Health Information Technology Policy Committee
September 4, 2013

Overview

The Health Information Technology Policy Committee (HITPC) held an in-person meeting on August 7th to hear from the Food and Drug Administration Safety and Innovation Act (FDASIA) Workgroup, Meaningful Use (MU) Workgroup, and program updates from the Office of the National Coordinator for Health IT (ONC). Members also received a Data Analytics update from CMS and ONC followed with announcement of upcoming hearings.

Background

The HITECH Act, as part of the American Recovery and Reinvestment Act of 2009, was passed to help promote the adoption of health information technology (health IT) for a better health care system. HITECH established two federal advisory committees, one them being the HITPC, to assist ONC in implementing provisions of the act. The HITPC itself is composed of many workgroups, including meaningful use, information exchange, privacy & security, quality measures, and others.

Opening Remarks

This HITPC meeting marks the last for Dr. Mostashari as he plans to step down in the coming months. Dr. Mostashari went over the purpose of Meaningful Use (MU) Stage 3 and provided an overview of the overall path of the policy committee and health IT to fundamentally change how we deliver health care. "Many of the capabilities we have been laying tracks for are exactly what we need for the next step," Dr. Mostashari expressed to his peers.

Dr. Mostashari reiterated that the current roadmap in moving Stage 2 to Stage 3 is "absolutely in the right direction." A long road still lies ahead for health care professionals to be able to use electronic health records (EHRs) in the way they want to. EHRs still lack in the ability to track patient adherence to medications and provide real-time notifications on a patient's well-being or remittance. EHR tools for improving population health management needs to also be addressed.

He concluded by thanking the HITPC for their hard work and their ability to communicate among the diverse set of members to find the solutions and consensus on health IT issues, all while keeping in mind the public's benefit as the ultimate goal.

FDASIA Workgroup Update

Dr. David Bates, MD, MSc, Chair FDASIA Workgroup, presented on the Food and Drug Administration Safety and Innovation Act (FDASIA) Workgroup's Draft report on a "risk-based regulatory framework pertaining to health IT that promotes innovation, protects patient safety and avoids regulatory duplication." Following the comments presented in this meeting, the next step is to share the recommendations with the Food and Drug Administration (FDA), the Office of the National Coordinator for Health IT (ONC), and the Federal Communications Commission (FCC). These agencies will use the input from the FDASIA Workgroup to develop the risk based regulatory framework.

Dr. Bates provided updates from the three subgroups: Taxonomy, Risk/Innovation, and Regulation:

The Taxonomy Subgroup defined principles for considering what the bounds are for what is health IT and might be considered for regulation. The group assigned health IT innovations into two categories: "Subject to Risk-based Regulatory Framework" or "Not Subject to risk-based regulatory framework." Dr. Bates went over the defining characteristics of what should be included as health IT. These are known as the "Eight Key Dimensions of HIT:"

1. Intended use
2. Conditions of use
3. User type
4. Developer/ 'Manufacturer' type
5. Distribution model
6. Phase of the product lifecycle
7. Product categories
8. Other

The Risk/Innovation Subgroup has provided proposed recommendations around the development of a risk framework which will be useful in stratifying health IT by risk and assessing if any regulation is needed. The presentation included sample charts created to assess the risk of patient harm according to specific use cases. Dr. Bates pointed out that it is harder for the group to classify more complex software precisely, where the software is more dependent on context of use (often falls into the "it depends" category) The policy implications of the risk framework include the following:

- Define clearer criteria for software functions that are not regulated, but might have labeling requirements to promote transparence
- Define clearer criteria for software functions that warrant regulation, or at least greater attention
- Create a robust surveillance mechanism to track adverse events and near misses for the majority of software functions that lie in between.

The Regulation Subgroup provided details on the issues of the current regulatory framework, including potential new approaches and deficiencies, ambiguities and duplication for FDC Medical Device Regulation, ONC Certification Regulation, and FCC Regulation. The group provided the following recommendations:

- For FDA, Health IT should not be subject to FDA premarket requirements, except for some high risk products such as certain types of Clinical Decision Support (CDS) or medical device accessories.
- Vendors should be required to list products which are considered to represent at least some risk if a non-burdensome approach can be identified to doing so.
- To develop better post-market surveillance of health IT
- This approach would be provisional, to be re-examined periodically.
- These following should be further developed, which may be accomplished through private and/or public sector efforts:
    - Adoption of existing standards and creation and adoption of needed new standards addressing areas such as interoperability
    - A public process for customer rating of health IT to enhance transparency.

