

**HIT Standards Committee  
Final  
Summary of the September 19, 2012 Meeting**

**ATTENDANCE**

The following Committee members were in attendance at this meeting:

- Jonathan Perlin
- John Halamka
- Dixie Baker
- Anne Castro
- Christopher Chute
- John Derr
- Lorraine Doo
- Floyd Eisenberg
- Jamie Ferguson
- Leslie Kelly Hall
- Stanley Huff
- Elizabeth Johnson
- Rebecca Kush
- Arien Malec
- David McCallie
- Nancy Orvis
- J. Marc Overhage
- Wes Rishel
- Cris Ross
- Walter Suarez
- James Walker
- Sharon Terry – via phone
- Kamie Roberts for Charles Romine – via phone

The following Committee members did not attend this meeting:

- Tim Cromwell
- C. Martin Harris
- Kevin Hutchinson

## KEY TOPICS

### 1. Call to Order and Opening of the Meeting

MacKenzie Robertson, Office of the National Coordinator (ONC), welcomed participants to the 40<sup>th</sup> meeting of the HIT Standards Committee (HITSC). She reminded participants that it was a Federal Advisory Committee (FACA) meeting, with two opportunities for the public to make comments, and that a transcript of the meeting will be available on the ONC Website. She reminded members to state their names before speaking.

### 2. Opening Remarks

Farzad Mostashari, National Coordinator, mentioned that contrary to what was stated in the *Wall Street Journal*, considerable progress in standards setting has been made over the past few years. Although FACA meetings are transparent, it is important to communicate progress to a broad audience. He gave credit to the industry, saying that vendors realize that their customers demand interoperability.

### 3. Review of the Agenda

Jonathan Perlin, Chair of the Committee, said that interoperability has made much possible. Organizing capacity is increased. There is now the ability to bring heterogeneous data together. Committee members can help others to understand the practical application of standards for both providers and patients. At home monitoring devices present great opportunities for reducing hospital admissions. The world is changing. He asked members about amendments or comments to the summary of the August 2012 meeting, which was circulated with the meeting materials. He asked that the recent response of the HITSC to the questions from the HIT Policy Committee about the availability of standards to support preliminary Stage 3 objectives be appended to the summary. Hearing no objections, corrections or amendments, he declared the summary approved as submitted.

**Action item #1:** The summary of the August 2012 meeting was declared approved.

He thanked Mary Jo Deering, ONC, for her work on behalf of the committee and welcomed Robertson, who has extensive experience in the management of FACAs. As a result of her recommendation, two periods for public comments were included in the agenda.

### 4. Comments

John Halamka, Vice-Chair of the Committee, reported that the workgroups' had completed their responses to the HITPC questions. He announced that he would present the responses to one of the subgroups of the HITPC Meaningful Use Workgroup on September 20. He reported that the authors of the *Wall Street Journal* article had agreed to meet with him at which time he will explain to them the considerable work accomplished on standards. He and Perlin plan to submit a letter to the editor. He went on to say that there is now a vendor-neutral EHR with interoperability. Standards have been implemented to enable interoperability throughout Massachusetts. He asked the members to evangelize the accomplishments of HIT.

Mostashari announced that ONC monitors Twitter. He invited listeners to tweet and encouraged their participation in the dialogue.

## 5. Briefing on Meaningful Use Stage 2 Final Rules

Travis Broome, CMS, reported that the CMS rule includes the following:

- Changes to Stage 1 of meaningful use
- Stage 2 of meaningful use
- New clinical quality measures
- New clinical quality measure reporting mechanisms
- Payment adjustments and hardships
- Medicaid program changes

He informed the group that although CMS received many comments on eligibility, eligibility is defined by HITECH. Congress has made no changes in the law since its passage. Therefore, the only eligibility changes are those within regulatory purview under the Medicaid EHR Incentive Program. For Stage 2, EPs can demonstrate that they fund the acquisition, implementation, and maintenance of CEHRT, including supporting hardware and interfaces needed for Meaningful Use without reimbursement from an EH or CAH — in lieu of using the hospital's CEHRT — and can potentially receive an incentive payment.

