Tag, You’re It!

You Just Became a FDA regulated Manufacturer of Medical Devices

Effect of new FDA regulations covering Medical Device Data Systems (MDDS) on Healthcare Providers

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The Objective of this Presentation

The FDA published its Final Rule on Medical Device Data Systems (MDDS) on February 15, 2011. This Rule becomes effective on April 18, 2011.

This Rule has been anticipated for 3 years and is meant to address some real patient safety issues associated with the new “connected” medical technologies increasing deployed by healthcare organizations today.

We believe this rule has major implications for healthcare providers ... many of whom will now find themselves de facto medical device manufacturers and therefore subject to certain FDA regulations for the first time.

We believe that today most healthcare providers remain unaware of the MDDS rule and its implications for their organizations.

The purpose of our presentation is to acquaint healthcare providers at a high level with

- the basic provisions of the MDDS rule
- potential implications of the rule for their organizations and how begin assess the reality of those implications
- reasonable first steps that can and should be taken now given the short timeframe for compliance
Session Outline

- Patient Safety & MDDS
- What are Medical Device Data Systems (MDDS)?
- Illustrations of MDDS
- Background of FDA’s Role in Medical Device Regulation
- Overview of FDA’s Medical Device Regulations
- FDA’s Concerns about MDDS Risks
- FDA’s Requirements for MDDS Manufacturers
- Timetable for compliance with FDA’s new MDDS regulations
- Summary
- Next steps
Connecting a device/system to a Medical Device for data transfer

This is a Medical Device if put together or modified with intent to (i.e., “labeled” for) connection to a medical device for data transfer

It may be a MDDS, an accessory or another category of medical device

ALL medical devices used/sold in US are regulated by FDA

- Nature/extent of regulation depends on category & class of medical device
- Identity of the “manufacturer” is determined by who puts together components with intent of connecting to a medical device
Patient Safety and MDDS

- Complex, connected and integrated medical devices represent an rapidly growing segment of the healthcare technology environment

- By virtue of their interconnections, integration and complexity, these medical devices often introduce unique vulnerabilities that can result in major compromises to patient safety when these devices fail

- To address the challenges of one broad medical device category, the FDA just finalized a regulation pertaining to Medical Device Data Systems (MDDS).

- This new regulation has been issued to address significant patient safety issues by insuring those who assemble these systems (including many healthcare providers) adopt FDA’s relevant safeguards
What are Medical Device Data Systems (MDDS)?

MDDS is a category of medical device defined by FDA and subject to new FDA regulations that were finalized and published in Federal Register on Feb 15, 2011 designated: Final MDDS Rule (21 CFR 880.6310)

FDA has defined MDDS as a device (or system that is connected to a medical device and) is

1) ... intended to provide one or more of the following uses, without itself controlling or altering the functions or parameters of any connected medical devices:
   i. The electronic transfer of medical device data;
   ii. The electronic storage of medical device data;
   iii. The electronic conversion of medical device data from one format to another format in accordance with a preset specification; or
   iv. The electronic display of medical device data;
What are Medical Device Data Systems (MDDS)?

(continued)

2) MDDS may include software, electronic or electrical hardware such as a physical communications medium (including wireless hardware), modems, interfaces and a communications protocol. This ... does not include devices intended to be used in connection with active patient monitoring

(i.e., monitoring to facilitate immediate clinical actions ... because speed of data transmission or conversion are critical)

Medical devices that don’t meet definition of MDDS may be subject to more stringent regulations (e.g., systems designed to send alarms from physiological monitoring to wireless personal devices to facilitate IMMEDIATE clinical actions)
Illustrations of Medical Device Data Systems (MDDS) Types
Electronic **Transfer** of Medical Device Data via MDDS

**MDDS**

If put together or modified with intent ("labeled") to use with (i.e., connected to) a medical device

**MDDS adds NO FUNCTION** to a medical device (e.g., no alarms, no interpretation)

**MDDS itself provides NO CONTROL** over a medical device

**BUT may transfer control data from one medical device to another**
Electronic Storage of Medical Device Data via MDDS

**MDDS**

If put together or modified with intent ("labeled") to use with (i.e., connected to) medical device

MDDS adds NO FUNCTION to a medical device (e.g., no alarms, no interpretation)

MDDS itself provides NO CONTROL over a medical device

BUT may transfer control data from one medical device to another
**Electronic Conversion of Medical Device Data via MDDS**