Dr. Bates also provided information on how current FDA mechanisms that could enable innovation, such as establishing a policy of "Enforcement Discretion" for lower-risk health IT devices.

Lastly, Dr. Bates presented on what the new risk-based framework would look like, including slides on lessons learned, innovation requirements and a summary of the overall recommendations for the FDASIA framework. The report is due by January 2014.

The following are additional resources provided from the FDASIA Workgroup:
Notes for FDASIA Recommendations Draft (Word document found on the meeting materials website)
FDASIA Promoting Innovation Summary

FDASIA Regulation Summary
FDASIA Taxonomy Summary

Meaningful Use Workgroup – Meaningful Use Stage 3 Update
Dr. Paul Tang, Chair, and George Hripcsak, Co-Chair, presented an update on an outcome-based framework for Meaningful Use (MU) Stage 3.

Mr. Tang walked through how connecting MU through outcomes works in the 'Million Hearts' goal to reduce heart attacks and strokes by 1 million every year. In this example, he showed how health IT software impacts the hospital experience from identifying risks patients, to the pre-vist scheduling, to check-in, into the exam room, and lastly, the follow-up visit.

Mr. Tang sought after the approval on the thematic strategy for developing Stage 3 rules. The strategy is to start the focus on MU Stage 3 outcomes first, then to consider the functional goals, and lastly the functional objectives for MU Stage 3 to achieve the desired outcomes. In this backwards approach, he illustrated how the group translates the desired health outcomes into MU functionality in the following examples:

- Improving quality of care & safety,
- Engaging patients and families in their care
- Improving care coordination
- Improving population and public health
- Affordable care
- Reducing health disparities

Lastly, Mr. Hripcsak provided updates on the new Deeming Framework. "Deeming" is an optional pathway that promotes innovation, reduces burden, and rewards good performance. Basically, Deeming allows high MU performers (or significant improvers) who have been doing a good job to lessen their reporting burdens for MU.
Here are the potential elements for determining eligibility for the Deeming Framework:

- Eligibility: High performer or high improver (based on 12 months reporting)
- Achieve high performance on 2 electronic clinical quality measurements (eCQMs) in each of two high priority categories (total of 4 measurements)
- Reduce disparity gap in 1 area

The next steps for the project include a new QM/ACO Tiger Team, which will review the eCQM landscape for health IT-sensitive, outcomes–oriented measures for deeming options. The tiger team will report back in two months. Then, the group can develop recommendations that can be used for Stage 3 and for the "Deeming Pathway."

The HITPC members approved of the MU Stage 2 outcomes-oriented framework and charged the workgroup to establish the complete stage 3 functionality objectives for HITPC approval in the next few meetings.

Data Update
Robert Anthony at the Office of eHealth Standards and Services at CMS presented on data collected at the end of July 2013. Here are a few key points:

- Meaningful Use (MU) has 409,839 active registrants for the program:
  - 272,550 Medicare Eligible Professionals (EPs)
  - 132,779 Medicaid Eligible Professionals
  - 4,510 Eligible Hospitals (EHs)
- A total of $15,884,674,565 in EHR Incentive Programs has been provided to participants
- 63% of all Medicare EPs who are MUers are non-primary care
- For August 2013:

- Medicare & Medicaid payments show a spike from the July 2013 slump. Mr. Anthony predicts a greater spike to occur in November where MUers jump in towards the end of the year.

