

**HIT Policy Committee
DRAFT
Summary of the November 7, 2012 Meeting**

ATTENDANCE

The following Committee members attended this meeting:

- Farzad Mostashari
- Paul Tang
- Theresa Cullen for Madhulika Agarwal
- Christine Bechtel
- Christopher Boone
- Neil Calman
- Patrick Conway
- Arthur Davidson
- Judith Faulkner
- Thomas Greig
- Gayle Harrell
- Charles Kennedy
- David Lansky
- Deven McGraw
- Marc Probst
- Scott White

The following Committee members did not attend this meeting:

- David Bates
- Richard Chapman
- Connie White Delaney
- Paul Egerman
- Frank Nemec
- Joshua Sharfstein
- Latanya Sweeney
- Robert Tagalicod

KEY TOPICS

Call to Order

MacKenzie Robertson, Office of the National Coordinator (ONC), welcomed participants to the 42nd Health Information Technology Policy Committee (HITPC) meeting. She reminded the group that this was a Federal Advisory Committee (FACA) meeting being conducted with two opportunities for public comment and that a transcript will be posted on the ONC website. She called the roll and reminded members to identify themselves for the transcript before speaking. She turned the meeting over to HITPC Chairperson Farzad Mostashari.

Remarks

Mostashari referred to recent extreme weather events and the election, which he noted summarized the power of “data.” Truth and accuracy of data are appreciated as is prediction based on science. There is relief when data converge in a zero-sum resolution. Now the administration has more time to finish the

job of HIT. The HITPC members, appointed by Republicans and Democrats, include representation of many interests. They come together to solve problems through the painstaking work of building consensus. He asked the members to look afresh at the task and challenged them to push more on interoperability. He asked whether more can be done on queries, privacy and security, safety, and setting the stage for innovation.

Review of Agenda

Paul Tang, Vice Chairperson, mentioned each of the items on the agenda, which had been distributed in advance of the meeting. No changes in the agenda were requested. He referred to the summary of the October 2012 meeting, which was circulated with the meeting materials, and asked for a motion and a second to approve the summary. The motion was made and seconded and a voice vote resulted in unanimous approval.

Action item #1: The summary of the October 2012 HITPC meeting was approved as circulated.

Update from Centers for Medicare and Medicaid Services (CMS)

Robert Anthony presented slides showing the most recent numbers on the EHR incentive program through September and the end of the fiscal year. Medicare specialty data have stabilized. 50% of payments are going to non-primary care providers. 7005 pediatricians participated in the Medicaid incentives program. Data are consistent from month to month. 80% of hospitals are registered and about 60% have received payments. About 60% of EPs have registered. Increasing numbers are registered and paid. About 25% of EPs have been paid under Medicare or Medicaid. Since EHs attest in October and November, the numbers will increase in the immediate term. On average, all measure thresholds were greatly exceeded, but every threshold had some providers on the borderline. Drug formulary, immunization registries and patient list are the most popular menu objectives for EPs. Advance directives, drug formulary and clinical lab test are most frequently reported by EHs. Transition of care summary and patient reminders were the least popular menu objectives for EPs, compared to transition of care and reportable lab results for hospitals. Anthony said that comments received for Stage 2 were not surprising. Although he expects that most providers will meet the objectives, the provision of the summary of care document will be difficult. CMS intends to provide educational materials.

Q&A

Regarding a letter from a group of senators to Secretary Sebelius inquiring about Stage 2, Anthony reported that a briefing is being scheduled.

Final Walkthrough of Meaningful Use Stage 3 Request for Comment (RFC)

Tang directed members' attention to the draft RFC to be published next week with a 45-day comment period. ONC staff will compile and analyze the comments and the workgroups will use the comments to revise their recommendations to the HITPC for the notice of proposed rulemaking (NPRM).

In his role as Meaningful Use Workgroup Chairperson, Tang read through the document, noting only the changes made since the previous meeting. This summary lists the relevant statement(s) from the draft, followed by highlights of the discussion and decisions, if any were voiced.

