REGULATORY ISSUES AND IMPLICATIONS FOR HEALTHCARE UNBOUND

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Description

Healthcare Unbound means widespread and ubiquitous integration of medical device sensors with consumer electronics and electronic medical records. The regulatory implications of these interfaces and applications are complex and rapidly changing. Recent announcements by the FDA on EMR regulation have highlighted these issues and their implications for medical device vendors, EMR vendors, clinicians, and hospitals.

Michael Robkin, Dane Stout, and Scott Thiel will present one mHealth product scenario and examine the regulatory risks and rewards from the perspective of the major stakeholders: medical device manufacturers, technology & infrastructure vendors, and providers & caregivers. The latest information on FDA regulation and how it will affect all players will be presented along with some possible solutions to the most challenging regulatory questions.
Agenda

- Regulatory Update for mHealth
- Scenario for Discussion
- Manufacturer Regulatory Issues
- Infrastructure Regulatory Issues
- Provider Regulatory Issues
- Q&A

Notes: Expect minimum understanding of FDA.
Regulatory Updates

  - “How can we be assured that a system of interconnected medical devices — in a potentially unknown configuration and possibly from different manufacturers — performs safely and effectively?
  - Who is responsible when the system fails?
  - With clinical users demanding increased capability to configure these complex systems, where does one draw the line between systems engineering and the practice of medicine (for example, can a bedside physician install an arbitrary clinical protocol)?
  - How will we review devices that claim interoperability with others as part of their intended use? What criteria will we use for such reviews?”
Regulatory Updates

- **MDDS proposed classification (2/8/08)**
  - Medical Device Data System
  - “The Food and Drug Administration (FDA) is proposing to reclassify, on its own initiative, the Medical Device Data System (MDDS) from class III (premarket approval) to class I (general controls). “
  - Data in, data out
  - No processing
  - Clinical Professional use
Regulatory Updates

• ONC & FDA discussions on EHR regulation (4/21/09)
  - "We recommend that the ONC work with the FDA and representatives of patient, clinician, vendor and health care organizations to determine the role that FDA should play to improve the safe use of Certified EHR Technology."
Regulatory Updates

• Senator Grassley Letter (1/20/10)
  – “Some HIT products…are …. regulated by the …FDA. Therefore, the manufacturers of these devices are required to meet specific reporting requirements…. However, for HIT products that may not fall under FDA regulation, there appears to be a lack of a national system for reporting product errors or failures and adverse events associated with the use of such products. ”
Regulatory Updates

- FDA Interoperability Workshop 1/25/10
- FDA/Continua/CIMIT hosted workshop at CDRH on “Medical Device Interoperability: achieving safety and effectiveness.”
  - The purpose of the workshop is to facilitate discussion among FDA, industry, academia, professional societies, clinical investigators and other interested parties on issues related to safe and effective interoperable medical devices.
  - http://mdpnp.org/FDA_Interop_Workshop.php
Regulatory Updates

• Jeff Shuren, at HIT Policy Committee 2/26/10

  “Under the [current law] HIT software is a medical device. Currently, the FDA mandates that manufacturers of other types of software devices comply with the laws and regulations that apply to more traditional medical device firms. These products include devices that contain one or more software components, parts, or accessories… systems used to monitor patient activity… devices that are composed solely of software (such as laboratory information management systems). To date, FDA has largely refrained from enforcing our regulatory requirements with respect to HIT devices. The FDA recognizes the tremendous importance of HIT and its potential to improve patient care. However, in light of the safety issues that have been reported to us, we believe that a framework of federal oversight of HIT needs to assure patient safety.”
Regulatory Updates

• Jeff Shuren, at HIT Policy Committee 2/26/10

• The FDA could consider a range of approaches for addressing HIT-related safety concerns

• One possible approach would be to focus on postmarket safety by requiring HIT device establishments to electronically register and list their HIT devices, and to submit Medical Device Reports (MDRs) to the FDA.

• A second possible approach would be to focus on manufacturing quality and postmarket safety by requiring HIT device manufacturers to also to adhere to FDA’s Quality Systems Regulation (QSR)

• Under a third approach, the FDA would apply our traditional regulatory framework, in which HIT device manufacturers would be required to meet all the same regulatory requirements
Regulatory Updates

• MiMvista iPhone Medical app denied (3/15/10)

• [http://mobihealthnews.com/category/slides how/page/2/](http://mobihealthnews.com/category/slides how/page/2/)
Regulatory Updates

• FCC/FDA meeting on converged communications and healthcare devices
  - Goal is to obtain public comment and to share thoughts on how the two agencies can work together to oversee mobile healthcare technology

• http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm215046.htm
Scenario

Infrastructure Manufacturer

Medical Device

Glucometer

Weight Scale

Home Gateway

Internet

Home

Hospital

Physician
Manufacturer
Scenario

Medical Device

Glucometer

Weight Scale

Infrastructure Manufacturer

Internet

Home Gateway

Home

Hospital

Physician
Main Concern

PREDICTABILITY
Predictable

- Market needs
- Development tools
- Project timelines
- Production throughput & yield
- Distribution methodologies
- Market feedback methodologies
- Life cycle management tools
Specific for our scenario, predictable...