The stages were clarified, giving some extra time and staggered on-board time. Starting in 2014, all EHR Incentive Program participants will have to adopt certified EHR technology that meets ONC's Standards and Certification Criteria 2014 Final Rule. The reporting period was reduced to three months to allow providers time to adopt 2014 certified EHR technology and prepare for Stage 2. All participants will have a three-month reporting period in 2014. Starting in 2014, the menu exclusions will no longer count towards the number of menu objectives required. Batch reporting will be allowed but not group averaging. Regarding objectives, only a few changes were made from the NPRM, notably in patient engagement thresholds and electronic exchange. He showed slides and moved through the core and menu objectives for EPs and EHS.

Changes to Stage 1 include the CPOE and vital signs objectives. The HIE test requirement was removed and e-copy and online access was changed. Some options to all of the vital signs are now permitted. CQM reporting will remain the same through 2013. In 2012 and continued in 2013, two reporting methods will be available for reporting the stage 1 measures:

- Attestation
- e-Reporting pilots
  - Physician Quality Reporting System EHR Incentive Program Pilot for EPs
  - e-Reporting Pilot for eligible hospitals and CAHs

Broome also noted that the order of elements in the summary is not set. Immunizations allow credit for being actively engaged in on-boarding with the state health agency. No new privacy and security requirements are imposed but users are asked about updating their risk management processes during reporting period.

Clinical Quality Measures (CQMs) are no longer a core objective of the EHR Incentive Programs beginning in 2014, but all providers are required to report on CQMs in order to demonstrate meaningful use. All providers must select CQMs from at least three of the six HHS National Quality Strategy domains. Alignment across CMS programs includes finalizing the same CQMs for reporting beginning in 2014 for the Hospital IQR Program, PQRS, CHIPRA, and Medicare SSP and Pioneer ACOs. Beginning in 2014, all Medicare-eligible providers in their second year and beyond of demonstrating meaningful use must electronically report their CQM data to CMS. Medicaid providers will report their CQM data to their state, which may be by electronic reporting. He referred to several slides that summarized the many changes in reporting.

He continued. The HITECH Act stipulates that for Medicare EPs, subsection (d) hospitals and CAHs a payment adjustment applies if they are not a meaningful user. An EP, subsection (d) hospital or CAH becomes a meaningful user when it successfully attests under either the Medicare or Medicaid EHR Incentive Program. A provider receiving a Medicaid incentive for AIU would still be subject to the Medicare payment adjustment. Payment adjustments are based on prior years' reporting periods. The length of the reporting period depends upon the first year of participation. EPs must continue to demonstrate meaningful use every year to avoid payment adjustments in subsequent years. He described the hardship exception categories of inadequate infrastructure; new EPs; unforeseen circumstances; lack of face-to-face or telemedical interaction with patients; and for EPs who practice at multiple locations, the lack of control over the availability of EHRs for more than 50% of encounters. Exceptions are also available for EPs whose primary specialties are anesthesiology, radiology or pathology.

Before concluding, he cited these resources:

- [http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Stage\\_2.html](http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Stage_2.html)
- Tip sheets
  - Stage 2 Overview
  - 2014 Clinical Quality Measures
  - - Payment Adjustments & Hardship Exceptions (EPs & Hospitals)
  - - Stage 1 Changes
  - - Stage 1 vs. Stage 2 Tables (EPs & Hospitals)

### **Q&A**

Regarding electronic transmissions, more of which are sent electronically than received electronically, CMS defined the denominator so as to allow providers to meet thresholds. Many comments were received on the item. Centers for Medicare and Medicaid Services (CMS) officials wanted to make the menu item attractive for EHRs. Halamka observed that the more robust standards apply to lab results rather than to orders. Radiologists, anesthesiologists and pathologists are concerned about the imposition of the 3% penalty because they cannot document smoking status. He asked CMS staff to telegraph the rule to those specialists. Broome recognized the need for a FAQ to clarify the measure on lab reporting. Since it is a menu item, only EHRs that both send and receive electronically will report.