101 – Certification Only for EPs: EHRs must have the ability to identify abnormal test results and track when results are available or not completed by a certain time. EHRs must record the date and time test results are reviewed and by whom. Members had no comments or objections.

105 – Certification criteria only: Use of lab test results, medications, and vital signs (blood pressure, height, weight, BMI), to support clinicians' maintenance of up-to-date accurate problem lists. Systems provide decision support about additions, edits and deletions for clinicians' review and action. For

example, if diabetes is not on the problem list, but hypoglycemic medications are on the medication list, the EHR system might ask the provider whether diabetes should be on the problem list. It would not automatically add anything to the problem list without professional action. Members had no comments or objections.

106 – Certification criteria only: EHR systems should provide functionality to help maintain up-to-date, accurate medication list. Certification criteria only: Use of problems and lab test results to support clinicians' maintenance of up-to-date accurate medication lists. Systems provide decision support about additions, edits, and deletions for clinicians' review. For example, an antibiotic (not for acne) has been on the medication list for over say a month, the EHR system might ask the provider whether the medication is a chronic medication. The system will not make any changes without professional approval. A member asked where the data would be obtained. Tang said that vendors would provide the capability to write rules (but not the rules themselves) to prompt clinicians and the latter would likely pick the most common conditions. Judith Faulkner referred to the extraordinary effort involved and suggested calling out and restricting the requirements to three conditions. Tang informed her that they would come back to the topic under the CDS section. Another member agreed with Faulkner, saying to either specify the conditions or the functionalities. Tang reminded them of the purpose of a RFC.

107 – Certification criteria only: EHR systems should provide functionality to code medication allergies and link to related drug family, and code related reaction. Faulkner asked about the programming. Neil Calman said that this criterion belonged under medication interaction and suggested moving it to CDS. Tang agreed.

109 – Retire measure because it is topped out (achieved 80% threshold). Track progress to improve outcomes via CQM NQF 0028. Calman objected to the retirement of measures such as smoking status when it is known that the process is important and the outcomes are unknown and unmeasured. Calman went on to repeat his objection to retiring things that are not self-sustaining. David Lansky noted that the program is intended to drive technology; it is not an incentives program. He suggested a question to solicit comments that address this tension. Tang agreed to include an explicit question about retirement of objectives. No objections were heard. Art Davidson asked about inclusion of pregnancy as a vital sign. Tang said that the topic had not been brought up in the workgroup, although he believed that EHRs captured that information. No one argued for its inclusion.

113 – Use of structured SIG standards and ability for EHRs to consume CDS interventions from central repositories (e.g., rules for drug-drug interactions, rules for reporting diseases for public health departments, preference-sensitive care lists). The draft also included a future stage recommendation and several questions. Lansky noted the relation to quality measures questions on process suites. Mostashari said that standards for representation could be used for lists and CDS as well as quality measurement. In response to a suggestion from Lansky, Tang suggested adding a description of the ideal state and asking the public how to achieve it. Mostashari talked about the usefulness of obtaining descriptions of experiences. Someone opined that the payer community would be supportive; there may be draft standards out there somewhere. Someone else opined on broad interest from the physician community. Tang instructed staff to include all of this conversation in the RFC. Marc Probst wondered about defining a scope of interventions. Since systems cannot consume everything, it would be better to focus on specific problems. Tang said that it would be put in the RFC for crowd sourcing. He told Faulkner that this addressed her concern. Gayle Harrell asked who will develop the central repositories and who will write the rules. Tang gave an example of a RAND study that resulted in a list of clinical interventions from which an organization can choose. Faulkner said that some guidance would be helpful. Tang reminded her that the focus of the discussion was certification only. Faulkner said that the result could be every vendor programming differently. Tang explained that the HITSC and ONC staff are working on standards, which are expected to be available for Stage 3. Calman talked about the need for rapid acceleration. Perhaps application developers should develop engines for providers. A standardized way to

