Health IT Policy Committee

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

HIT Policy Committee
FINAL
Summary of the June 30, 2015, 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 and called the role. She reminded the group that this was a Federal Advisory Committee Act (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 instructed members to identify themselves for the transcript before speaking.

Remarks

National Coordinator and HITPC Chairperson Karen DeSalvo welcomed members.

Review of Agenda

Vice Chairperson Paul Tang noted the agenda items. The agenda was distributed in advance of the meeting. He asked for a motion to approve the summary of the May 22 meeting as circulated. A motion was made and seconded. The motion was approved unanimously by voice vote.

> **Action item #1: The summary of the May 22, 2015, HITPC meeting was approved unanimously by voice vote.**

Tang thanked Deven McGraw for her years of work on behalf of the committee. McGraw has accepted a position at OCR, where she will continue to work on security and privacy.

Inpatient Prospective Payment System NPRM

Quality Measure Task Force (QMTF) Co-chairperson Cheryl Damberg presented recommendations on a CMS proposal. In addition to the following recommendations, the slides listed rationales and qualifications:

- The QMTF supports Release 3 of the Quality Reporting Document Architecture (QRDA) Category I standard for individual-level quality reports and the November 2012 version of the QRDA Category III standard with the September 2014 errata for aggregate-level quality reports.
- ONC and CMS should continue supporting development and pilots of the harmonized CDS and CQM standards — namely the Quality Improvement and Clinical Knowledge (QUICK) FHIR-based standards — and drive stakeholders and vendors to move promptly in this direction when the standards become more stable and mature.
- The QMTF recommends CMS indicate its commitment to implementation milestones that will align with the industry and provider implementation of these harmonized standards. This

alignment will allow the industry, providers and CMS to adopt the QUICK FHIR-based standards in a coordinated and timely fashion.

- Data elements known to be required for risk-adjusted measurement should be included in the core data set.
- CMS should identify innovation and measurement centers that have the following capabilities and leverage them to quickly advance measurement of outcomes.
- CMS and ONC should prioritize alignment of the data elements across programs.
- Rather than specifying a list of data elements, the QMTF suggests better integration of the reporting requirements with existing EHR standards for reporting CQM data, such as QRDA.
- Data collection requirements should be very specified and suited for a specific application (pre-defined) rather than broad to reduce burden.
- The QMTF recommends that CMS accelerate its work to identify the data elements, as well as the definitions of those elements, that they intend to require so that an appropriate standard can be determined.
- The QMTF also recommends CMS use pilot projects and other approaches to test an expanded set of data elements for potential use in quality measurement by a wider set of entities (e.g., health care payers). The QMTF suggests that CMS undertake such pilots after first defining the core set of clinical data elements.

Discussion

In response to questions from David Lansky, Damberg indicated that the task force did not discuss interfaces with hospitals, although it could be an item for subsequent meetings. Task force members agreed that it does not make sense to collect data without a specific purpose in mind. It recommends the collection of data needed for specific applications. Task Force Co-chairperson Katherine Blake said that the quality of data can be better ensured when collection is focused. Lansky talked about the advantages of a flexible platform. Damberg said that it was covered in the first recommendation. Tang explained that in the past the HITPC had recommended use of a platform to enable more flexibility with measures. He asked that Damberg and Blake review those recommendations and incorporate them in their subsequent work.

Regarding a time frame for new standards, Blake noted that the variation in maturity of standards and ongoing work and fixes on standards make it difficult to predict time of implementation.

> **Action item #2: It was moved and seconded to approve the recommendations of the QMTF. The motion carried unanimously by voice vote.**

Recommendations on Advanced Health Models and Meaningful Use

In his role as chair of the Advanced Health Models and Meaningful Use Workgroup, Tang reported. He described a hearing convened June 2 and showed slides prepared by staff summarizing output from the testimonies. The following recommendations were presented and explained:

- Promote greater standardization and usefulness of human services and clinical data across systems utilized by all health and service professionals, caregivers, individuals, and their families.
- Promote greater standardization for social determinants of health data, including data reported by individuals, families and caregivers, and related performance measures.

