

Clinical Operations Workgroup

March 28, 2011

Medical Device Hearing

9:00 a.m. to 5:30 p.m./Eastern Time

Renaissance Washington, DC Dupont Circle Hotel
1143 New Hampshire Avenue, NW, Washington, DC

Instructions and Questions for Panelists

Background

Testimony from this hearing will help the Clinical Operations Workgroup formulate recommendations to the HIT Standard Committee and the National Coordinator on barriers and enablers for medical device interoperability. If you have any questions, please contact Jamie Ferguson, Workgroup Chair: jamie.ferguson@kp.org

Format of Presentation:

The Workgroup respectfully requests that panelists limit their prepared remarks to **five (5) minutes**. This will allow the Workgroup to ask questions of the panelists and allow every presenter time to present his or her remarks. We have found that this creates a conversation for a full understanding of the issue. You may submit as much detailed written testimony as you would like, and the Workgroup members will have reviewed this material in detail before the hearing. PowerPoints will not be needed.

Pre-Presentation Questions/Themes:

The questions below represent areas the Workgroup intends to explore at the hearing. Please feel free to use them in preparing your oral and written testimony; the Workgroup recognizes that certain questions may not apply to all presenters.

The Workgroup respectfully requests panelists to provide written testimony by **March 21, 2011**. Please submit the testimony to Judy Sparrow at Judy.sparrow@hhs.gov

Presenter Biography

In addition, the Workgroup requests that all presenters provide a short bio for inclusion in the meeting materials. Please send your short bios to Judy Sparrow, judy.sparrow@hhs.gov

THEMES/QUESTIONS

Questions related to health care devices and device interoperability with EHR technology:

All Panels – General Questions

1. What is your experience with health care devices and device interoperability? Have you experienced specific problems where standards might contribute to solutions?
2. Are there areas where standards are more mature or less mature?
3. What standards or standards-related capabilities are most relevant and important to the meaningful use of EHR technology?
4. What do you see as key barriers to effective use of health care devices to advance health and wellness?
5. If you could wave a magic wand to effect one change to enable more effective and widespread use of health care devices, what would that be?

Patient/Consumer Panel

6. Please comment on your needs and issues related to the use of health devices in managing health and wellness, in home care and remote health monitoring.
7. What issues and requirements are most important for health care devices?

Provider Panel and Interoperability/Data Integration Panel

8. What data about devices is needed in EHRs?
 - a. Devices that are prescribed, implanted, or become part of the care record
 - b. Devices that transmit or record data used in the EHR
9. Questions related to Meaningful Use
 - a. How would device data in EHRs affect Stage 1 measures?
 - b. What device-related patient safety and/or quality issues should be measured or reported?
10. What is the impact of the recent FDA MDDS rule on device integration with EHRs?
11. How should integration of home and remote monitoring with EHRs be addressed?
12. How should integration of regulated clinical devices with EHRs be addressed?
13. Please consider comments on identification of devices related to use of EHRs
 - a. In supply chain management and other management processes
 - b. In safety processes including identification of recalled implanted devices

Data Accuracy & Integrity Panel

14. What are the data accuracy and data integrity requirements for device data in EHRs?
 - a. Product metadata (data about devices)
 - b. Interoperability data (health data from devices)
 - c. What are the differences and similarities for patient-collected data vs. provider-collected data, and what are the requirements for both?
 - d. Are there different accuracy and integrity requirements for patients or providers in different care settings, e.g. SNIF vs. Hospital vs. Home?

Data Accuracy & Integrity Panel, continued

15. What risks relate to device data accuracy and integrity?
16. How does patient identification relate to device data in different care settings?

Device Security & Data Security Panel

17. What are the security requirements for devices in different care settings, e.g. SNIF vs. Hospital vs. Home or other remote monitoring?
18. How do existing security standards support network-enabled devices today?
19. What network and connectivity issues relate to remote monitoring with intermittent connectivity?

Unique Device Identification (UDI)

20. What are the requirements for unique device identification? How do they relate to the use of EHR technology? For providers vs. patients? For different care settings?
21. To what extent are the standards for device identification used today by US providers of health care? Are there different patterns of use for consumer health and wellness devices vs. professional-use clinical devices? What issues arise from the use of multiple identification standards? How does device identification relate to patient identification?
22. What device classification/nomenclatures are in use, and how do they relate to UDI?