develop content related to evidenced-based practice is needed. Theresa Cullen, alternative for Madhulika Agarwal, asked for clarification that the issue is functionality of EHRs. Tang declared that the members agree that this is important and challenging; the RFC will solicit ideas. Numerous other topics and considerations were raised—overly broad scope, difficulty of implementation, multiple variables, cost, patents, and limited choice. Tang asked staff to arrange an update on Healthy Decisions for the next meeting, saying that information on that project could resolve some of the questions. He observed that Open CDS is an attempt at open source access. Charles Kennedy suggested stating outright that the purpose is to cause a clinical decision not otherwise taken. Tang said that the system is required to capture feedback on the use of alerts. A member said that vendors may just focus on any 15 interventions without adequate consideration of their relative importance. Davidson asked about NLM value set. Mostashari talked about having a vision that the democratization of tools will enable providers to choose. Tang affirmed the concept of provider choice as well as patient support tools.

204 A – Explore the readiness of vendors and the pros and cons of including certification for the following in this objective: images (actual images, not just reports); radiation dosing information from tests involving radiation exposure in a structured field so that patients can view the amount of radiation they have been exposed to. MENU: Progress notes (re: OpenNotes project). Someone pointed out that the latter phrase is incomprehensible.

204 B – Readiness of standards to include medical device data from the home? Someone wanted to have a dialogue with non-EHR users who produce data. Tang agreed that their feedback would be of interest but they are not part of the incentive programs. Mostashari noted various policy levers that are available, such as coordinating with FDA standards. He asked Jodi Daniels to follow up with FDA staff.

204 D – Objective: Provide patients with the ability to request an amendment to their record online (e.g., offer corrections, additions, or updates) to the record through a patient portal in an obvious manner. Christine Bechtel asked that patient portal be removed to make the statement technology neutral.

205 – Question category: What specific information should be included in the after-visit summary to facilitate the goal of patients having concise and clear access to info about their most recent health care, and understand what they can do next, as well as when to call the doctor if certain symptoms/events arise? Mostashari observed that the most important comments are those based on experience, not opinion. Tang offered to put that directive in the preamble. Faulkner reported that patients respond to information in the summary using their preferred language (which is the language in which they received the summary), thereby creating a problem for organizations that do not have the capacity to interpret that language. She argued for not allowing responses when an organization does not have interpreters. Bechtel pointed out the legal requirement for languages and said that even English speakers have problems with understanding medical language; the provider must be responsible for communicating with patients. Tang reminded them once again that the document is an RFC only.

207 - Assess readiness of raising threshold to 30% based on experience in Stage 2. Bechtel requested a question about an “appropriate” increase. Tang appeared to agree.

209 – A clarification. No objection.

302 – Feasibility to add additional fields for reconciliation e.g. social history. No objection.

304 – How might we advance the concept of an electronic shared care planning and collaboration tool that crosses care settings and providers, allows for and encourages team based care, and includes the patients and their non-professional caregivers? Think through these priority use cases: patient going home from an acute care hospital admission; patient in nursing home going to the ED for emergency assessment and returning to nursing home; patient seeing multiple ambulatory specialists needing care coordination with primary care; and patient going home from either hospital and / or nursing home and receiving home health services. What are the most essential data elements to ensuring safe, effective care transitions and

ongoing care management? How might sharing key data elements actually improve the communication? Consider health concerns, patient goals, expected outcomes, interventions, including advance orders, and care team members. What data strategy and terminology are required such that the data populated by venue specific EHRs can be exchanged. How might existing terminologies be reconciled?

What are the requirements (legal, workflow and other considerations) for patients and their identified team to participate in a shared care plan? Is it useful to consider role-based access as a technical method of implementing who will have access to and be able to contribute to the care plan? How will such access be managed? Lansky inquired about interoperability. Tang replied that the medical professions do not have a common understanding of a care plan. The data elements are free text. He indicated that the purpose of the questions was to get a better understanding of care plans. Lansky recommended asking about experience in implementation of care plans in pluralistic settings. Tang agreed to add something to solicit information on problems that were solved. Mostashari wanted to know about payment environments.

305 – Measure: For patients referred during an EHR reporting period, referral results generated from the EHR, 50% are returned to the requestor and 10% of those are returned electronically. No objections voiced.

