Health Information Technology Policy Committee
August 07, 2013

Overview

The Health Information Technology Policy Committee (HITPC) held an in-person meeting on August 7th to share data updates from the Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC). Presentations were made from representatives of the FDASIA Workgroup, Privacy & Security Tiger Team, the Meaningful Use (MU) Workgroup, and the Information Exchange Workgroup.

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

Opening remarks were made by Farzad Mostashari, MD, ScM, who spoke about his recently announced fall resignation as National Coordinator of Health Information Technology. Originally coming on board as the deputy national coordinator in June 2009, Dr. Mostashari was a champion for patients engaging in their healthcare through the "Blue Button" initiative and many times shared personal stories about the value and importance of bringing healthcare into the digital age. He spoke about the importance of a true partnership between a smart government and the public and private sectors in transforming and bettering healthcare. He did not share details regarding his next role though he assured everyone his commitment to transforming healthcare: "I will continue to feel passionately about the mission of improving how our system knows its patients, how our health system cares for its patients, and the difficult but necessary transitions we have to go through to deliver care differently, to engage with patients differently and to pay for care differently." He also acknowledged the "indispensible role of data and information and insights and actions that are fueled and supported by health IT."

Food and Drug Administration Safety and Innovation Act (FDASIA) Workgroup

Dr. David Bates, MD, MSc, Chair, FDASIA Workgroup, gave an update on the Food and Drug Administration Safety and Innovation Act Workgroup which is charged with developing a report by January 2014 that "contains a proposed strategy and recommendations on a risk-based regulatory framework pertaining to health IT, including mobile applications, that promotes innovation, protects patient safety and avoids regulatory duplication" to help the ONC, Food and Drug Administration (FDA), and the Federal Communications Commission (FCC), develop the risk-based framework. Dr. Bates explained that the FDASIA Workgroup and its three subgroups – Taxonomy, Risk & Innovation, and Regulation – have been meeting and deliberating for three months and incorporating public commentary.

The FDASIA Workgroup update had several key points. First, the Taxonomy Subgroup, based on a set of guiding principles, defined the assignment of health IT innovations into two categories: "Requires for Risk-based Regulation" or "Does not require risk-based regulation." Secondly, the decision tree guides assignment based on function and potential for harm. Third, the eight characteristics of what should be included as health IT innovations were defined as:

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

Dr. Bates also gave updates on the Risk Framework which "enumerates various important factors influencing the risk of software systems" and "serves as a framework to assess the factors to consider when evaluating the potential risk of patient harm arising out of the use of the software system." He presented the definitions of several terms, including harm, hazard, risk, transparency and purpose of software, and presented the matrix for the framework which includes dimensions (lower risk, medium risk, higher risk/more attention) of assessing risk of patient harm. Dr. Bates then spoke about potential issues related to the FDA, ONC and FCC, as well as cross-agency issues. He acknowledged stringency, flexibility and information as measurements of regulatory impact on innovation, noting that stringency leads to less innovation, and listed several innovation requirements. He also included a summary of recommendations for a new framework through both national accountability and local control/local accountability. He concluded with the overall recommendations, listed below:

FDASIA Workgroup Overall Recommendations

- Definition of what is included in HIT should be broad but have also described exclusions
- Patient-safety risk framework and examples should be used as building blocks to develop a more robust and transparent framework
- The agencies should address the deficiencies, ambiguities and duplication the FDASIA group has identified
- New frameworks with some of the characteristics aimed at stimulating innovation may be helpful
- Substantial additional regulation of HIT beyond what is currently in place is not needed and would not be helpful (should be Class 0), except for:
    - Medical device data systems (MDDS)
    - Medical device accessories
    - Certain forms of high risk clinical decision support
    - Higher risk software use cases
        - For the regulated software, it will be important for the FDA to improve the regulatory system
- In addition, we believe that as recommended by the IOM Committee:
    - Vendors should be required to list products which are considered to represent at least some risk and a non-burdensome approach should be developed for this
    - Better post-market surveillance of HIT is needed
        - Standard formatting of involved reports
        - Also post-implementation testing
        - Approaches to allow aggregation of safety issues at the national level, including federal support to enable this

- FDA and other agencies need to take steps to strongly discourage vendors from engaging in practices that discourage or limit the free flow of safety-related information

Privacy & Security Tiger Team: "Query/Response and MU Stage 3 Security Risk Assessment Update"