Jim Walker asked about the cancellation of prescriptions at discharge. He reported that his organization had concluded as a result of a safety analysis that it was not safe to transmit discharge prescriptions electronically because the systems do not handle cancellations reliably. Although hospital pharmacies are not included in the regs, Mostashari inquired about the extent of the lack of capacity to cancel. Walker acknowledged that it is not an issue for outpatients. But in hospital, care teams begin planning for discharge 24 hours in advance. Over this time, changes in meds occur. Although the 10.6 version of NCPDP reportedly enables the receipt of cancellations, not all pharmacies have upgraded to that version, and since pharmacies are not included in the meaningful-use program, they are not compelled to upgrade to it. Halamka agreed that it is a receiving capacity, not an EHR issue. Someone noted that there is a 2013 deadline for the use of the 10.6 version, saying that the problem described by Walker has essentially been taken care of. Halamka observed that the problem is similar to the issue of receipt of electronic controlled substance prescriptions. A member suggested that ONC follow up on the prescription cancellation concern with Surescripts and take it into account in certification. Perlin concurred.

**Action item #2:** Mostashari took an action to follow up with Surescripts to ask about the capabilities of pharmacies to receive cancellations.

Hospitals are not required in Stage 2 to receive electronic transmissions from nursing homes and home health agencies. Closing the transition and referral loops may be incorporated into Stage 3.

Mostashari thanked Broome and Steve Posnack, ONC, for their excellent work in coordinating the two final rules and their due diligence in reviewing and taking into account the many complicated comments on the NPRMs.

### ***The Certification Rule***

Posnack reported on the standards and certification criteria final rule. He observed that comments on the NPRM reflected a better understanding and were more detailed compared to comments received on stage 1. These higher quality comments helped ONC staff to perfect the final rule, which includes 50 certification criteria. Themes in the final rule include the following:

- Enhancing standards-based exchange
- Promoting EHR technology safety and security
- Enabling greater patient engagement
- Introducing greater transparency
- Reducing regulatory burden and introducing flexibility

He reminded the members that ONC's scope is a technical one that specifies the capabilities EHR technology must include and how they need to perform in order to be certified. It does not specify how the EHR technology is to be used. The Meaningful Use Rule specifies how eligible providers need to use Certified EHR Technology (CHERT) in order to receive incentives. Although distinct, the rules are intended to be read together.

The new regulatory framework provides more flexibility and contains new, revised, and unchanged criteria. A common data set was created. He presented slides that showed changes from the NPRM to the final rule in each of the criteria and the respective standards for the categories of clinical care, care coordination, CQMs, privacy and security, patient engagement, public health, and utilization.

Several members interjected comments pertaining to revised transport standards for the summary documents. The revision permits two optional approaches in addition to the primary Direct Project specification: [(1) Secure App Statement + XDR/XDM for Direct Messaging; (2) SOAP RTM +XDR/XDM for direct messaging. Someone said that one or the other may have to be picked for testing. Halamka said that the statement was confusing and must be clarified. Wes Rishel pointed out that in some communities XDR will be the sole option.

Posnack continued. The potential number of 2014 edition certification criteria to which EHR technology needs to be certified (for an eligible provider to have EHR technology that meets the CEHRT definition) is limited to the stage needs of an EHR technology developer's customer. Two types of certifications can be issued: Complete EHR (i.e., EHR technology certified to all mandatory criteria) or EHR module (i.e., EHR technology certified to less than all mandatory criteria). The scope of a certification issued to EHR technology represents only the capabilities for which the certification was sought and granted. EHR technology developers get to choose the type of certification sought for EHR technology and its scope (i.e., for EHR modules, the number of certification criteria to which it would be certified). Additional capabilities beyond those for which certification criteria have been adopted are not within the scope of ONC's regulatory framework and reflect a business decision made by the EHR technology developer if they are included with an EHR technology to which a certification is issued. Single EHR module certification is a new option, making it possible for an EP to have just enough EHR technology certified to the 2014 edition EHR certification criteria to meet the CEHRT definition. He explained how certification criteria were changed to align with meaningful use requirements. Certification is no longer tied to stages. The 2014 edition EHR technology supports the achievement of either stage. The certification criteria are a subset of the EHR's functions. Capabilities can be provided by different modules.

All EPs, EHs and CAHs must have EHR technology certified to the 2014 edition EHR certification criteria that meets the base EHR definition and would support the objectives, measures, and their ability to successfully report the CQMs, for the stage that they seek to achieve.