Tang moved on to a section of the draft RFC that listed recommended objectives for Stage 3 added in response to a letter from the CDC director describing his request to incorporate conditions characterized by high prevalence and low treatment.

Use EHR technology features (such as structured recording of vital signs and registry capabilities to identify patients meeting criteria for hypertension disorder. In some studies, up to 30% of patients with hypertension remain undiagnosed.

Use EHR technology features (registries, CDS, patient reminders) to achieve improvements in hypertension control across their practices.

Report the adequacy of blood pressure control in their practice populations using NQF measure 0018. Mostashari suggested asking about approaches other than core. Someone wondered about the logic used by providers in selecting measures. Probst opined that organizations that are already managing hypertension well should be allowed to select other conditions more relevant to their populations. Lansky opined that CDC should work with payers, rather than use this technology program, to achieve its objectives. Mostashari opined that the incorporation of the measure would give providers a way to use evidence in payment; the absence of a universal measure inhibits the use of outcomes in payment policy. Faulkner talked about obesity being a root cause of chronic conditions. She wanted to add childhood BMI as an example. She also talked about dental problems and the lack of coverage.

EPs and EHs should use EHR technology to refer tobacco users to public health sponsored tobacco quit-line services. Members had no comments.

Reducing tobacco use is critical to achieving the Million Hearts goal, and CDC opposes retiring the objective that EPs and EHs need to record and respond to tobacco use in patients, whether or not they have elected to report on the smoking cessation CQM. Tang asked about making a fifth category in the CDS or a core measure. Calman observed that repeated discussions about the value of core measures have revealed that they do not work well because they are not relevant to all practices. Lansky said that insofar as there are many high priority conditions, comments on preferred conditions should be obtained from the public. Mostashari reminded him that there was no need to ask the public when CDC has the expertise in and the responsibility for disease prevention. CDC experts have discussed and weighed the priorities and the committee should defer to their advice. Several members indicated their preference for asking the public. Tang called the question—to include the CDC recommendations beginning with hypertension. Members agreed with including the CDC recommendation in the RFC.

Having concluded the discussion of the CDC request, Tang moved to another item: Is there flexibility in achieving a close percentage of the objectives, but not quite achieving all of them? What is the downside of providing this additional flexibility? How will it impact providers who are achieving all of the criteria? If there is additional flexibility of this type, what are the ways this can be constructed so that it is not harmful to the goals of the program and advantageous to others? Probst announced that although he favored flexibility, he was concerned about interoperability, which is affected by the weakest link. Tang acknowledged that the CMS report indicates that interoperability is the “most highly avoided” measure.

David Lansky, Chair, Quality Measures Workgroup, reported on that section of the draft RFC. In response to Mostashari’s remarks, he talked about seeking opportunities for increasing interoperability. He asked about calling out specific conditions. The list of high priority conditions blends with qualitative improvements in quality measurement. He asked about a question on a more aggressive effort. He mentioned a transformational platform and suggesting adding a preface regarding more dramatic change. Members expressed opinions on realistic scope, disruptive innovation, alignment of CMS programs, doing more versus doing less, could do versus should do, and implications for ACOs. Eventually, Lansky asked for the committee’s agreement to invite public comments on these concerns. No disagreement was heard.

Mostashari suggested asking about competencies and capabilities to reduce the burden on developers and vendors. Faulkner objected to being overly prescriptive.

In response to a question about the start of the 45-day comment period and the burden of commenting over a holiday period, Robertson announced that the publication of the RFC is scheduled for next week. Someone requested a 60- or 90-day comment period. A staff member responded that lengthening the comment period would adversely affect the overall schedule for Stage 3.

There were no changes in privacy and security objectives to report and discuss.

Mostashari reported on the ONC addendum and said that he was looking for more disruption. He asked the members to reconsider some of their recommendations, for example, to include more robust query and patient matching. Mostashari said that some of his requests were for highlighting; others were for reconsideration. Following his explanation for each, Tang proceeded to move through the list for discussion.

