

HIT Policy Committee Information Exchange Workgroup Meeting Summary: **September 20, 2009**

A public meeting of one of the three subcommittees of the HIT Policy Committee – the Information Exchange Workgroup – was held on Tuesday, September 20, 2009.

Highlights of the meeting are as follows:

- All materials (agenda and written testimony) from the meeting may be found at http://healthit.hhs.gov/portal/server.pt?open=512&objID=1269&&PageID=16497&mode=2&in_hi_userid=11113&cached=true. The Workgroup announced that it would be developing recommendations on laboratory data exchange over the next two months and would take this testimony into account in formulating its recommendations. The Workgroup also stated that it decided to focus on this particular area given the importance of laboratory data exchange to meeting the “meaningful use” criteria that are under development.
- The Workgroup heard background presentations from the Centers for Medicare and Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC) and heard testimony from vendors, laboratories, states, and policy experts.
- During her background presentation on the Clinical Laboratory Improvement Act (CLIA), Angela Brice-Smith of CMS stated that:
 - CMS does not see CLIA as a “significant barrier” to the electronic exchange of laboratory data, although she acknowledged that: (1) this does not mean CMS won’t need to change its interpretive guidelines; and (2) her team has not yet discussed this position with their legal advisors.
 - In general, she seemed committed to the idea that CMS would *not* draft new CLIA regulations but instead would revise and update the agency’s (sub-regulatory) manuals and guidance.
 - Ms. Brice-Smith’s statement that CLIA did not pose a “significant barrier” was met with a fair amount of disagreement in the room.
 - CMS’s three key principles around electronic exchange of laboratory data are:
 - Simultaneous reporting of data to the authorized party and the HIE;
 - No changes in responsibility for the aggregate data reporting; and
 - After reporting to an “authorized person,” CLIA responsibility ends.

Note: This meeting summary is in draft form only and is not designed for publication or distribution. It is meant to serve as a resource for AAMC members and represents the impressions of the author regarding the activities that took place at the meeting.

- Broadly speaking, issues the participants discussed included:
 - What to do about the current lack of unified standards or common vocabulary and large amounts of customization;
 - The bounds of CLIA responsibility, the definition of an “authorized person” under CLIA (with a particular interest in the variations between states), and variations in CLIA enforcement;
 - Possibility of focusing policy-making attention on the relatively small number of tests (200+) that account for 95 percent of all tests ordered;
 - Lack of patient identifiers and patient matching problems;
 - The design and implementation costs associated with building custom interfaces for physicians; concern that labs do not build interfaces for physician offices with few referrals;
 - The difficulty of entering lab data into a physician EHR when there is not an interface;
 - Creation of standard interface and uniform compendium for the most commonly ordered ambulatory lab services;
 - Whether the lab should be responsible for final delivery and presentation to ordering physicians, or whether it is sufficient to successfully deliver the data to a certified HIE or EHR interface;
 - What role the government *should* play in facilitating electronic exchange; and
 - What regulatory changes can be implemented to simplify the exchange of lab data and provide appropriate access to necessary parties.

- Toward the end of the presentation, Workgroup members discussed whether hospitals with outreach lab services should be required to conform to the national standards required under CLIA in order to meet “meaningful use” criteria.

- The public may submit comment to the Workgroup on the above topics through the end of October.

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