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

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Association of American Medical Colleges

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

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MOBILE HEALTH: A BRAVE NEW WORLD OF REGULATION

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Video

Mobile Health: A Brave New World Of Regulation

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

Expansion Of Regulatory Purview

- Regulatory overlap
- Mobile health and medical devices are subject to multiple privacy/security regulations
  - FDA
  - FCC
  - FTC
  - ONC
  - HHS/OCR
  - State Law

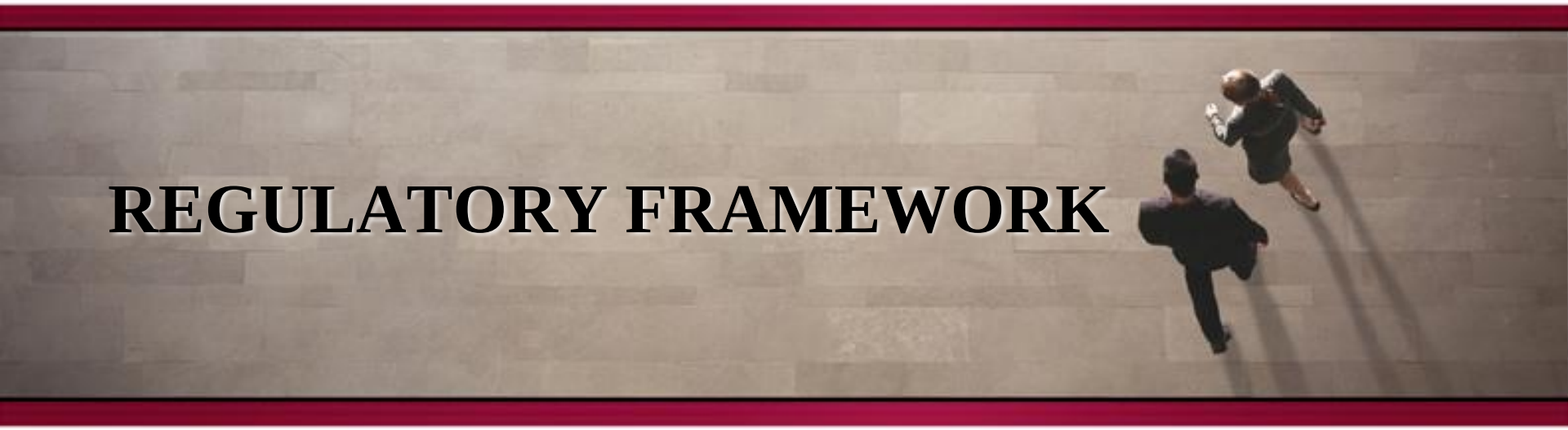
Consistency Across Regulations

- 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

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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?

Regulatory Framework

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

Regulatory Framework Food & Drug Administration

- 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

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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)

Regulatory Framework

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.”

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

Federal Trade Commission

- 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

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

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