- Accelerate the implementation of dynamic, shared, longitudinal care planning models that incorporate information from both clinical and non-clinical services and empower individuals to manage and inform their own health and care.
- Explore better individual matching strategies to facilitate aggregation of data across clinical and non-clinical settings and other high-priority use cases.
- Provide clarifying guidance and disseminate best practices related to sharing individual data among HIPAA-covered entities and other community organizations.
- HHS should support additional development and promote utilization of population-based outcome measures that can measure health across an accountable community.

Each of the six recommendations was further elaborated by a list of questions for HHS and ONC to consider.

Discussion

Troy Seagondollar asked about discussion of APIs and interoperability. Tang responded that the hearing participants wanted standards so that data can flow seamlessly.

Blake talked about potential harmonization with the recommendations from the IOM report on measures of societal well-being. She referred specifically to the roles of social and community organizations in prevention and reduction of obesity and unintended pregnancy, as well as other outcomes for which the clinical influence is minimal.

Lansky observed that the scope of the recommendations is quite broad; he suggested sequencing the recommendations beginning with the sixth one. Perhaps the establishment of a learning collaborate could be helpful. Recommendations on pilots may be overly prescriptive. Regarding standards, someone should analyze the extent to which learning about standards and flexibility over the past 5 years has been captured. Lansky advised caution about letting the health care system try to drive other domains. A global payment approach may be driving such an approach. A multi-stakeholder process is needed.

DeSalvo noted the importance of aligning policy and technology. Precision medicine requires a digital picture of the individual. She agreed on the need to prioritize. In accordance with the Interoperability Roadmap, ONC wants good policy and standards for data beyond the clinical.

Tang responded to Lansky by saying that many stakeholders do not realize they are part of the health care team. There is much to learn from community-based organizations, which is the reason for the recommendation to stage a summit.

Anjum Khurshid asked about a definition and scope of community and wondered about a role for the National Information Exchange Model. Tang responded that “accountable care community” refers both to the community that impacts an individual’s health and to a geographic area. The National Information Exchange Model works in various areas. ONC and CMS should build on its work. The workgroup will continue to make recommendations on advanced care models.

> **Action item #3: It was moved and seconded to approve the recommendations of the Advanced Care Models and Meaningful Use Workgroup, and the motion was approved unanimously by voice vote.**

Big Data Report

Privacy and Security Workgroup (PSWG) Co-chairperson Stanley Crosley showed slides on provisional recommendations. He explained that the workgroup was asked to consider privacy and security issues and potential harmful uses of big data. He presented provisional recommendations in four categories as follows:

§ 6.1 — Addressing Harm, Including Discriminatory Practices

- Without a national consensus on what constitutes harm (beyond more obvious cases of discrimination), we encourage ONC and other federal stakeholders to promote more public inquiry to fully understand the scope of the problem — both harm to individuals and to communities
- Call on policymakers to continue to monitor the use of health big data (both health data and data used for health purposes) to identify gaps in law and regulation and areas for further inquiry
- With respect to increasing transparency re: algorithms, consider an approach similar to that used in FCRA

§ 6.2 — Address Uneven Policy Environment

- Leverage most recent recommendations by the PSWG on better educating consumers about the privacy and security laws and uses of data both within and outside of the HIPAA environment
- Promote FIPS-based protections for data outside of HIPAA such as HHS and Federal Trade Commission guiding voluntary self-governance codes of conduct
- Consistent with previous HITPC recommendations, policymakers should re-evaluate existing rules governing data uses that contribute to a learning health system to be sure they provide incentives for responsible re-use of data for learning purposes
- Individuals should have strong rights to access their health information, sufficient to enable them to access, download, and transmit their health information as easily as they can with their financial information, either for their own use or to allow them to contribute their information for research into diseases that impact them or in any area of learning that they seek to support. This will require creating a “right of access” in entities not covered by HIPAA as part of the voluntary codes of conduct (see prior recommendation); it will also require strengthening HIPAA over time to bring it into the digital age.
- Educate consumers, health care providers, technology vendors, and other stakeholders about the limits of legal protection; reinforce the previous recommendations by the PSWG

§ 6.3 — Protect Health Information by Improving Trust in De-identification Methodologies and Reducing the Risk of Re-identification

- Call on OCR to be a better steward of HIPAA de-identification standards and conduct by ongoing reviews, seeking assistance from experts, and evaluating statistical methods for reducing risks of re-identification, and granting safe harbor
- OCR should also consider establishing risk-based de-identification requirements in circumstances where re-identification risk has been lowered other than through treatment of the data
- PSWG desires accountability for re-identification or negligent de-identification — but recommends against specifically asking Congress to address at this time