Deven McGraw, Chair, and Paul Egerman, Co-Chair, presented the Privacy & Security Tiger Team update which included a focus on the final recommendations on 1) non-targeted query and 2) Meaningful Use (MU) Attestation for Safety. Mr. Egerman introduced three types of query scenarios with a focus on "Scenario 3": query based on patient demographics using aggregator to find patient ("non-targeted"). Ms. McGraw summarized the previous recommendations and listed the existing obligations for query and response. Ms. McGraw then reviewed a panel discussion held on June 24th that included eight testimonies from panelists on operational models of non-targeted query and the policies governing those queries. After hearing the testimonies, the Tiger Team decided that the existing recommendations on meaningful choice and targeted query are sufficient in addressing non-targeted queries, and no additional policy is needed currently. Some examples of the existing recommendations include:

- Data holders may be reasonably assured of a requester's identity through, for example, the use of DIRECT certificates, membership in a trusted network or a pre-existing relationship; the data holder may be reasonably assured of a requester's treatment relationship with a patient if, for example, there is prior knowledge of the relationship, the relationship can be confirmed within a network or if the requester provides some communication of consent
- A requester's query should, ideally, present no more (but also no less) PHI that what is necessary to match to a record. Available demographics should be used prior to more specific information.
- Data holders should respond to queries consistent with their professional and legal obligations.

Next, Ms. McGraw discussed the question of any possible security risk issues (or HIPAA Security Rule provisions) that should be subject to MU Stage 3 attestation. The Tiger Team subgroup charged with deliberating this question decided that it wanted to improve accountability for complying with the existing MU security measures, specifically the requirement to perform a security risk analysis. Ms. McGraw concluded with a list of recommendations relating to this question:

- For MU Stage 3, CMS should emphasize that when an entity attests to having conducted or reviewed a security risk analysis with respect to its certified EHR technology, the entity is attesting to compliance with the HIPAA Security Rule with respect to such analysis.
- To achieve compliance with this objective, entities must:
  - Conduct a security risk analysis or review an existing risk analysis
  - Document the results of the risk analysis or review, including the actions taken (or the schedule for actions planned to be taken) to correct any deficiencies identified during the analysis or review
- Add an accountability measure, requiring entities to identify the individual(s) who is/are responsible for conducting and documenting the risk assessment.
- Link attestation to specific MU objectives, rather than present as a single, stand-alone measure.
- CMS should provide additional education, such as FAQs, to the meaningful user community on the expectations and importance of conducting and documenting security risk analyses, and correcting deficiencies. For example:

- Expand FAQs to discuss the availability/use/benefits of third party assessment tools and services, and of risk analysis checklists, particularly those developed by the regulators.

More information on recommendations, examples, and the virtual hearing can be found on the presentation slides.

Data Update

Robert Anthony, CMS, and Jennifer King, ONC, presented an update on the progress to Meaningful Use according to June figures for eligible hospitals (EHs) and eligible providers (EPs). Mr. Anthony presented on MU attestation trends. Here are a few key points:

- Meaningful Use (MU) has 405,000 active registrants for the program:
  - 269,580 Medicare EPs
  - 131,380 Medicaid EPs
  - 4,477 EHs
- $15.5 billion have been paid in incentives to 310,000 provider recipients for Meaningful Use
- Approximately 79% of all eligible hospitals have received an EHR incentive payment for either MU or AIU
- About 8 out of 10 eligible hospitals have made a financial commitment to an EHR
- Approximately 55% or 1 out of every 2 Medicare EPs Are meaningful users of EHRs
- Approximately 68% of all Medicaid EPs have received an EHR incentive payment
- 12% of Medicaid EPs are meaningful users
- Over 58%, nearly 3 out of every 5 Medicare and Medicaid EPs have made a financial commitment to an EHR
- Over 309,000 Medicare and Medicaid EPs have received an EHR incentive payment

A dip in the number of Medicare and Medicaid Payments is expected for July 2013 which has been the pattern for every July since 2011. Mr. Anthony provided further charts on the percentage of EPs and EHs meeting, excluding, and deferring the available health IT functions.

Jennifer King followed with a presentation on the progress to meaningful use for EHs and EPs. Here are a few highlights for hospitals and professionals:

Hospitals

- Two-thirds of hospitals have attested to MU
- Over 7 in 10 beds in US hospitals have attested to MU
- Increased attestation of MU by 5% for hospitals and 10% for professionals
- Breakdown of hospitals attesting for MU:
  - Large hospitals, small rural hospitals, and medium hospitals are steadily increasing in number attesting to MU
  - Critical Access Hospitals had a huge surge in middle of 2012 but are now increasing mildly in 2013
  - Small urban hospitals have lowest numbers and steadily increasing

Professionals

- 44% of all EPs have attested to MU, consisting of 56% of Medicare EPs and 12% of Medicaid EPs
- Breakdown by specialty and geographic location:
  - Primary care numbers are higher than specialty EPs attesting to MU, however both are improving along the same rate.
  - Both rural and urban EPs have nearly identical numbers attesting to MU.