Query – IEWG101: Certification criteria: The EHR must be able to query another entity for outside records and respond to such queries. The outside entity may be another EHR system, a health information exchange, or an entity on the NwHIN Exchange, for example. Could a MENU objective be added to recognize providers who are proactively querying (e.g. for patients transitioned without a care summary, an individual in the practice should query an outside entity)? Should the measure be for a number of patients or a percentage of patients? Members agreed to include the questions in the RFC.

Identity matching – What could facilitate identify matching – query e.g. maintain external patient id, standards for matching attributes? Members agreed.

Transitions of Care –SGRP303: The EP, EH or CAH that site transitions or refers their patient to another setting of care (including home) or provider of care provides a summary of care record for 65% of transitions of care and referrals (and at least 30% electronically). Could the electronic threshold be raised to 50% for this measure? Members agreed to include the questions in the RFC.

Patient Generated Data – SGRP204B: Provide 10% of patients with the ability to submit patient-generated health information to improve performance on high priority health conditions, and/or to improve patient engagement in care. What information would providers consider most valuable to receive electronically from patients? What information do patients think is most important to share electronically

with providers? What data would be most valuable as an initial minimum set for patients to send to providers electronically outside the clinical visit? What other data could be added in the future? McGraw asked how the ONC staff's reformulation was different from the original statement. She reminded Mostashari that a public hearing had already generated the requested information. The Tiger Team and workgroups used that information in their deliberations. Mostashari agreed to reconsider this request. Tang asked McGraw to work with ONC staff to resolve the issue.

Clinical documentation – What is the best balance between ease of clinical documentation and the ease of practice management efficiency? Members agreed to include the questions in the RFC.

Test tracking – Could an additional objective be added for test tracking (e.g. 10% of test results are acknowledged within 3 days)? Members agreed to include the questions in the RFC.

Safety risk assessment – To ensure the safety of EHRs, should there be a meaningful use requirement for providers to conduct a health IT safety risk assessment? Are there models or standards that we should look to for guidance?

Consent management – Some federal and state health information privacy and confidentiality laws, including but not limited to 42 CFR Part 2 (for substance abuse), establish detailed requirements for obtaining patient consent for sharing certain sensitive health information, including restricting the recipient's further disclosure of such information. How can EHRs and HIEs manage information that requires patient consent to disclose so that populations receiving care covered by these laws are not excluded from health information exchange? How can MU help improve the capacity of EHR infrastructure to record consent, limit the disclosure of this information to those providers and organizations specified on a consent form, manage consent expiration and consent revocation, and communicate the limitations on use and restrictions on re-disclosure to receiving providers? Are there existing standards, such as those identified by the Data Segmentation for Privacy Initiative Implementation Guide, that are mature enough to facilitate the exchange of this type of consent information in today's EHRs and HIEs? McGraw declared agreement.

Application programming interface – There are many cases where EHR systems supply clinical information to other systems, e.g. registries and accountable care organizations. Is it possible to create an application programming interface (API) to represent the information defined in a CCDA so that systems can communicate with each other? Is the information defined in the CCDA the appropriate content for other uses of clinical information? Faulkner expressed worry about the limitations of API and Mostashari requested her help in rewriting the questions. Members agreed to include the questions in the RFC.

Prescription drug monitoring – SGRP113: Use clinical decision support to improve performance on high priority health conditions. Could certification criteria be added for EHR access to prescription drug monitoring programs (PDMP)? Certification criteria: EHR technology supports streamlined access to the PDMP data, for example, via a hyperlink or single sign-on for accessing the PDMP data or via automated integration into the patient's medication history. Members agreed to include the questions in the RFC.

Non-percentage based measures – What can be included in EHR technology to give providers evidence that a capability was in use during the EHR reporting period for measures that are not percentage based? This capability will need to support measures that occur in all stages of meaningful use (e.g. there are yes/no measures in Stage 1 that still need to be supported). Are there objectives and measures that should be prioritized to assist providers in showing that the capability was enabled during the reporting period? Members agreed to include the questions in the RFC.