The temporary certification program will sunset upon the 2014 edition final rule effective date. The program name is changed to the ONC HIT Certification Program. The EHR module certification requirements were revised so that certification to privacy and security certification criteria for the 2014 edition will not be required. The policy outcome is now reflected in the Base EHR definition, which includes all privacy and security certification criteria.

ONC-ACBs are required to ensure that EHR technology developers notify eligible providers about additional types of costs (i.e., one-time, ongoing or both) that affect a certified complete EHR or certified EHR module's total cost of ownership for the purposes of achieving meaningful use. The final rule requires that ONC-ACBs submit a hyperlink of the test results used to issue a certification to a complete EHR or EHR module. Through October 2012, ONC will release weekly waves of test procedures and electronic test tools. The test procedures and tools will be made available for comment. During November and December, ONC will sponsor a testing workshop, and the National Coordinator will approve the 2014 edition test procedures. Testing and certification to the 2014 edition will be available early in 2013. He urged members to comment on the testing criteria.

## **Q&A**

Halamka said that his organization will no longer have to certify functions that are not used. The acquisition of new technology can be tailored to requirements. Providers can pick and choose and build and buy.

Arien Malec recognized that the ONC staff did an amazing job with a very complex process. Because of the complexity, it is inevitable that something will get messed up. What is the plan for dealing with post-certification hearings and corrections? Someone responded that various tools are available—another final rule, FAQs, or an agreement with the industry on testing. Legal counsel would have to approve the approach. Mostashari reminded them that an opportunity for public comment on significant changes is required by law. Malec went on to ask about the reference to encounter diagnostic vocabulary IDC 10 DM —on or after October 2014.” Posnack said that the date should be ignored. Malec then presented a hypothetical situation in which a noncertified EHR sends lab orders and someone builds an adapter to translate them. What would have to be certified? Posnack indicated that whatever is presented for certification must meet the criterion. The adapter might be part of what is presented for certification.

Halamka initiated lightning responses only due to time constraints.

Doug Fridsma talked about regulation in the electrical industry. Regulation is a blunt tool. He said that he hopes HIT will move to industry consensus. The first step is to identify where the problem is. Then the problem must be sent to a place where it can be corrected. Prevention of problems is important.

Rishel talked about ONC having a bully pulpit. Vendors want to work together all the way to implementation, going beyond the demonstration of success. It is similar to program debugging. But the difference is to determine whether the problem is due to an incorrect standard or an ambiguous standard. ONC needs a forum for those who wrote the standards and those who are implementing them to work out solutions. Consensus driven rapid solutions are the goal. For example, the CCDA fixed the previous versions and generated a tuned-up version.

A secure channel is the same as secure messaging.

## **6. Update on ONC Policy Activities**

Farzad Mostashari, National Coordinator, reported that after consideration of the responses to the RFI on governance of the Nationwide Health Information Network (NwHIN), he concluded that regulation is not needed at this time. Based on comments received, things are currently working well.

Jodi Daniel, ONC, asked that members review the slide deck used for the presentation to the HITPC and included in meeting materials. She informed the group that Christopher Boone, American Heart Association (AHA), was appointed by the GAO to fill a vacancy on the HITPC. ONC plans to convene two new consumer engagement workgroups, one for the HITPC and one for the HITSC. They will be assigned clear tasks. A website for nominations of members will be set up.

Mostashari reported that several members, staff and observers had been tweeting during the meeting. However, no listeners had sent tweets.

## **7. Public Comment**

Shirley Shapiro spoke about her organization, a pharmacy collaborative. Pharmacists are important members of the health care team. Her organization works with NCCDP and HL7 on standards for a structured document for patients to inform their use of drugs. On January 1, 2013, a new regulation on Part D will be effective. Pharmacy reconciled med lists will be generated. She requested that the HITSC recommend to CMS a standardized document for med reconciliation for patients.

Mostashari distributed letters from President Obama commemorating HIT week.

### ***Q&A***

Baker referred to the certification requirement that EHR modules no longer are required to be certified against any of the privacy and security criteria, saying that the requirement is contrary to the recommendation of the Privacy & Security Workgroup. Posnack responded that the decision resulted from a tradeoff on the effort to get certified. The module requirement was dialed back. The policy that the vendor is responsible for making sure the modules work together continues. Baker voiced her disappointment with ONC's decision, saying that there is now no assurance that EHR modules will be capable of supporting any security functionality.