Jennifer King, Research and Evaluation Branch Chief at ONC, provided a data analytics Update. Here are a few highlights:

- For Hospitals: 67% are attesting to MU through July 2013.
  - Critical Access Hospitals are showing slowest growth than other hopitals (Small urban, small rural, medium, and large hospitals). Ms. King expects further slow yet steady growth.
  - In a graph showing hospitals attesting to MU, Dr. Mostashari noted that the upper half of hospitals that have done well in attesting to Stage 1 will move onto Stage 2 in 2014. While, the lower half of hospitals (CAHs and small urban hospitals) that need more time, will be moving on to Stage 2 in 2015.
- For Professionals: 45% have attested to MU through July 2013.
  - A graph of Medicare professionals attesting to MU shows steady growth in the past few months.
  - 53% of Medicare professionals attesting to Meaningful Use in July 2013 will be moving to Stage 2.

Ms. King also presented was the 2014 Edition EHR certification update:

- ONC has updated the certified Health IT list of products that have gone through the pipeline or are currently in the pipeline for the 2014 EHR certification. The list is called CHAPEL, or CHPL, and includes 991 vendors.
- Out of the 991 vendors who have a certified 2011 certified product, 6% (56 vendors) have a certified 2014 Edition product.
  - 40 of those 56 have not met the base criteria of all 2014 requirements, but are on the path.
  - 16 have met the base criteria
- For professionals, 66% of EPs that have attested to Stage 1 used a primary vendor that had any 2014 edition product as of August 2013.
- For hospitals, 64% of EHs that have attested to Stage 1 used a primary vendor that had any 2014 edition product as of August 2013.

The last slide displays a chart on the characteristics of hospitals that have not yet attested to MU as of July 2013. An interesting highlight is that a majority of CAHs in this list (75%) are enrolled in a Regional Extension Center (REC), indicating that they are making progress in EHR adoption and use.

ONC Updates

Policy & Programs

Seth Pazinski, Division Director of Planning and Operations at ONC, quickly reviewed the following events and news. There are no new updates since the last HITPC meeting on August 7th.

1. September 16, 2013 Consumer Health IT Summit on accelerating the Blue Button Movement
2. HHS Principles & Strategy to Accelerate Health Information Exchange (HIE): Reflects stakeholder input on policy options to advance HIE.
3. Federal Health IT Strategic Plan Progress Report: describes the Federal government's strategy to improve health and health care for all Americans through use of health information and technology for 2011-2015.
4. MU Success Stories: Health IT success stories highlighting EHR implementation and MU experiences from providers around the country.
5. MU Case Studies: ME and HIE examples of successful implementation efforts.

6. MU Solutions: tools, trainings, success stories and other resources to address key challenges.
7. EHR Contracts: Guide for Purchasers and Users available here.

Standards and Interoperability (S&I) Update

Lauren Thompson, from the Office of Science & Technology at ONC, presented on the S&I Framework, initiated in January 2011. Ms. Thompson provided a summary, status, and leadership review of each of the 14 on-going S&I initiatives, organized in the following order:

Three new initiatives:

1. Structure Data Capture:
2. EU/US eHealth Cooperation
3. Data Access Framework

Others:

4. Longitudinal Coordination of Care (LCC)
5. Public Health Reporting Initiative (PHRI)
6. Blue Button Plus
7. Health eDecisions (HeD)
8. Data Segmentation for Privacy (DS4P)
9. Laboratory Results Interface (LRI)
10. Laboratory Orders Interface (LOI)

These initiatives are either completed or have not been updated:

11. Transitions of Care (ToC)
12. Provider Directories (PD)
13. esMD – Electronic Submission of Medical Documentation
14. Query Health (QH)

Announcements

Dr. Paul Tang concluded the meeting with a few announcements on upcoming hearings and a new charge:

- A virtual hearing on advanced directories on September 23rd from 9:00am-1:00pm ET
    - Will hear from four panels to talk about legal and states issues, implementers, patients & advocates.
- Virtual Hearing for accounting for disclosure on September 30th from 11:45am-5:00pm ET. The purpose is to give patients more awareness and better control over their data
    - Will hear from small and large healthcare providers, users of technology, and non-health technology
- New Charge: the Certification/Adoption workgroup will follow through with the concern from Congress on the missing players that are not eligible for MU funds, such as long-term care providers. The workgroup will research the recommendation to see if the missing players can be included in a voluntary certification program.

Meeting Materials

All meeting materials and an audio recording of the meeting can be found here, on the HITPC meeting website.

Next Meeting

The next HITPC meeting will be on October 2, 2013.