Data converted according to a fixed, unchangeable algorithm

**MDDS**
If put together or modified with intent ("labeled") to use with (i.e., connected to) medical device

MDDS adds **NO FUNCTION** to a medical device (e.g., no alarms, no interpretation)

MDDS itself provides **NO CONTROL** over a medical device
BUT may transfer control data from one medical device to another
**Electronic Display of Medical Device Data via MDDS**

- **MDDS**
  - If put together or modified with intent ("labeled") to use with (i.e., connected to) medical device

  - **MDDS adds NO FUNCTION** to a medical device (e.g., no alarms, no interpretation)

  - **MDDS itself provides NO CONTROL** over a medical device

  - **BUT may transfer control data from one medical device to another**
Individual Components are not Medical Devices

If individual components not specifically intended (i.e., not “labeled” or not advertised) for connection to medical devices ...

Data converted according to a fixed, unchangeable algorithm

The manufacturers of these types of individual components are not subject to FDA regulations
Systems of Connected Components are Medical Devices

If data from a connected medical device is transferred and/or stored and/or displayed and/or converted

The organization that assembles a new MDDS or modifies intended use of an existing MDDS is a medical device MANUFACTURER ... and therefore subject to FDA regulations
MDDS can pass control data from one Medical Device to another

**If data is transferred to a medical device**

**MDDS**

If put together or modified with intent ("labeled") to use with (i.e., connected to) medical device

but the MDDS only transmits control data from the controller and does control the medical device

The organization that puts together a new MDDS or modifies intended use of an existing MDDS is a medical device MANUFACTURER ... and therefore subject to FDA regulations
**System is a Medical Device (but not a MDDS) if part of “Active” Monitoring**

*Data from a connected medical device is used for active monitoring*

**Medical Device subject to FDA Regulation (but not a MDDS)**

- **Active monitoring** (i.e., monitoring relied upon for immediate clinical action or continuous monitoring)
- **Data converted according to a fixed, unchangeable algorithm**
- **Display and/or Sound** (e.g., alarms, waveforms)
- **Smart Phone** (e.g., alarm notifications)
FDA Role in Medical Device Regulations

FDA given authority to regulate US sale and distribution of medical devices in 1976 Medical Device Amendments to the 1938 Food, Drug and Cosmetic Act

FDA definition of what constitutes a medical device:
SEC. 201. [321] For the purposes of this Act –

(h) The term “device” ... means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or accessory, which is

1) Recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

2) 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, or

3) intended to affect the structure of any function of the body of man or other animals, and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.
FDA’s Mission, Approach and Focus

**FDA’s Mission** is to “promote health and reduce risk of harm” by “assuring safety, efficacy and security of ... medical devices”

**FDA’s Approach** is *risk based* to assure medical devices are “reasonably” safe & effective

**FDA’s Focus** is in two main areas

- **Premarket**
  Oversight before a new product enters market or exposes patients

- **Postmarket**
  Monitor safety and act as a feedback mechanism to industry, users and patients
FDA’s Premarket Oversight
Depends on Risk Based Device Classification Scheme

FDA has categorized MDDS as Class I

- Class I
  - No Premarket review except in certain circumstances

- Class II
  - Premarket review required unless exempt
  - Demonstrate Substantial Equivalence (SE) to legally marketed devices in the US

- Class III
  - Premarket approval required

Increasing risk = increasing oversight & regulation
FDA’s Risk Based Approach to Oversight of Medical Device Manufacturing & Safe Usage

Increasing Risk
Classification determines extent of regulatory control (i.e., Risk Based)

**Class I**
- General Controls

**Class II**
- General Controls
- Special controls

**Class III**
- General Controls
- Premarket approval (PMA)

**General Controls**
- Electronic establishment registration
- Electronic device listing
- Adulteration/misbranding
- Premarket notification [510(k)] *unless exempt*
- Quality systems
- Labeling
- Medical device reporting (MDR)

**Special Controls**
- Guidelines (e.g., Glove Manual)
- Mandatory Performance Standard
- Recommendations or Other Actions
- Special Labeling (e.g., 3825970, cranial orthosis)
FDA’s Oversight “Tools

Registration & Listing
• Register: who is the manufacturer?
• List: what is the device?