Walker spoke about the need for simplifying information for small providers. Who will help, for instance, a dentist to make decisions? Posnack said that he is engaged in outreach and making presentation to many groups. He will continue to simplify the illustrative slides. Vendors should help providers understand requirements and alternatives as well. Walker emphasized the importance of communication although he acknowledged that it is not necessarily ONC's role. He suggested that ONC develop informational tools that can be used by intermediaries to inform a broader audience.

Cris Ross praised ONC's work. He expressed concern about small providers. Buying products and attestation are challenging. A check-off list could be helpful. Posnack repeated that he will continue to work to simplify the slides. However, it is difficult to account for the variation in practice scopes.

## **8. Implementation Workgroup Update on Testing Methods**

The report and slides were presented by ONC staff and the workgroup co-chairs Elizabeth Johnson and Cris Ross. ONC will implement scenario-based test procedures, which will be modularly developed so that individual tests can be skipped for products that do not have that capability. This approach reflects a typical clinical workflow in multiple care settings and allows persistence of data elements, which provide a model for data threading between different certification criterion and various destinations within an EHR. Testing flexibility (e.g. add/remove—unit test) will be maintained. Testing will be performed in iterative steps completed sequentially to match the workflow described. At the conclusion of the scenario, the EHR will have demonstrated its ability to perform both the scenario sequence and the individual certification criteria tested during that scenario sequence. They walked through an example scenario of medication management in an inpatient setting and an emergency department. The scenario describes an iterative workflow in three phases—ordering, dispensing and administration of medications. Ordering, for example, includes COPE, drug-drug and drug-allergy interaction checks, medication list, medication allergy list, and drug formulary checks.

The scenarios will be tested in real-life settings. Johnson thanked Halamka for offering his organization as a test site.

Carol Bean, ONC, talked about the 2014 testing timeline. She noted the availability of modular testing, the quest for innovation, and the retention of capacity for unit-based testing. The scenario allows the joining of units. ONC is releasing the scenarios and procedures in four waves, each followed by a comment period. A workshop with NIST will be held in October. After review of the comments on the documents, the final test procedures will be published and certification will commence in January. She told them that the test procedures and the data have been separated; test data will be available from numerous sources.

The Implementation Workgroup will meet weekly to develop the scenarios and to provide input on the procedures. A hearing will be convened in 2013 on the experience with certification moving to 2014 edition.

### ***Q&A***

Rishel said that ONC should have plans for testing for interoperability. Things that go wrong typically fall into a few categories. ONC should be prepared.

Halamka emphasized the importance of ensuring that clinical data can be transmitted.

Walter Suarez inquired about the involvement of the Privacy & Security Workgroup in the development of testing scenarios. Ross indicated that a security scenario would be helpful. Regarding the capability to transmit CQMs, Johnson indicated that it would be taken up at a later point.

Baker asked for clarification of Johnson's comment that the scenario approach will avoid having to test for the same functionality multiple times. Johnson clarified that when a criterion is tested for in a scenario, it is not retested in the unit test.

Nancy Orvis observed that as a provider she wants interoperability scenarios. She volunteered to participate as a test site.

Floyd Eisenberg inquired about the lists used to manage problems in a clinical setting. He announced that a National Quality Forum on September 21 will discuss relevant topics. Johnson reiterated that the scenarios are limited to what is specifically required for certification.

Ross, on behalf of the Implementation Workgroup, asked for clinicians to volunteer for the workgroup. Perlin told interested parties to submit their names to Robertson.

Malec talked about the need to begin realistic planning for Stage 3. When Johnson responded that the workgroup intended to begin work with the Meaningful Use Workgroup in January, Malec urged her to begin now. Johnson agreed to do so. Fridsma referred to being six months behind and urged an incremental approach. ONC staff agreed to add practicality and to think beyond 2014.

Walker urged ONC to consider the comparative cost effectiveness of interviews with key informants in lieu of a hearing on experiences with certification. Perlin concurred.

