

Health IT Policy Committee Meeting
March 17, 2010
Summary

Discussion on safety implications of HIT. The Adoption and Certification workgroup of the HIT PC gave a summary of a hearing held on the patient safety issues involved in adoption of health IT. Marc Probst (CIO at Intermountain Healthcare and co-chair of the group) noted that many issues involving safety of IT systems are part of local configurations and use, not the IT code itself. He noted that a rushed pace for implementation heightens the possibility for safety issues. Marc and co-chair Paul Egerman also noted that there was very little data on this question and we are working mostly with anecdotes and reports from users. They see 4 groups of concerns: technology issues, complex interactions of people and technology (such as alert fatigue and poor workflows), training and implementation failures, and interoperability failures (needed data didn't make it from the lab to the EHR).

The group made initial recommendations that could be fairly far-reaching, if implemented. The most notable of those was a recommendation that the next round of meaningful use criteria REQUIRE reporting of technology-related patient safety concerns to a national patient safety organization. They seem to be talking about setting up a new set of structures, not making this part of the existing PSO process. They expressed a real desire to avoid regulation of EHRs and other health IT systems by FDA, but seemed open to post-implementation surveillance activities to check for safety issues. That would presumably involve investigators checking out systems after they have been established in the hospital or physician office. They also brought up the possibility of including how vendors deal with safety concerns as a part of the certification process (such as keeping a log of reports from customers and providing notices of safety issues to customers). Neil Calman recommended that there be "competency testing" of users – both vendors to install and train and providers to change workflow and follow safe practices. The workgroup will have conference calls on March 25 and 29, and make a final presentation on the topic to the full HIT PC on April 21.

1. ONC Certification Process Rule. Steve Posnack of ONC presented the certification process rule. The presentation followed the NPRM but provided a bit of additional information. For example, even in the temporary certification process, NIST will be involved by developing the evaluation criteria and designing the testing methods to be used by the temporary testing and certification bodies (tools, data, and scripts). Slides are available at the link below.

2. CMS NPRM. Tony Trenkle/CMS summarized comments on the CMS MU rule. Over 2000 comments received. Process will include internal vetting, identification of major policy issues for consultation, and vetting both within HHS and with OMB. He highlighted comments from providers asking for greater flexibility and signaled that the final rule may be less aggressive than the NPRM. This is the 3rd time he has mentioned that a percentage approach is a possibility. He also noted substantial comment on the hospital-based EP and multi-campus issues, concerns over reporting burden and quality reporting requirements, the need to limit state flexibility, and recommendations by some to add back in objectives such as providing patient

education materials. In later discussion, he noted that operational realities may limit CMS' ability to provide flexibility. The timetable continues to be "late spring" for a final rule to be released.

3. **ONC IFR.** Steven Posnack of ONC briefly summarized the comments on the ONC IFR. ONC received 300+ comments. He highlighted concerns that ONC align its final rule with the CMS MU final rule and provided reassurances the agency would do so. He also noted that providing flexibility in meeting meaningful use would not necessarily result in flexibility in certification (i.e., complete EHRs would still need to meet all criteria). He also noted that there were many comments on specific certification criteria and specific standards. During this discussion, Tony Trenkle noted that the certification process needs to synch with the CMS MU processes, particularly with respect to any CMS audits of provider attestations that they are using a certified EHR product.

Other presentations focused on the latest developments on the NHIN (still in process), comments from the members of the standards committee on the ONC IFR, and recent CMS guidance on how health IT fits into CLIA (makes it much easier to install lab interfaces and allows for more sharing of lab data with patients).

[Link](#) to Meeting Documents.