HIT Policy Committee
DRAFT
Summary of the May 22, 2015 Virtual Meeting

ATTENDANCE (see below)

KEY TOPICS

Call to Order

Michelle Consolazio, Office of the National Coordinator (ONC), welcomed participants to the Health Information Technology Policy Committee (HITPC) meeting. She reminded the group that this was a Federal Advisory Committee (FACA) meeting being conducted with opportunity for public comment (limited to 3 minutes per person), 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.

Remarks and Review of Agenda

Vice Chairperson Paul Tang announced that the meeting had been called to act on the reports of three workgroups' responses to the HITPC's comments made on their presentations of May 12.

2015 Certification NPRM

Implementation, Usability, and Safety Workgroup Co-chairperson Larry Wolf reported. He emphasized that the workgroup had much diversity of thought and opinion, making it challenging to achieve consensus. He encouraged readers of the comments to pay particular attention to the information contained in the appendices so that nuances, cautions, and recommendations can be well understood. He presented slides that clearly stated agreement or disagreement with each item NPRM assigned to the workgroup in addition to the main points of discussion and recommendations:

- In-the-Field Surveillance and Maintenance of Certification - Disagree
- Transparency and Disclosure Requirements - Agree
- Open Data Certified Health IT Product List (CHPL) – Agree
- Complaints Reporting – Agree
- Adaptations and Updates of Certified Health IT - Agree
- Decertification - Disagree
- 170.315(g)(3) (i) User-centered design processes (UCD) - Agree
- § 170.315(g)(4) Quality Management System - Agree
- §170.315(g)(5)Accessibility Technology Compatibility – Agree
- §170.315(g)(8) Accessibility-centered Design - Agree

Regarding summative testing, the workgroup said that formative evaluation must be required. On pharmacogenomics data, it said that a process to advance standards that highlight priorities is needed, but certification should not be required. Wolf went on:

- Base EHR & Certified EHR Technology Definition - Agree
- Subpart E – ONC Health IT Certification Program - Agree
- Modifications to the ONC Health IT Certification Program - Agree

- Removal of Meaningful Use Measurement Certification - Agree
- Types of care and practice settings - Agree
- Referencing the ONC Health IT Certification Program - Agree
- Design & Performance - Agree
- ONC Health IT Certification Program & Health IT Module – Agree

The workgroup also listed comments on utility of CHPL, other software sources, expansion use of certification, timeline, complexity, maturity of standards, variations among partners, UCD, and requiring teams to use UCD process. Finally, although the workgroup was not specifically opposed to decertification as a deterrent, ONC must gather information on process and planning for consequences must be outlined before the workgroup could support this element. ONC has produced a Report to Congress: Report to Congress on Health Information Blocking.

Discussion

National Coordinator and Acting Assistant Secretary of Health Karen DeSalvo said that the presentation was responsive to the questions raised at the May 12 meeting.

Paul Egerman, a member of the Implementation, Usability, and Safety Workgroup, said that the group process had not been an easy one. He acknowledged that he had contributed to the lack of consensus. He said that he was opposed to the report and intended to vote against it. Certification should be only for software testing not to regulate the industry. It is not the right tool for regulation. The UCD and software testing discussion was frustrating because the emphasis is on process not outcomes. The desired outcome is usability and patient safety. Discussion should have focused on factors that contribute to usability and safety. He complained about the NIST representatives being overly religious about standards.

Deven McGraw emphasized the importance of noting votes in opposition. Kathy Blake said that the conditional certification option is worthy of consideration. She asked that ONC staff think about downstream implications. What would happen to providers if conditional certification were lost? Wolf acknowledged that today's presentation in response to questions of May 12 did not contain input from workgroup members. The response was based on input from Chairperson David Bates, himself and staff. Conditional certification would be based on a smaller test pool; it is a gray area.

Tang called for an electronic vote on agreement with the recommendations as presented. Consolazio announced that the three new members who were introduced at the May 12 meeting were not eligible to vote. Several members were not able to vote electronically; consequently, voice votes via phone and e-mail votes were accepted. Scott Gottlieb announced his vote no. DeSalvo and Christine Bechtel announced their abstentions, the latter saying that she had joined late and did not hear the complete report. Tang announced that the report was approved with 8 in favor, 3 opposed and 2 abstained.

> **Action item #1: The recommendations of the Implementation, Usability, and Safety Workgroup on the Certification NPRM were accepted without modification by a vote of 8 in favor, 3 opposed and 2 abstentions.**

Tang asked for a motion to approve the summary of the May 12 meeting as circulated although he said that he had several changes to submit. A motion for approval was made by Gayle Harrell and seconded by Troy Seagondollar. The motion was approved unanimously by voice vote.

