance
- Social, psychological, and behavioral data
- Creating common clinical data set summary records
- Receiving common clinical data set summary records
- Sending data segmentation for privacy
- Receiving data segmentation for privacy
- Care plan
- Filtering clinical quality measures

Lipinski emphasized that a number of changes are expected to contribute to patient safety. Finally, he showed several slides that described the use of the HIT modules to support stage 3 in 2018 and beyond. The 2015 edition final rule becomes effective January 14, 2016, except for § 170.523(m) (adaptations/updates reporting) and (n) (complaints reporting), which are effective April 1, 2016. There is no comment period for this final rule. The 2015 edition final test procedures are available for a 30-day comment period. The Certification Companion Guides are not undergoing a formal public comment period, but ONC encourages stakeholders to review the Certification Companion Guides during the public comment period of the 2015 edition final test procedures (https://www.healthit.gov/policy-researchers-implementers/2015-edition-test-method)

Q&A

Baker expressed approval of the privacy and security criteria, which she said were identical to the recommendations of the Privacy and Security Workgroup. Kelly Hall inquired about secure messaging and email. Lipinski indicated that this falls under the purview of HIPAA. From a standards perspective, an encrypted method at the minimal level II is required. Sweeney Anthony added that CMS is restricted

from commenting during the public comment period, but CMS staff may be open to clarification. She suggested that Kelly Hall submit a comment. Baker said that according to the HITECH introduction, unencrypted messaging may be used with the patient's permission. The issue is one of policy, not standards.

In response to a question from Floyd Eisenberg about safety design, Lipinski said that the reference is to summative evaluation. The public comments indicated insufficient consensus on formative evaluation. ONC staff settled on a minimum threshold of 10 testers rather than 20; he encouraged more test sites and the use of appropriate testers. This rule sets out explicit criteria for the summative evaluation report. In addition, guidance for 2014 was issued.

Derr apologized for his comments on the Meaningful Use Stage 3 and Modification Rule presentation, saying that he now realized that his recommendations for LTPAC were included in the certification rule. He thanked ONC staff and said that the certification provisions will be very helpful to LTPAC providers.

Elmore commented that auditors have been challenged by the complexity of the regulations for field surveillance. What process is in place to ensure adequate dialogue with developers and providers? Lipinski indicated that these concerns will be addressed with an upcoming guidance. Providers' concerns have been recognized in the rule. There is opportunity for comments from the vendor, which is consistent with ISO's standards for certification programs. This rulemaking is setting parameters to ensure that surveillance is actually happening. The certification bodies will have to maintain a close dialogue with both the vendor and provider to determine whether there is a problem with a product. The goal is to correct any problems and ensure patient safety. Elmore said that ONC staff should be very thoughtful about the examples for testing.

Halamka noted that the rule does not require a specific standard with API, which may result in chaos. Lipinski acknowledged that the same comment had been made in public comments. However, standard readiness had to be considered. The rule indicates movement to a standard in the future and requires the vendor to document the standard used.

Public Comment

None

SUMMARY OF ACTION ITEMS:

> **Action Item #1: The summary of the October 2015 meeting was accepted as distributed.**

Meeting Materials:

- Agenda
- Summary of October 2015 meeting
- Meeting presentation slides and reports

MEETING ATTENDANCE

Name	11/03/15	09/22/15	08/26/15	06/24/15	05/20/15	04/22/15	01/27/15	03/18/15
Andrew Wiesenthal	X	X	X		X	X	X	X
Angela Kennedy	X	X						
Anne Castro	X			X	X		X	X
Anne LeMaistre	X	X	X	X	X	X	X	X
Arien Malec	X		X	X	X	X	X	X
Charles H. Romine	X				X	X	X	X
Christopher Ross				X	X	X	X	X
Dixie B. Baker	X	X	X	X	X	X	X	X
Elizabeth Johnson		X		X		X	X	X
Eric Rose	X	X	X		X	X	X	X
Floyd Eisenberg	X	X	X	X	X		X	X
James Ferguson		X	X		X	X	X	X
Jitin Asnaani		X						
John Halamka	X	X	X	X	X	X	X	X
John F. Derr	X	X		X		X	X	X
Jon White	X	X	X	X	X	X	X	X
Josh Mandel	X	X						
Keith J. Figlioli			X	X	X			X
Kim Nolen	X	X	X	X	X	X	X	X
Leslie Kelly Hall	X	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		X	X	X
Patricia P. Sengstack	X	X						
Rebecca D. Kush		X	X		X		X	
Richard Elmore	X	X						
Steve Brown		X		X		X		
Wes Rishel	X	X		X	X	X	X	X