



Health IT Policy Committee Meeting

Meeting Notes

April 21, 2010

[Meeting Agenda](#)

On April 21, the Health IT Policy Committee hosted the 11th HIT Policy Committee meeting. Dr. Blumenthal welcomed the group, and then turned the meeting over to HITPC Co-Chair Paul Tang. The HITPC members approved the meeting minutes of the March 17th meeting and Dr. Tang reviewed the agenda for the meeting.

Certification/Adoption Workgroup Presentation on Patient Safety

Co-Chairs Paul Egerman and Marc Probst reviewed the February 25th Workgroup meeting on HIT and Patient Safety. Please note, this hearing was where Dr. Jeffery Shuren of the Food and Drug Administration presented potential FDA options for regulating electronic medical records. Mr. Egerman noted three themes stemming from the testimony on February 25th:

- Concerns were based on anecdotes and experience. Very little data was presented regarding potential patient safety issues resulting from health IT.
- Presenters continued to express confidence in the benefits of HIT implementation.
- Potential Areas for Concern include:
 - Interoperability
 - Technology Issues
 - Complex Interactions of People and Technology
 - Training
 - Implementation
 - Alert Fatigue

Mr. Egerman announced that the workgroup was submitting a revised goal and nine recommendations to the National Coordinator for consideration. The full list of recommendations can be found at: http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_11673_911602_0_0_18/CAWG_PatientSafetyRecommendations_042110.ppt#281,15,Final

Of the nine approved recommendations, the Goal, Rec. 1, Rec. 7, Rec. 8, and Rec. 9 were discussed at the meeting.

Recommendations approved (with slight edits to recommendation 1 and 2 that will appear in the upcoming meeting minutes.)

Goal: Establish a patient-centered approach to HIT safety that is consistent with the National Coordinators Vision of a learning health and healthcare system. To achieve this goal, a culture of improvement needs to be created by each healthcare entity.

- 1) A National, Transparent, oversight process and information system is proposed, similar to a Patient Safety Organization (PSO) with the following components
 - a. Confidential reporting with liability protection
 - b. Ability to investigate serious incidents
 - c. Provision of standardization data reporting formats that facilitate analysis and evaluation
 - d. Receive reports from patients, clinicians, vendors, and healthcare organizations
 - e. A reporting process to cover multiple factors including usability, processes, and training.
 - f. Receive reports about all HIT systems.
 - g. Receive reports from all software sources (vendors, self-developed, and open source)
 - h. Ability to disseminate information about reported hazards

(*The workgroup intentionally did not specify an endorsement of FDA as this body or a PSO. Instead, they listed the required criteria and intend to explore the proper organization.)

1.1) The workgroup recommends that ONC commission a formal study to thoroughly evaluate HIT patient safety concerns and to recommend additional actions and strategies to address those concerns.

7) For each stage, certification criteria should be finalized at least 18th months prior to the beginning of the certification period. If this recommendation is followed, the Phase II Meaningful Use NPRM would have to be released in December, 2010, with a final rule out by April 2011. This suggestion echo's lines 995-1045 of HIMSS public comment response on the CMS NPRM.

8) ONC work with FDA and representatives of patient, clinician, vendor, and healthcare organizations to determine the role that the FDA should play to improve the safe use of certified EHR's

9) The Workgroup recommends that ONC continue its efforts to encourage implementation of EHR systems.



Recommendations 1 and 8 both fostered discussion regarding the role that FDA would play in monitoring patient safety. The Workgroup commented on positives and negatives regarding FDA serving as the patient safety oversight body for health IT:

1. The FDA already has statutory authority over health IT if they choose to use it, and the FDA already has many of the mechanisms highlighted in Recommendation 1.0.
2. The Workgroup expressed concern that the FDA focused on problems committed by individual devices. As a result, the FDA can't react to situations where adverse events occur even when the software is working correctly.
3. The FDA reporting system focused on serious injuries and death caused by individual devices.
4. The FDA's Quality Systems Regulation (QSR) process is inconsistent with the incremental nature of HIT development, and, as result, could harm innovation and increase vendor and product costs.
5. The increased costs of FDA Class II regulation could become a barrier to entry for small vendors (example: iPhone applications.)
6. The workgroup suggests that ONC and FDA should collaborate on certification criteria that improve patient safety, and both should focus on selected HIT areas that are creating safety risks for EHR implementations.

FDA Center for Device and Radiological Health (CDRH) Director Jeffery Shuren joined via telephone. Dr. Shuren offered the following comments regarding the workgroups concerns.

- The FDA looks beyond technology in its safety analysis.
- The FDA analysis looks at both ensuring that technology works, that end users have the appropriate training, and works to ensure that technology is redesigned to reduce potential human error.
- QRS reporting is legally required for medical devices in class 2-3. QRS reporting covers major adverse events, while minor adverse events and potential averted adverse events are reported through the voluntary FDA Medwatch network.
- QSR Quality manufacturing allows for incremental adoption and innovation. Some manufacturers voluntarily adopt QSR standards without an FDA mandate.
- FDA de-identifies all reports sent by end users to protect reporters from being sued. (There were significant concerns by the Workgroup regarding the ability of a patient safety organization to protect end users from liability claims.)
- All quality reports are made available to end users and vendors through the FDA MedSun network.

Centers for Medicare and Medicaid Services Status Report on Meaningful Use Regulations

Tony Trenkle, Director of the CMS Office of E-Health Standards and Services, delivered the following status report:

- CMS has finished cataloging all comments, and all comments and responses are being reviewed by CMS and OMBC
- Most comments are directed towards several key issues:
 - Flexibility on implementations (all or nothing incentive payments)
 - Percentages
- Regarding required quality measures, there is significant stakeholder pushback on the start date. Stakeholders have requested that testing be the standard in 2011, and reporting on quality measures would take place in 2012. Also, many stakeholders are concerned that the quality measures are not mature.
- A number of stakeholders have commented that their organizations should not be included in requirements where information can not be captured through the EHR.
- A number of stakeholders have indicated that they hope ONC will give very little flexibility to states to add additional requirements for Meaningful Use. Numerous additional requirements could pose additional barriers to adoption according to respondents.
- Numerous stakeholders have recommended extending the length of each Meaningful Use stage.
- Other issues of concern: Eligible providers at Multi-Campus Health Systems and the exclusion of requiring administrative functions in Meaningful Use (example: insurance eligibility, claims processing)
- CMS is hoping to release a Final Rule in “late spring” of 2010.
- CMS staff members are meeting with members of Congress on Friday, April 23 to discuss several of the same key issues found in the public comment responses.

