



Government Relations Roundtable

August 1, 2011

12:00 p.m. – 1:30 p.m. Eastern

Harris Corporation - 600 Maryland Ave, SW, Suite 850

Minutes

1. Welcome & Introduction:

Steve Erd

- Group Networking
- Roll Call
- Welcome

2. Draft Guidance for Industry and Food and Drug Administration Staff – Mobile Medical Application

Bakul Patel
FDA

The Food and Drug Administration's Centers for Devices and Radiological Health (CDRH) released [draft policy guidance](#) for mobile medical applications on July 21, 2011.

Mobile medical applications are defined as:

- Intended for use that meets the definition of medical devices under section 201(h) and either:
 - Are used as an accessory to already regulated medical device or
 - Transforms a mobile communication device into a regulated medical device

Of note, this FDA guidance does **not** classify mobile applications that perform the functionality of an electronic health record system or a personal health record system as medical devices. That does not mean those functionalities will not be addressed in future guidance.

FDA is actively seeking feedback on this draft guidance.

Specifically, FDA is seeking feedback on:

- Scope of medical apps and other aspects of the guidance
- Proposed approach for accessories to medical devices
- Framework for stand-alone software that provides support in making clinical decision

Comments due October 19, 2011.

Comments can be submitted at: <http://www.regulations.gov/#!home>

3. Health IT Landscape

Geoffrey Gerhardt
ONC

ONC Activities – Summer to Fall 2011:

- First years of Meaningful Use were focused on setting up infrastructure and policies – focus is shifting toward implementation now
- Goals of improving the patient experience and the nation's health care delivery system through IT
- Working closely with the Center for Medicare and Medicaid Innovation (CMI)
- FACA Committees have been meeting regularly all summer – [Meeting calendar](#)
- Very interested in what the RECs, Beacon Communities, and other ONC grantees have been doing – ONC has been meeting with grantees across the country this summer
- Stepping up focus on communication - Revamped website - <http://healthit.hhs.gov>
- New media campaign – *Putting the I in health IT*
- Possible ONC event focused on consumers during [National Health IT Week](#) – September 12-16, 2011

5. Federal Update:

Tom Leary

HIMSS submitting comments on Accounting of Disclosures NPRM – Letter will be posted on the HIMSS website at http://www.himss.org/policy/about_federalAffairs.asp

Upcoming Regulatory Responses HIMSS Plans on Submitting Comments on:

- [Changes to Meaningful Use Stage 1 Quality Reporting Requirements for Hospitals and Critical Access Hospitals](#) – Comments due August 30, 2011
- [Changes to Meaningful Use Stage 1 Quality Measure Reporting Requirements for Eligible Providers](#) – Comments due August 30, 2011
- [Administrative Simplification: Adoption of Operating Rules for Eligibility for a Health Plan and Healthcare Claim Status Transactions](#) – Comments due September 6, 2011

Upcoming Events:

- [National Health IT Week](#) – September 12-16, 2011
- HIMSS Policy Summit – September 14 – 15, 2011 – [REGISTER NOW!](#)

6. Adjournment