§ 6.4 — Supporting Secure Use of Data for Learning

- Urge the development of voluntary codes of conduct to address robust security safeguards that can be enforced by FTC
- Call on public and private sectors to educate stakeholders about cybersecurity risks and recommended precautions
- Call on policy makers to provide incentives for entities to use privacy-enhancing technologies and architectures (e.g., secure data enclaves, secure distributed data systems)
- Re-endorse prior Tiger Team recommendations
    - Security policy for entities collecting, storing, and sharing electronic health information needs to be responsive to innovation and changes in the marketplace.
    - Security policy needs to be flexible and scalable
    - Providers need education and guidance on how to comply with security policy requirements
    - HHS should have a consistent and dynamic process for updating security policies and rapid dissemination of new rules and guidance to all affected. Call on NIST to update the NIST 800-66 Revision 1 to include a description of technology to help meet the requirements

Discussion

Tang asked Crosley to use more definitive action verbs in the final recommendations. Regarding slide #14 on re-identification, he talked about the expense involved and suggested that an alternative approach to punish violations rather than prevent them be considered. Crosley assured him that the workgroup had discussed the relative benefits of penalties and the extent of liability. Not enough is yet known to recommend legislation. Workgroup members fear bad legislation. Tang said that laws to target bad behavior would be less costly than taking measures to limit access to data. How to target bad outcomes is the issue.

Blake suggested that the workgroup do further work on the movement of data back and forth, especially with regard to patient entered data. A question is whether the data or the use of data is the focus of liability. According to the PCAST Report, the latter is the focus. Breach is always a possibility. She suggested the use of the concept of proportionate liability. Crosley assured her that the workgroup members had discussed patient generated data and other data sources. He agreed that the use of the data is the issue, but a better understanding of harm is required.

Crosley said that the workgroup will use the points made during the discussion to finalize the recommendations. It is not advisable to wait for congressional action when voluntary efforts can be put into place now. Lucia Savage, ONC, said that the final recommendations will be submitted to the HITPC at the July 14 meeting. The submission will be a narrative document in the form of transmittal letter.

Blake commented again, asking that the report reference private efforts for trust authorities, such as the Sequoia Project, formerly Healtheway. Savage will follow up with Blake.

Public Comment:

Shelly Spario, Pharmacy HIT Collaborative, read a statement from her organization, which represents more than 250,000 pharmacists. Pharmacists at all levels and settings of care play a critical role in patient care and outcomes. They want to be represented in policy and standards development. They play an increasing role in wellness in primary care as well. Pharmacists want to be involved in the use of HIT to support outcome focused advanced models for health care delivery and value-based payment.

SUMMARY OF ACTION ITEMS

Action item #1: The summary of the May 22, 2015, HITPC meeting was approved unanimously by voice vote.

Action item #2: It was moved and seconded to approve the recommendations of the QMTF. The motion carried unanimously by voice vote.

Action item #3: It was moved and seconded to approve the recommendations of the Advanced Care Models and Meaningful Use Workgroup, and the motion was approved unanimously by voice vote.

Meeting Materials

- Agenda
- Summary of May 22, 2015, meeting
- Presentations and reports slides

Meeting Attendance

Name	06/30/15	05/22/15	05/12/15	04/07/15	03/10/15	02/10/15	02/10/15	01/13/15
Alicia Staley					X			
Anjum Khurshid	X	X	X	X	X	X	X	X
Aury Nagy								
Brent Snyder	X	X	X					
Chesley Richards				X	X			X
Christoph U. Lehmann			X	X	X			X
David Kotz	X			X	X	X	X	X
David Lansky	X	X	X	X	X	X	X	X
Devin Mann					X	X	X	X
Donna Cryer	X	X	X					
Gayle B. Harrell		X	X	X	X	X	X	X
Karen DeSalvo	X	X	X		X	X	X	X
Kathleen Blake	X	X	X					
Kim Schofield	X	X		X		X	X	X
Madhulika	X			X				

Agarwal								
Neal Patterson			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			X
Troy Seagondollar	X	X	X	X	X	X	X	X
Total Attendees	**12**	**13**	**14**	**16**	**17**	**17**	**17**	**17**