## 9. Update on ONC Standards Activities

Doug Fridsma, ONC, showed a slide that listed the projects in the current S&I Framework portfolio. He noted that there are some inconsistencies in the standards that must be corrected. At some point, he said that he wants to discuss dental vocabularies. He wants to engage communities on how to test standards. He repeated a comment that he had made earlier: ONC can be guided by the experience in some other industries in which government regulation plays a lighter hand. ONC has responsibilities that were not tied to ARRA funding. But with the end of ARRA monies, priorities must be set. ONC must work more closely with partners. ONC can bring people together.

Referring to Fridsma's reference to work funded by the California Health Care Foundation (CHCF), Rishel asked that the record show that CHCF's work on lab reporting is national.

Fridsma continued. Ongoing work includes with Standards Development Organizations (SDOs) on standards maintenance, data segmentation piloting, and longitudinal care coordination. Although long-term care providers are not eligible for meaningful use, they want to contribute to HIT. He described Health eDecisions, a new project built upon two use cases for artifact sharing. Barriers exist to the adoption and implementation of CDS despite research demonstrating effectiveness in improving quality and safety. There is a lack of widely accepted, implementable standards for importing and/or sharing proven CDS interventions (reminders, order sets, documentation templates). ONC and AHRQ have invested in multiple research projects such as GLIDES, CDSC, ACDS, SHARP and eRecs to advance CDS implementation, sharing and adoption. At the April 2012 Face 2 Face Meeting, stakeholders gathered from across the vendor, academic and health care communities to discuss how to share CDS interventions and build on the research and existing standards.

Health eDecisions will identify, define and harmonize standards that facilitate the emergence of systems and services whereby shareable CDS interventions can be implemented via:

- Standards to structure medical knowledge in a shareable and executable format for use in CDS, and (Use Case 1 – CDS Artifact Sharing)

- Standards that define how a system can interact with and utilize an electronic interface that provides helpful, actionable clinical guidance (Use Case 2- CDS Guidance Services)

It is expected that repositories or catalogues can emerge, supplied by a range of content creators, whereby CDS artifacts can be selected and imported into HIT systems. Each intervention will represent a standardized expression of a guideline that can be accessed by EHR system developers and users to simplify the process of incorporating guidelines into EHRs. CDS support services can interact with EHRs and/or other HIT implementations. Fridsma read through a list on one of the slides of the many relevant standards and models from which to select.

A member interjected that some of the standards could be used for matching patients with clinical trials. Walker noted that CDS implementation is sometimes more business management than knowledge representation.

Marc Overhage said that the workflow is one challenge and data finding is another challenge. The underlying data model is not standardized: Is this premature since there is little experience in sharing CDS? Fridsma acknowledged that it may be possible to low/right regret problems and the characteristics of problems on which incremental progress can be made. Scientific understanding is needed. He suggested that the HITSC consider these issues.

Fridsma talked about the automatic blue button initiative (ABBI), which was launched August 15. It builds off the Veteran Administration's work with Blue Button, which has extended to EHR vendors, CMS, UnitedHealth Group and Aetna, and is the centerpiece of ONC's Consumer Health IT Pledge Community. ABBI's scope is to consider standards and specifications that will facilitate consumer-mediated exchange of patient health information. It will involve a move from ASCII text file to standardized structures and from one-time download to ~~automated~~ download, via V/D/T and/or restful approaches. Three workgroups have been formed:

- Push: to automate transmission of personal health data to a specific location
- Pull: to allow a third party application to access my personal health data on demand
- Content: to ensure that a blue button file is machine-readable and human-readable

### ***Q&A***

Rishel commented that the Blue Button did send information to the patient, thereby eliminating many issues regarding consent. The momentum should be used to add structured data and to use the PHR to control patient input.

Perlin announced that dental vocabularies will be an agenda item for an up-coming meeting. Upon seeing Deering in the room, he again thanked her for her support of the committee.

[I think this is when Steve mentioned the conversation that he and I had had over the break re the certification of EHR modules, and that we would talk further about this.]

### **10. More Public Comment**

None

### **SUMMARY OF ACTION ITEMS:**

**Action item #1:** The summary of the August 2012 meeting was declared approved.

**Action item #2:** Mostashari took an action to follow up with Surescripts to ask about the capabilities of pharmacies to receive cancellations.

### **Meeting Materials:**

- Agenda
- Summary of August 2012 meeting
- Meeting presentation slides