Premarket Notification (510k) or Premarket Approval (PMA)
• Confidential independent review prior to commercial distribution
• Provide cross product lessons learned

Investigational Device Exemption (IDE) for clinical studies
• Allowing new technology creation

Quality System (QS) regulation
• Non-prescriptive principles for good engineering & manufacturing
• Suitable for technology

Labeling requirements
• Establishes clear user expectations

Medical Device Reporting (MDR)
• Understand device issues and impact on patients

Compliance Program
• Correct defective product consistently
• Periodic monitoring to assure device quality is sustained

MDDS
FDA’s general concerns about medical device trends

Today, medical devices (hardware & software) are

- more complex
- contain additional functionality intended to reduce burden on clinicians or caretakers
- decentralized & mobile
- accessible & often in hands of more lay users
FDA’s concern with Medical Device Data Systems

FDA wants to assure that clinical data generated by medical devices

- Can be used reliably after being transferred, stored, and/or displayed by a MDDS
- Maintains integrity after being transferred, stored, and/or displayed by a MDDS
- Is not changed during process of transferring, storing or displaying (note difference between changing and converting)

FDA wants to set a solid foundation for all future advancement in health information technologies
**MDDS Risks identified by FDA**

- FDA believes MDDS risks are
  - Inadequate software quality
  - Incorrect functioning of device

- FDA sees failure that can result in incorrect treatment or diagnosis of patient
  - Inaccurate or incomplete data transfer
  - Inaccurate or incomplete data storage
  - Inaccurate or incomplete data conversion (according to preset specifications)
  - Inaccurate or incomplete display of medical device data

- FDA believes the application of the an effective **quality system** can significantly reduce the risks of inadequate design and unreliable performance associated with a MDDS
FDA Requirements of MDMS Manufacturers

Manufacturers (including affected healthcare providers)

- must register with FDA as a manufacturer of medical devices
- must list their product(s) with the FDA
- are exempt from pre-market submission if
  - healthcare professionals or lay users
  - they include systems with irreversible data compression
- must implement adverse event reporting according to FDA’s Medical Device Report (MDR) requirements
- must establish and document a good manufacturing practice (GMP) according to FDA’s Quality System (QS) requirements. These include methods used in, and the facilities and controls used for,
  - design,
  - manufacture,
  - packaging,
  - labeling,
  - storage,
  - installation, and
  - servicing of devices
FDA Timetable for Compliance with MDDS Rule

- **Feb 15, 2011**
  *FDA published it’s Final Rule on Medical Device Data Systems (MDDS) in the Federal Register*

- **April 18, 2011**
  *The MDDS regulation becomes effective*

- **May 18, 2011**
  *Manufacturers are required to register their organizations with FDA & list their MDDS*

- **Feb 18, 2012**
  *Manufacturers are to have a compliant quality system (QS) & medical device reporting (MDR) system*
What are the Compliance Costs?

FDA estimates that compliance costs

- for Registration & Listing requirements are
  - a $2,179 in 2011 ($2,364 in 2012) “user fee” for a manufacturer (including affected healthcare providers) to register and list their devices with FDA
  - 2 hours labor per year for organizations unfamiliar with the registration/listing process

- for Quality System (QS) and Medical Device Reporting (MDR)
  - one time $20,000 cost to initially establish QS & MDR systems
  - annual cost of $143,000 (salary & benefits) for full time employee to manage the QS & MDR systems
Enforcement

What are Consequences of Failure to Comply?

FDA is in the process of establishing an appropriate enforcement and compliance policy.

Hospital administrators and device makers should be aware that FDA

✓ does not intend to start enforcing quality system requirements before the one-year compliance schedule mentioned in the Federal Register announcement

✓ does expect manufacturers (including affected healthcare delivery organizations) to register and list their MDDS. Health care facilities should evaluate their current design/development practices for the portions of the systems modified or added by them. This evaluation should reference the principles outlined in CGMP/QSR to appropriately address any identified gaps

FDA is working with the Association for the Advancement of Medical Instrumentation (AAMI), hospitals, industry and other stakeholders to gather input and help us implement the MDDS regulation in a targeted and practical way.
**Summarizing key points**

A manufacturer is anyone who
- assembles a new MDDS or
- modifies an existing MDDS (i.e., a “modification” from original manufacturer’s *intended use*).

A MDDS is
- hardware or software or some combination thereof
- connected to (and acquires its data from) a medical device
- only communicates (i.e., transfers, stores, displays and/or converts) medical device data.

Medical device data is data available directly from a medical device or obtained originally from a medical device.
- manually entered into a medical device is not considered medical device data
- electronically transmitted data (even if originally entered manually) is medical device data.