- understanding of user(s) needs / requirements.
- understanding of when a device is or is not a medical device; if a medical device, what classification.
- and acceptable indications for use statement, especially for an interoperable medical device.
- reliable and consistent methods for confirming that requirements (including rules) are met.
- understanding of what are acceptable failure types and rates.
- metrics and process for what to report with field issues.
- process for root-cause analysis with multiple manufacturers.
- and reliable root cause failure analysis methodologies.
- way to manage updates to individual products in the “system”.
- reliable and cost-effective methods of updating product in the field.
Grey Areas

Medical device?
– Current regulations aren’t entirely clear on whether or when some of these devices are medical devices. Requires a close analysis of the intent behind the device.

Development?
– Verification and validation of an interoperable medical device meant for a plug-and-play system is challenging at best (combinatorial problem).

“Every silver lining’s got a touch of grey.”
- Grateful Dead
Grey Areas

Field information?
- Who will the customer call with an issue?
- What manner will quality issues be communicated and how much responsibility does each mfg have to monitor / collect this information?

Root-cause analysis?
- How to resolve could be challenging if all parties involved in an undefined system don’t know each other, can’t agree, or are competitors, especially with discrepant info.

Recalls / field notifications?
- Which company reports this? Which is responsible for executing notifications?
Lifting the fog

Grey areas can either be viewed as barriers or opportunities. Here are some groups that view the opportunities and are working on solutions to some questions.

- CCHIT
- CIMIT
- Continua Health Alliance
- HIMMS
- HITSP
- IHE
- mHealth Regulatory Coalition
- ONC

“A pessimist sees the difficulty in every opportunity; an optimist sees the opportunity in every difficulty. 
- Winston Churchill
Infrastructure
Top General IT Focus Areas

- Virtualization
- Consolidation
- Cloud Computing Adoption
  - Private
  - Public
  - Integrated
- Analytics
  - Insight from Data
- Vendor consolidation and platform selection
- Converging Infrastructure
  - Servers
  - Storage
  - Bandwidth
- Increasing automation
- “Internet of Things”
Top HIT Issues for IT Infrastructure Providers

• Mobility and remote access not controlled environments like traditional desktop
• Ensuring Security Data and Privacy Compliance
• Data Storage Management, Archival, Retrieval
• Clinical use and semantic meaning of code sets and terminologies not well understood
• Interoperability
• Workflow
• Application Performance Management across heterogeneous environment
Healthcare is one of Top IT Growth Targets

• Healthcare IT attracts companies from across multiple industries
• Many previously horizontal only technology companies are moving aggressively into HIT and Mobile Health
• Interconnected devices and health records means entry into unfamiliar areas
  – Regulated Medical Device sector
  – Healthcare Delivery Clinical Systems
Increasing Scrutiny by FDA in response to Public and Congressional Criticism

- Personal Care Products Claims
- Personal Genetics Testing
- Medical Device Approval Process
- Pharmaceutical manufacturing processes
- Concern over EMR and other software is growing and is somewhat political
  - Semantic Interoperability and Coding is crucial to patient safety
The Impact of Networks on Medical Device Companies

- No longer have complete control over product design, use, and performance
- Regulations consider the registered manufacturer responsible for the entire system, regardless of control
- FDA Guidance in place for software development and COTS use, but not network services
- Regulation remains device centric even as their use does not
  - Accessories vs. systems of systems
  - “Standalone Software” doesn’t really exist anymore
Provider Issues
Scenario

Medical Device

Glucometer

Weight Scale

Home

Infrastructure Manufacturer

Home Gateway

Internet

EMR PHR

Hospital

Physician
Impact on Healthcare Providers

• In the past FDA regulation never affected Providers directly
  – Practice of Medicine
  – Already regulated: CCHIT, CLIA, AHRQ, etc…
Impact on Healthcare Providers

• New world: Technology
  – Convergence of IT and Clinical Engineering.
    • CIO’s taking over Clin. Eng. Departments
  – Convergence if Medical Devices and Clinical Systems and EHRs
  – Integration of IT to medical devices:
    • Modification of regulated systems
    • Provision of infrastructure and components
Impact on Healthcare Providers

• New World: mHealth
  – Home health and consumer health devices are outside hospitals
    • And clearly within the scope of the FDA
  – Root Cause analysis, when provider has responsibility but little authority
  – Customer Service
    • Nurse Call Center vs. Verizon Call Center
Impact on Healthcare Providers

• New world: Interoperability means different things to different stakeholders
  – System of Systems
  – Root Cause Analysis
  – Blurred lines and gaps between Manufacturer’s “intended use” and Provider’s “practice of medicine”
    • Old: Handed off - no worries.
    • New: configured, modified, interfaced, integrated, combined.
Interoperability References By Domain
So What?

• Players are no longer silo-ed.
• FDA open to ideas, feedback, information
• Need collaboration between MDM, IT, Providers, and the FDA
  – But different speeds, different cultures, different definitions of success
• The Network Changes Everything
  – Magnificent benefits
  – New kinds of interdependencies
  – New unknowns in Companies and Systems that despise unknowns

“The Network Knows What the Nodes Do Not” Kim Rachmeler, Amazon
Q&A
THANK YOU!

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