Webinar: Implications of FDA Regulation of Medical Devices: When is an iPad More Than an iPad?

Additional resources on this topic may be found at: www.aamc.org/FDAMobileDevice

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July 23, 2014
Implications of FDA Regulation of Medical Devices: When is an iPad More Than an iPad
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TODAY’S TOPICS

• Mobile Health
• Regulatory Framework
• Practical Takeaways
• Questions
MOBILE HEALTH: A BRAVE NEW WORLD OF REGULATION
Video
Proliferation of smart medical devices comes with vulnerabilities and a confusing web of regulations

- Cybersecurity incidents increasingly likely in wireless and network-connected devices transferring data electronically

- With increased risk comes increased regulation
• Regulatory overlap

• Mobile health and medical devices are subject to multiple privacy/security regulations
  – FDA
  – FCC
  – FTC
  – ONC
  – HHS/OCR
  – State Law
Consistency Across Regulations

- National Institute of Standards and Technology (NIST)
- Privacy by Design
- Transparency
- Control
- Simplify Patient Choice
- Security
Challenges Across Regulatory Agencies

- No pre-emption
- Inconsistent provisions
- Additional audits
- Cumulative fines/penalties
REGULATORY FRAMEWORK
There’s An App For That

- Inform/Instruct
- Record
- Display
- Guide
- Remind/Alert
- Communicate

Available on AppStore
Regulatory Framework

**Food & Drug Administration**

- Mobile Medical Applications (Guidance, Sep 25, 2013)
  - Software as a Medical Device
  - FDA intends to regulate mobile medical software that poses a threat to public safety
  - Which software applications will be regulated?
Food & Drug Administration

- Mobile Medical Applications
  - The key regulatory factor is the **intended use** of the mobile health application
Food & Drug Administration

- Mobile Medical Applications
  - Regulated Applications:
    - Extending the medical device to control the device or to display device data
    - Using attachments, screens, sensors to transform a mobile platform into a medical device
    - Performing patient specific analysis
    - Assisting with diagnosis or treatment recommendations
Regulatory Framework

**Food & Drug Administration**

- Mobile Medical Applications
  - Non-Regulated Applications
    - Supplementing clinical care by helping patients manage their health
    - Providing patients with tools to organize/track health information
    - Providing easy access to patient’s health conditions
    - Helping patients document or communicate medical information to providers
    - Performing simple calculations used in clinical practice
    - Enabling individuals to interact with PHRs and EHRs
• An Apple a Day
  – Apple’s HealthKit
  – Payor and Provider Partners
  – Patient Engagement
Regulatory Framework

Food & Drug Administration

• Mobile Medical Applications
  – Regulatory Requirements
    • Establishment Registration and Medical Device Listing
    • Investigational Device Exemption (IDE) requirements
    • Labeling requirements
    • Premarket submission for approval or clearance
    • Quality System Regulation (QS Regulation)
    • Medical Device Reporting (MDR) (Adverse event reporting)
    • Correcting Problems
Regulatory Framework

Food & Drug Administration

• Medical Devices
  – Threats to medical devices
  – Ramifications of cybersecurity breaches
Regulatory Framework

Food & Drug Administration

• Management of Cybersecurity in Medical Devices (Draft Guidance, Jun 14, 2013)
  – Information Security Requirements
    • Confidentiality
    • Integrity
    • Availability
  – Security Guidelines
    • Limited Access
    • Trusted Content
    • Fail-Safe & Recovery Measures
  – Emergency Issues
Regulatory Framework

Food & Drug Administration

• Management of Cybersecurity in Medical Devices
  – Documentation
    • Risk Analysis
    • Update Control
    • Disabling Code
  – Industry Response
    • Existing devices
    • No retroactive implementation
    • Transition period
    • Intended Use

• Radio Frequency Wireless Technology in Medical Devices (Guidance, Aug 14, 2013)
Federal Communications Commission

- Regulates the airwaves
- Wireless technology issues
- Wireless co-existence with electromagnetic compatibility
- Root cause analysis of problems with connectivity
- 802.11 wireless data security not robust
Regulatory Framework

**Federal Trade Commission**

- FTC Chairman Edith Ramirez:
- “Like a vigilant lifeguard, the FTC’s job is not to spoil anyone’s fun but to make sure that no one gets hurt.”
Regulatory Framework

Federal Trade Commission

- Congress has been unable to pass a Federal Privacy Bill.
- Protecting Consumer Privacy in Era of Rapid Change (Report, Mar 2012)
  - Blue print for potential federal legislation, currently self-regulatory best practices.
  - “Privacy by Design”:
    - Promote privacy throughout the organization and at every stage of development of products and services
    - Delete consumer data no longer needed and allow consumers to do the same
    - Provide reasonable security for data
    - Limit collection of data (consistent with context of particular transaction)
    - Implement reasonable data retention and disposal policies
    - Maintain reasonable accuracy of data
Protecting Consumer Privacy in Era of Rapid Change

- Simplify Consumer Choice:
  - Provide consumer choice for any communications not related to original transaction
  - “Do Not Track” mechanisms allow consumer to control collection and use of their online data
  - Certain choices require consumer to “opt in”

- Improve Transparency to Consumers:
  - Clearer and shorter privacy notices
  - Provide access to consumer data
  - Educate consumers about company’s data privacy practices
Regulatory Framework

Federal Trade Commission

• Mobile Privacy Disclosures, Building Trust Through Transparency (Report, Feb 2013)
Regulatory Framework

Office of the National Coordinator for Health IT

- HIT coordination
- Meaningful use
- Direct protocol under VA
- Secure email/fax
- Facilitates interoperability
- Promotes electronic medical records
- Not focused on patient safety
Regulatory Framework

**HHS – Office of Civil Rights**

- HIPAA/HITECH/Omnibus Final Rule
  - Business associates & Subcontractors
  - Direct Enforcement
  - Security Rule
    - Risk assessment
    - Technical, Physical, Administrative Safeguards
    - Policies & Procedures
Regulatory Framework

**HHS – Office of Civil Rights**

- HIPAA/HITECH/Omnibus Final Rule
  - Breach Reporting
  - Privacy Rule
    - Patient Access
    - Permitted disclosures for FDA regulated activities
    - Sale and marketing of information
    - Research
Regulatory Framework

State Law

- Privacy/Security of patient information
- Breach reporting
- Licensing
- Telemedicine/telehealth
Practical Takeaways

• Appoint committee to monitor relevant regulatory guidance
• Educate developers of mobile medical applications when regulatory line(s) are crossed
• Keep software separate from regulated medical devices
• Follow and document privacy/security and quality principles
• Take precautions to eliminate malware contamination
• Monitor network connectivity for misuse
Practical Takeaways

• Perform and update risk analysis for security/privacy
• Develop incident response programs especially for life sustaining devices
• Obtain consent for collection of personally identifiable information
• Look for common compliance principles across regulatory agencies
• Document compliance with privacy/security criteria
ABOUT PEPPER HAMILTON
For more information: www.pepperlaw.com
www.aamc.org/gir

Resources related to this topic:
www.aamc.org/FDAMobileDevice

For more information about the GIR or materials related to this webinar, please contact: gir@aamc.org

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