A MDDS does NOT
- modify, interpret, or add value to medical device data
- control the function or parameters of another medical device
- provide or is not used in connection with active monitoring.
What should healthcare providers do now?

- Review the final MDDS rule in detail with relevant stakeholders (e.g., administration, clinical engineering, IT, risk management, legal)

- Identify and inventory all MDDS in your organization (e.g., what is connected to medical device ... is the connected hardware and/or software an MDDS or another category of medical device?)

- Determine whether the FDA will consider you a manufacturer
  - Have you assembled any of your MDDS? or
  - Have you modified any of your existing MDDS from original manufacturer’s intended use?

- If you meet the FDA’s definition of a MDDS manufacturer now
  - Register with FDA as a manufacturer by May 16, 2011
  - List any MDDS you “manufactured” with the FDA by May 16, 2011
  - Begin to establish/document your GMP & according to FDA’s QS requirements ... must have in place by February 15, 2012

- Assess the likelihood of your organization “manufacturing” MDDS in the future ... many organizations should take steps to insure they are prepared for compliance
References & Resources

- **Medical Device Data Systems: Final Rule** (Federal Register, February 15, 2011)

- **Medical Device Regulation: An Overview from the Food and Drug Administration**
  (HIMSS Webinar, April 13, 2011)

- **The Impact of FDA’s Ruling on Medical Device Data Systems**
  (2011 AAMI Conference and Expo, San Antonio, TX, June 27, 2011)
  [http://www.aami.org/meetings/aami2011/sessions.mon.html#monot3](http://www.aami.org/meetings/aami2011/sessions.mon.html#monot3)

- **ANSI/AAMI/IEC 80001-1: 2010 Application of risk management for IT Networks incorporating medical devices - Part 1: Roles, responsibilities and activities**
  Association for the Advancement of Medical Instrumentation (AAMI) approved/published October 2010.

- **Sentinel Event Alert #42: Safely Implementing Health Information and Converging Technologies** (The Joint Commission, December 11, 2008)
References & Resources (continued)

- 2011 Top 10 Health Technology Hazards--Is Your Hospital at Risk?
  ECRI Institute Webinar, February 23, 2011

- Integrating the Healthcare Enterprise Patient Care Device Domain (IHE®-PCD)
  http://www.ihe.net/pcd/ (accessed 4/11/11)

- IHE®-PCD Alarm Communication Management Profile

- HIMSS Medical Devices and Patient Safety
  http://www.himss.org/asp/topics_MDPS.asp (accessed 4/12/11)
Flowchart for Evaluating Implication of FDA’s Medical Device Data Systems (MDDS) Rule on Healthcare Delivery Organizations (HDO)

A SYSTEM may include:
- any software
- any electronic or electrical hardware such as a physical communications medium (including wireless hardware), modems, interfaces and a communications protocol
- any combination of above

START

Is the SYSTEM intended (i.e., "labeled" or advertised) for connection to a medical device?

YES

Karen is the SYSTEM currently used in connection with active monitoring systems (i.e., monitoring to facilitate immediate clinical actions... e.g., remote alarms?)

NO

SYSTEM is not a MDDS

Does the SYSTEM itself control or alter functions or alter parameters of medical device?

NO

SYSTEM is not a MDDS

YES

SYSTEM is not a MDDS but is another category of Medical Device and likely subject to more regulation

Does the SYSTEM convert medical device data?

NO

Does the SYSTEM transfer medical device data?

NO

Does the SYSTEM store medical device data?

NO

Does the SYSTEM display medical device data?

NO

SYSTEM is not a MDDS

YES

SYSTEM is a MDDS

Has healthcare delivery organization (HDO) either
- put together hardware and/or software into system or added or otherwise modified SYSTEM hardware and/or software provided by original MDDS manufacturer?

YES

HDO is considered a manufacturer by FDA and must:
- register as manufacturer with FDA
- list MDDS with FDA
- implement Adverse Event Reporting according to FDA’s Medical Device Reporting (MDR) requirements
- establish Good Manufacturing Practices (GMP) according to FDA’s Quality System (QS) requirements

NO

HDO is not manufacturer of this MDDS and not required to meet FDA’s MDDS regulations for this MDDS

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For more information, visit www.himss.org/davies or contact David Collins, Director, Healthcare Information Systems, at dcollins@himss.org

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Thank You!

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