The Shifting Sands of Medical Software Regulation

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September 10, 2014
What Software is Regulated by FDA?

- FDA regulates medical devices.
- FDA regulates software that meets the definition of a medical device.
What’s a Medical Device?

► instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is

► intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease in man or other animals ...

Section 201(h) of the Federal Food, Drug, and Cosmetic Act; 21 U.S.C. § 321(h)
How do I know
If my software is a device?

• Answer the following questions:
  – Is my software a component of a medical device?
  – Is my software an accessory to a medical device?
  – Do I “intend” for my software to be used:
    • In the diagnosis of disease or other conditions
    • In the cure of disease
    • In the mitigation of disease
    • In the treatment of disease
    • In the prevention of disease
How Does FDA Regulate Medical Device Software?

- Class I, II, III – 510(k) / PMA

- Guidance for the [Content of Premarket Submissions for Software Contained in Medical Devices, 2005](#)

- Documentation required depends on software's Level of Concern:
  - Major – failure could directly result in serious injury or death
  - Moderate – failure could directly result in minor injury
  - Minor – failure not likely to result in injury

- [Recognized Consensus Standards](#)

- Registration / Listing, QSR (design controls, CAPA, recordkeeping etc.) Recalls, Reporting, Inspections
Many devices software controlled

- Pacemakers
- Neuromodulators
- Imaging systems

Components generally take the classification of the “parent” device

Often reviewed as part of PMA submission
Manufacturing Software

- Software controlled manufacturing processes common
  - Includes labeling systems

- Manufacturing software may be included in PMA and some 510(k) submissions
  - Subject to traditional PMA review
  - Need to submit modifications
What about Electronic Health Records?

► FDA does not regulate electronic health records.

► An Electronic Health Record (EHR) is an electronic version of a patient's medical history, that is maintained by the provider over time, and may include all of the key administrative clinical data relevant to that person's care under a particular provider, including demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data and radiology reports.

Center for Medicare and Medicaid Services
What about Mobile Medical Apps?

► FDA Final Guidance: [Mobile Medical Applications](#) (September 2013)
  ► Risk-based approach to regulation- focus on software that could cause harm to patients due to faulty functionality vs. consumer-oriented apps

► Some in D.C. believe that further clarity is needed.
  ► In March, [Senator Orrin Hatch](#) and a group of bipartisan senators formally urged FDA to provide more transparency regarding regulation of MMAs
  ► FDA has yet to respond to the Senators’ letter
Mobile Medical App Guidance | Categories

Three categories:

1. The mobile app is not a medical device;

2. The mobile app might be a medical device, but is low risk and FDA will exercise enforcement discretion; or

3. The mobile app is a medical device (MMA) and will be subject to FDA oversight.
Category 1: Not a Device

FDA offered a number of examples of apps that are NOT devices:

- Mobile apps that are intended to provide access to electronic “copies” of medical textbooks or other reference materials
- Mobile apps that are intended for health care providers to use as educational tools for medical training or to reinforce training previously received
- Mobile apps that are intended for general patient education and facilitate patient access to commonly used reference information
- Mobile apps that automate general office operations in a health care setting and not intended for use in the diagnosis, cure, treatment, or prevention of disease
- Mobile apps that are generic aids or general purpose products
Category 2: Enforcement Discretion

Apps that are low risk so FDA will exercise “enforcement discretion:”

- Help patients self-manage their disease or conditions without providing specific treatment or treatment suggestions
- Provide patients with simple tools to organize and track health information
- Provide easy access to information related to patients’ health conditions or treatments
- Help patients document, show, or communicate potential medical conditions to health care providers
- Perform simple calculations routinely used in clinical practice
- Enable patients or providers to interact with Personal Health Record or Electronic Health Record systems
Category 3: Apps Subject to FDA Premarket Review

FDA identified three subsets of apps that it intends to regulate:

1. Mobile apps that are an extension of one or more medical devices by connecting to such device(s) for purposes of controlling the device(s), displaying, storing, analyzing, or transmitting patient-specific medical device data. Examples include:
   - Apps that display patient-specific medical device data (e.g., EEG waveforms, images from PACS)
   - Apps that control medical devices (e.g., apps that control inflation and deflation of blood pressure cuffs)
   - Apps that display, store or transfer medical device data in its original format (these will be regulated as Class I- lowest risk)
Category 3: Apps Subject to FDA Premarket Review cont.