Referral tracking – SGRP305: EP/EH/CAH to whom a patient is referred acknowledges receipt of external information and provides referral results to the requesting provider, thereby beginning to close the loop. Add receipt of test results? Members agreed to include the questions in the RFC.

Level AA conformance – SGRP204A: Add certification criteria for Level AA conformance? Members agreed to include the questions in the RFC.

After acknowledging agreement with the ONC requests, Tang asked for any final comment on the draft RFC. Bechtel pointed out that an objective pertaining to a warning prior to patient download had been omitted. Claiming that its approval was referenced in the October meeting summary, she asked for its reinsertion.

Robertson noted that members Scott White, Thomas Grieg and Pat Conway had joined the meeting.

Public Comment

Donna Mazik, National Association of School Nurses, informed the group that with regard to 303-304 and the shared care planning tool, children can be transitioned to school as well as home. School nursing and school health center care settings should be considered.

Jeff Huntle, Idaho and Washington Regional Information Center, commented on the importance of foundational data elements to meaningful and value-based reimbursement. He pointed out that the first efforts in CDS should focus on accuracy of the foundational data elements. If data are accurate, every condition can be managed. He reported that in his experience the PCP field is often inaccurate, thereby undermining efforts toward patient management by ACOs. He urged the committee to make efforts to increase accuracy of data.

Micki Maclean, Electronic Health Record Association, requested that the comment period be changed to 90 days. Her members need more time to comment on this very complex RFC.

Mari Savickis, American Medical Association, also requested an extension of the comment period to no earlier than January 31.

Healthway, Inc. and the eHealth Exchange

Mariann Yeager, Interim Executive Director, Healthway, Inc. described e-Health Exchange as a community of exchange partners who share information under a common trust agreement, using a shared set of technical requirements, policies and testing process. It is based upon national standards, NwHIN and other standards, services and policies. It started as an NwHIN program initiative (NwHIN Exchange), has been in production since 2009 and recently transitioned to a public-private partnership, operated by Healthway. A return on investment has been obtained through efficiencies and cost savings realized to date through a multi-party trust agreement and shared infrastructure and governance. Benefits include lessening the burden of testing prior to exchanging with a new partner and expanding coverage throughout the United States, reaching hundreds of hospitals, thousands of providers and millions of patients. Healthway is a nonprofit organization chartered to support the eHealth Exchange and focused on cross-industry collaboration to advance HIE implementation. Nearly 40 organizations participate with more joining weekly. Growth is particularly rapid in the private sector with the shift to support of private-to-private exchange. Technology partners are growing in numbers and diversity. Healthway assumed responsibility for operations October 1, 2012, including for the onboarding process (i.e. receipt / processing of applications), participation testing (facilitated by CCHIT as testing body), issuance of digital certificates and service registry. A coordinating committee provides support. The DURSA and operating policies and procedures will be maintained. Thus, NwHIN Exchange was rebranded and is operating as eHealth Exchange.

She went on to assure the members that DURSA remains in full force and effect. The coordinating committee retains all authorities as specified in the DURSA. The Healthway board has no oversight responsibilities with respect to Exchange; it will operate under an agreement with the coordinating committee. Service fees will be assessed in the future.

Testing is being revamped and moved from an internal function of eHealth Exchange to an accrediting testing lab. This is consistent with national strategy and raises the bar significantly with a focus on interoperability testing. The new approach will be significantly less costly for eHealth Exchange to support and will be cost effective for technology providers and applicants. Participation in testing is required as a condition of joining the eHealth Exchange.

Focusing on DURSA, she explained that a comprehensive, multi-party trust agreement will be signed by all eligible entities who wish to exchange data among eHealth participants. The DURSA eliminates the need for “point-to-point” agreements and requires signatories to abide by common set of terms and conditions that establish participants’ obligations, responsibilities and expectations. The obligations, responsibilities and expectations create a framework for safe and secure health information exchange, and are designed to promote trust among participants and protect the privacy, confidentiality and security of the health data that are shared. It assumes that each participant has trust relationships in place with its agents, employees and data connections (end users, systems, data suppliers, networks, etc.). As a living document, the agreement will be modified over time.