Ms. King provided a recap explaining that MU engagement is broad and is increasing; however, the recent months have been slower in growth compared to 2012. The month of June shows slightly modest improvements.

Meaningful Use Workgroup: Meaningful Use (MU) Stage 3 Update
Paul Tang, Chair, and George Hripcsak, Co-Chair, presented updates on MU Stage 3. Mr. Tang led the discussion of the Draft Recommendations for Meaningful Use Stage 3. He began by giving an overview of the original principles for Meaningful Use and lessons from stage 1 which he translated into implications for stage 3. The goals for stage 3 are as follows:

- Mature standards widely adopted or could be widely adopted by 2016 (for stage 3)
- Create a critical mass of users and data in electronic form in floating boats (e.g.setup for patient engagement, HIE)
- Simplify and reduce reporting requirements
- Rely more heavily on market pull (e.g., new payment incentives); to promote innovative approaches of health IT (i.e,reward good behavior)
- Address key gaps (e.g., information exchange, patient engagement, reducing disparities) in EHR functionality that the market will not drive alone, but are essential for all providers
- Simplify MU objectives where higher level objective implies compliance with subsumed process objectives
- Consider alternative pathway where meeting performance and/or improvement thresholds deems satisfaction of subset of relevant MU functionality implicitly required to achieve performance/improvement

He also pointed out that environment has changed with the move to engaging in new models of care, consisting of increased popularity for a provider team environment and new payment models. "Meaningful Use is a floor, not a ceiling," Mr. Tang emphasized.

George Hripcsak followed with a summary and provided illustrations of the simplification/consolidation work on reducing reporting requirements. The group has simplified 43 objectives into 27 objectives. A summary on the proposed additions, deletions, modified language, and sentence placement changes can be viewed on the slides. The goal of the simplification initiative is to simplify and reduce reporting requirements for clinicians while not impinging unreasonable for vendors.

The Meaningful Use group finished up with an explanation of the "Deeming Option," an alternative option for providers to achieve outcomes and lead innovation in different ways. The goal is to create an optional pathway to allow people to relieve some of their reporting burden on a few functional objectives by achieving good outcomes. The group is currently working to set up a good way to measure outcomes. Also included in the presentation is an example framework for this program and future steps.

The workgroup will incorporate HITPC feedback into revised recommendations to be presented for HITPC approval on September 4th.

Information Exchange Workgroup: Provider Directory/Data Portability Update
Micky Tripathi, Chair, gave an update on two initiatives: provider directory and data portability.

The provider directory recommendation initiative has been in the works since July's HITPC. The group's recommendations are to include a capability for authentication and to also require authentication of the provider directory-holding entity. The group aligned ideas with the Standards and Interoperability (S&I) Framework workgroup to confirmed the recommendation to have authentication on both ends.

Mr. Tripathi also highlighted that these are certification requirements. The recommendations are solely about the capabilities that certified EHR technology should have, not a policy requirement.

The recommendations are as follows:

- Search for provider: EHR systems have the ability to query external provider directories to discover and consume addressing and security credential information to support directed and query exchange
- Respond to search: EHR systems have the ability to expose a provider directory containing EPs and EH addressing and security credential information to queries from external systems to support directed and query exchange

Mr. Tripathi also reviewed the principles and guidelines to be used for establishing standards for provider directories. Two changes in the transaction procedures for authentication have been made since the July HITPC version and are displayed in the slides.

For the Data Portability initiative, Mr. Tripathi pointed out the two elements of data portability: provider-centric (provider switching from one EHR vendor system to another) and patient-centric use case (patient requests migration of records). The group expects to see a rising demand for data portability across vendor systems as the vendor market changes, causing providers to switch vendors. The presentation followed with the challenges involved in data portability. A key issue is the difficulty of data migration, serving as a barrier to exit for providers and as a barrier to continuity of care for patients seeking to switch providers. Huge safety concerns are also involved with data migration to make sure a patient's data is correct if a hospital choses to switch vendors. Standard for data portability is also a challenge with the difficultly to agree upon set rules. The Information Exchange workgroup hopes to set a ground floor in data portability to move on and solve the current challenges.

The workgroup recommendations and details on the principles and guidelines on data portability are included in the slides.

Meeting Materials

Click here to go to the HITPC August meeting webpage to download all of the event materials.

Next Meeting

The next HITPC meeting will be held on September 4, 2013 from 9:30am – 3:00pm ET.