2. Mobile apps that transform the mobile platform into a regulated medical device by using attachments, display screens, or sensors or by including functionalities similar to those of currently regulated medical devices. Examples include:
   - Attachment of a blood glucose strip reader to a mobile platform to function as a glucose meter
   - Attachment of ECG electrodes to a mobile platform to measure, store, and display ECG signals

3. Mobile apps that become a regulated medical device by performing patient-specific analysis and providing patient specific diagnosis, or treatment recommendations. Examples include:
   - Apps that use patient-specific parameters and calculate dosage for radiation therapy
What about Medical Device Data Systems?

- **Guidance document** issued June 20, 2014.
- FDA will exercise enforcement discretion.

- MDDS are hardware or software products that:
  - transfer
  - store
  - convert formats and
  - display
  medical device data.

- MDDS may not control functions or parameters, not to be used with patient monitoring.
Off-the-Shelf Software included in Medical Devices

Guidance: Off-the-Shelf Software Use in Medical Devices, 1999

This guidance document represents the agency's current thinking on the documentation that should be provided in premarket submissions for medical devices using OTS software.
Cybersecurity

Guidance: *Cybersecurity for Networked Medical Devices Containing OTS Software*, 2005

Guidance: *Content of Premarket Submission for Management of Cybersecurity in Medical Devices*, 2013

Manufacturers should develop a set of security controls to assure medical device cybersecurity to maintain information confidentiality, integrity, and availability.
Software Validation

► Guidance: General Principles of Software Validation, 2002

► The FDA Perspective on Human Factors in Medical Device Software Development, Molly Follette Story, 2012
Other Potential Regulatory Approaches

► Congress intensely interested in software regulation
  ► Some fear “over regulation”
  ► Others fear overlapping jurisdiction
► Breadth of FDA definition of “device”
► Concerns over Health IT including electronic health records (EHRs)
► Multiple agencies involved in software oversight
  ► FDA
  ► FCC
  ► Office of National Coordinator for Health Information Technology
► FDASIA (2012) mandated report
Health Information Technology (HIT)

► Efforts to both encourage national implementation and determine oversight needs

► 2004 – Executive Order
  ► [Office of National Coordinator for Health Information Technology](#) (ONC)
  ► Charged with advancing health information technology and electronic exchange of medical information

► Multiple initiatives
  ► Quality needs
  ► Reporting

► Risk based regulation
Committee included multiple stakeholders

FDA, ONC and FCC

Recommends three “categories”

Administrative health IT systems
- Billing systems
- Scheduling

Health management functions
- Clinical decision software
- Health information management systems

Medical device software
- “narrowly defined group”
- Bedside alarms
- Radiation control software
Draft Health IT Report Recommendations

► Recommends public private Health IT Safety Center
  ► Develop standards
  ► Assess performance reports

► Administrative health IT
  ► No premarket requirements
  ► Modest reporting
  ► Outside FDA

► Health Management IT
  ► FDA exercises enforcement discretion
  ► No oversight

► Medical device software
  ► Traditional FDA regulation
Many of the same questions as in the US
Role of CE mark and notified bodies
  Often simpler oversight requirements
Lower level of regulatory of some types of Health IT
Quality system requirements still exist for certain types
  Design controls
  Validation and verification
  Reporting
Overall desire for more commonality
IMDRF - SaMD Initiative

- **IMDRF** (International Medical Device Regulators Forum)
  - Preparing recommended global regulatory framework documents
- SaMD (Software as a Medical Device) current work stream
- Initial [draft regulatory framework](#) issued March 2014
- Many comments
- Revised “final” draft submitted to IMDRF management committee
- September review and potential approval
- Intended to be regulatory framework for individual countries
Current SaMD Approach

- Unclear content of final draft
- Risk based approach
- Four categories of product
  - Risk based
  - Variable level of premarket data needed
- Differences with current US approach
  - Higher regulation of clinical data support systems
  - Differing risk assessments
- Next steps require IMDRF approval
- More specific frameworks may then follow
Thank you!

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