> **Action item #2: The summary of the May 12, 2015 HITPC meeting was approved unanimously by voice vote.**

Meaningful Use Stage 3 NPRM Comments

When the NPRM was published, its eight objectives and key questions were assigned among four workgroups for comments. Those workgroups gave preliminary reports at the April HITPC meeting at which time members had opportunity to ask questions and give opinions. Only a few changes were requested prior to the committee's preliminary approval. The HITPC voted to accept each of the four preliminary reports. Following the April meeting, the workgroups met to complete their comments and recommendations. The chairpersons of three workgroups met with the Advanced Health Models and Meaningful Use Workgroup to identify and reconcile any differences in the recommendations across workgroups. The four workgroups reported again at the May 12 HITPC meeting. The recommendations by the Advanced Health Models and Meaningful Use Workgroup and the Consumer Workgroup on the stage 3 NPRM were accepted, but the reports of the Interoperability and HIE Workgroup and the Privacy and Security Workgroup were not accepted, pending additional discussion and resolution of select issues. The purpose of this May 22 meeting was to act on those revised recommendations.

Privacy and Security Workgroup Chairperson Deven McGraw reported on the updates and additions to the recommendations since the May 12 presentation. ONC is already working with FTC and OCR to develop mobile health best practice guidance for developers which will eventually promote protection of user data. The workgroup urges the agencies to work quickly to widely disseminate this guidance so it can be useful for stages 2 and 3. Guidance should include guidance for app developers on best practices for protecting privacy and security of information collected by the app and connecting with EHRs covered by HIPAA. Development of guidance for patients, consumers and providers should include: checklists for consumers on what to look for in a privacy and data use policy; and mechanisms for consumers to compare privacy policies across apps (similar to ONC's model PHR notice). She went on. ONC and OCR should issue guidance addressing the intersection between the meaningful use patient engagement objectives, the certification requirements, and HIPAA's patient access rights. The guidance should be updated to also address transmit-related risks and issued in a timely fashion to assist providers (and CEHRT vendors) in making VDT and APIs available to patients as part of meaningful use. She called for further exploration of a multi-stakeholder (including industry and patients) developed program for evaluating patient-facing health apps. Even a voluntarily adopted guideline could have some teeth: The FTC under its existing FTCA authority can enforce voluntary best practices for those who adopt. The Consumer Workgroup (with assistance from the Privacy and Security Workgroup) should continue to flesh out the details of a program to evaluate patient-facing health apps, considering such issues as:

- Whether it should be a certification program, which includes testing (similar to the CEHRT program), or some other evaluation vehicle (accreditation, registry, etc.).
- Whether it should be voluntary or connected to the CEHRT and/or MU program.
- Potential incentives/disincentives for vendors to participate.
- What should be the focus of the program?
- What should be the role of ONC and other federal entities?
- Costs and potential impact on innovation.

Discussion

Bechtel said that she fully supported the recommendations. Jody Daniel, ONC, inquired about the role of government. McGraw reiterated that the recommendation is to explore, not necessarily to do. Harrell said that ONC needs to examine whether it has authority to implement these recommendations.

Blake expressed concern about the size of the task. With the number of developers of apps, how would one determine which to evaluate. The concept is wonderful, but it should be scoped. McGraw responded again that the recommendation is to explore.

DeSalvo called for a voice vote to accept the recommendations of the Privacy and Security Workgroup. No opposition was heard. DeSalvo abstained.

> **Action item #3: The recommendations of the Privacy and Security Workgroup on the stage 3 NPRM were accepted with one abstention.**

Interoperability and Health Information Exchange Workgroup Chairperson Micky Tripathi outlined the issues that the HITPC sent back to the workgroup and responded to each:

> Request to review recommendation to not allow the inclusion of "selfies": The workgroup's consensus is that "selfies" do not support the intent of objective 7 which is enhancing transitions of care with clinical information otherwise unavailable to the receiving provider. While selfies may be useful as "alerting" mechanisms within large health care organizations, that is not the intent or goal of objective 7. Therefore, we affirm our previous recommendation to not allow "selfies".
>
> Approved Consumer Workgroup recommendation adds "or data from a non-clinical setting is incorporated in the EHR" to the HIE objective. How should it be incorporated? Reconciling these measures is not straightforward because they apply to different types of information from different types of providers for different groups of patients. The workgroup did not have time to get consensus on a specific recommendation that merges the measures. It recommended that CMS use the following principles in doing so:
>
> - Merge with measure 2 as recommended
> - Do not set separate targets for "non-clinical providers" (e.g., separate measure or X% for all providers, Y% for "non-clinical providers")
> - Set a two-tier objective, with a higher threshold with greater content/format flexibility and a lower threshold based on CCDAs (e.g., incorporate any type and format of clinically relevant information for 25% of TOCs/referrals, incorporate CCDAs for 15% of TOCs/referrals)
> - Retain TOCs/referrals + never before encountered + electronically queried as denominator
> - Require electronic means of transmission
> - Allow exclusion for "electronic means not available"
> - Allow incorporation of electronically queried information outside of specific episodes of care
> - Clearly define the meaning of "incorporate" for CCDA and non-CCDA information
>
> Can the workgroup provide any more guidance on which specialties should be allowed exclusions from information reconciliation requirements? The workgroup was not able to determine any additional criteria in the time allotted.
>
> Can reconciliations that happen prior to the patient visit count for measure: The measure does not address the timing of when a reconciliation can occur and count in the numerator. The workgroup asks that CMS provide clarity that reconciliations occurring prior to the patient visit can count towards the numerator.
>
> How are transfers and referrals counted if the patient doesn't show up for the appointment? The denominator for measure 2 only includes patient encounters so instances where the patient doesn't show up would not be included in the measure.
>
> Impact of data segmentation certification criteria on transitions of care approach: The workgroup does not see specific impacts from the addition of data segmentation to certification on the recommended approach to the HIE objective.

Discussion

Members asked no question. DeSalvo called for a voice vote to accept the recommendations. DeSalvo abstained. No opposed votes were heard.

> **Action item #4: The recommendations of the Interoperability and Health Information Exchange Workgroup on the stage 3 NPRM were accepted with one abstention.**

Announcements—Agenda Item Added

Consolazio announced that a Quality Measurement Task Force was being formed to respond in June to two CMS NPRMs on that topic. A public hearing is scheduled for June 2. The next meeting of the HITPC is scheduled for June 9.

Public Comment

David Tao, ICSA Labs, agreed with the IOWG's recommendation to disallow selfies. While there is benefit in an "alert" to a provider even if the provider is using the same EHR instance, sending a Summary of Care Record via Direct is not a good approach. Alerting can be done a variety of ways within the EHR. If there is no alert built into the EHR, then a secure message saying check the latest encounter in the record without a CCDA attachment would be a better option.

SUMMARY OF ACTION ITEMS

> **Action item #1: The recommendations of the Implementation, Usability, and Safety Workgroup on the Certification NPRM were accepted without modification by a vote of 8 in favor, 3 opposed and 2 abstentions.**
>
> **Action item #2: The summary of the May 12, 2015 HITPC meeting was approved unanimously by voice vote.**
>
> **Action item #3: The recommendations of the Privacy and Security Workgroup on the stage 3 NPRM were accepted with one abstention.**
>
> **Action item #4: The recommendations of the Interoperability and Health Information Exchange Workgroup on the stage 3 NPRM were accepted with one abstention.**

Meeting Materials

- Agenda
- Summary of May 12 2015 meeting
- Presentations and reports slides
- Workgroup reports and background materials

Meeting Attendance								
Name	05/22/15	05/12/15	04/07/15	03/10/15	02/10/15	02/10/15	01/13/15	12/09/14
Alicia Staley				X				X
Anjum Khurshid	X	X	X	X	X	X	X	X
Aury Nagy								X
Brent Snyder	X	X						

Chesley Richards			X	X			X	
Christoph U. Lehmann		X	X	X			X	
David Kotz			X	X	X	X	X	
David Lansky	X	X	X	X	X	X	X	X
Deven McGraw	X	X	X	X	X	X	X	X
Devin Mann				X	X	X	X	X
Donna Cryer	X	X						
Gayle B. Harrell	X	X	X	X	X	X	X	X
Karen DeSalvo	X	X		X	X	X	X	X
Kathleen Blake	X	X						
Kim Schofield	X	X	X		X	X	X	X
Madhulika Agarwal		X	X					
Neal Patterson		X	X		X	X		X
Patrick Conway								
Paul Egerman	X	X	X	X	X	X	X	
Paul Tang	X	X	X	X	X	X	X	X
Scott Gottlieb	X		X		X	X		
Thomas W. Greig			X	X			X	
Troy Seagondollar	X	X	X	X	X	X	X	X
Total Attendees	**13**	**16**	**16**	**17**	**17**	**17**	**17**	**14**