Q&A

McGraw suggested making a clearer differentiation between NwHIN and this new structure. She endorsed consumer participation in it.

In response to other comments, Yeager acknowledged that although all participants are exchanging information, they are not exchanging equally. Factors contributing to differential exchange should be studied. The participants include ACOs. The DURSA has been adapted for states and other organizations. The connectivity can be used for reporting on quality measures as well as exchange of patient information.

ONC Update

Jodi Daniel informed the group that the ONC annual meeting will occur in December, saying that members are invited although the focus is on grantees. The meeting can also be accessed via the Web. ONC launched the HIT FACA database to enable interested persons to volunteer for work on FACA-related groups. 379 individuals have registered. Staff will use the database, along with other avenues, to make appointments to the soon-to-be-formed consumer workgroups. ONC also wants to convene an ACO clinical care workgroup. The Infobutton design contest was launched October 15. A month-long e-consent project was funded to help patients make informed choice. The pilot sites are in New York.

Carol Bean talked about the HIT certification program. On October 4, 2012, the Temporary Certification Program sunsetted and the ONC HIT Certification Program began. This new structure consists of several components. The National Voluntary Laboratory Accreditation Program (NVLAP), administered by the National Institute of Standards and Technology (NIST), accredits Accredited Testing Laboratories (ATLs). The ONC-Approved Accreditor (ONC-AA) accredits and oversees ONC-Authorized Certification Bodies (ONC-ACBs). The NVLAP ATLs tests HIT, including Complete EHRs and/or EHR Modules. An ONC-ACB certifies HIT, including Complete EHRs and/or EHR Modules. The testing and certification entities are separated by a firewall. The certification body reports to ONC for posting on the certified product list. At the most recent count, 2,744 products are posted. These changes have no impact on Temporary Program certifications. Bean went on: ONC is releasing test procedures for comment in waves with the final release scheduled this week. The 2014 Edition will be live January 2, 2012. Over the next six weeks, test procedures will be finalized and operations set up. The technical requirements were

established in a final rule (September 4, 2012). Approximately 100 comments are being received per procedure. Eight tools have been developed for the 2014 Edition. The tools are available for downloading. A technical training session is scheduled for November 14 in DC.

In early 2013 ONC will introduce test scenarios as an option to unit based testing. This approach allows for changing the order of testing, removal of a test if not applicable and flexibility. The HITSC Implementation Workgroup worked closely with staff on the five scenarios, which will be evaluated per the 2014 Edition.

Q&A

In response to a question on quality control of the certifiers and difference in interpretation, Bean acknowledged that the use of multiple certifiers introduces the potential of variation. ONC has several control processes in place. The requirements are more stringently enforced now than previously. ONC convenes weekly meetings throughout testing and certification to achieve consistency. However, organizations are often reluctant to share information. ONC conducted a review of a sample of testing procedures. Staff has observed testing. The Office of the Inspector General conducted a review after which ONC emerged unscathed. She clarified that in the enumeration of the 2,744 products, different versions are included in the count.

Tang asked Mostashari about the increase in vendors and their expected consolidation over time. Mostashari said that approximately 400 vendors are involved in meaningful use. Most likely, concentration will follow the experience of other industries. In the beginning, there are many start-ups and lots of innovation. Over time, ownership becomes more concentrated. He indicated that he is trying to minimize the pain of vendors falling out of the market.

Bean outlined the steps purchasers should take when certified products do not perform. First, they should deal with the vendors. If satisfaction is not obtained, a purchaser may go to the certification body. The next step is to contact ONC. To date, no vendor has been removed from the program. Staff receives from 50 to 70 email complaints and questions per week. Nearly all complaints are resolvable. The complaint management system is public.

Public Comment

None

SUMMARY OF ACTION ITEMS

Action item #1: The summary of the October 2012 HITPC meeting was approved as circulated.

Meeting Materials

- Agenda
- Summary of October 2012 meeting
- Presentations slides: Privacy and Security Tiger Team, Meaningful Use Workgroup, ONC, CMS
- Draft RFC