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FDA Reauthorization Act of 2017

May 2018 FDA Report on Quality, Safety, and Effectiveness of Servicing Medical Devices

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Objectives

- Understand FDARA 2017 – Section 710
- May 2018 FDA Report on Quality, Safety, and Effectiveness
  - Cover Existing Authorities and Regulations
  - Review March 2016 Request for Comments
  - Review Data from the Public Workshop
  - Summary of Evidence – Medical Device Servicing
  - Cover Key Issues and On-going Activities
  - Review FDA Report Conclusion

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Intermountain Health and Healthcare Technology Management

33 Hospitals

$14.7 billion Total Revenue

Over 200K Inventoried Devices

4,699 Licensed Beds

63,000+ Caregivers

180 HTM Caregivers

7 Primary States
(UT, NV, ID, CO, MT, KS, WY)

385 Clinics

Classic Air Medical
16 Rotary Wing Aircraft
12 Fixed Wing Aircraft

Intro to the FDA Reauthorization Act of 2017

- Became Law on August 18, 2017
- Section 710 – Servicing of Medical Devices
- Requires Report from Secretary of Health and Human Services
- Encompasses Quality, Safety, and Effectiveness of Medical Device Servicing

May 2018 FDA Report - Three Key Entities

➢ Manufacturers, Original Equipment Manufacturers (OEM), Remanufacturers

- Manufacturer - Designs, manufactures, fabricates, assembles, or processes a finished device
- Remanufacturer – Processes, conditions, renovates, repackages, restores, or does any other act to a finished product that **significantly changes performance or safety specifications, or intended use**

➢ Healthcare Establishments and Hospital Based Service Providers

- Entities that **provide care to patients** and receive services from OEMs and other entities
- May directly **employ healthcare technology management professionals** that perform servicing
- **Subject to oversight** from CMS, state governments, or independent organizations such as TJC

➢ Third Party Servicers and Independent Service Organizations (ISO)

- Entities other than the manufacturer or healthcare establishment that maintain, restore, refurbish, or repair devices to **return them to the OEM safety and performance specifications, and intended use**

May 2018 FDA Report - Key Definitions

➢ Recondition/Refurbish/Rebuild

- Restores a medical device to OEM specifications or **to be "like new"**
- Any changes cannot impact the devices performance or safety specifications, or intended use
- Activities include repair of components, software/hardware updates, replacing worn parts

➢ Service

- **Repair** and/or **preventive or routine maintenance** intended to ensure device **meets OEM specifications**
- Excludes activities that change the intended use and/or safety and performance specifications
- FDA considers **remanufacturing** as a distinct activity from servicing that **raises different concerns**
- FDA considers **refurbishing, reconditioning, rebuilding, repairing and remarketing as service**

May 2018 FDA Report - Key Definitions

➢ Repair

- **Type of servicing** that returns a component to original specifications
- Includes replacing non-working components or parts outside of routine maintenance

➢ Remanufacture

- Process, condition, renovate, repackage, restore or other activity
- These activities **significantly change the devices performance** or safety specifications, or intended use

➢ Remarket

- Facilitating the transfer of a previously owned device from one party to another
- Can be accomplished through sale, donation, gift, or lease

Existing Authorities and Regulations

FDA's Authority and Regulation History

➢ The Federal Food, Drug, and Cosmetics Act of 1938

- Oversight of medical products and authorized factory inspections
- Mandates all devices have reasonable assurance of safety and effectiveness
- **Authorized the FDA to establish regulatory controls**

➢ Medical Device Amendments Issued May 1976

- Regulations classifying devices in **control categories of Class I, II, or II**
- Establishment of radiation control provisions
- Premarket approval, performance standards, post market surveillance – Safety and Effectiveness
- **Proper servicing is critical** to ongoing safety and effectiveness of many devices
- FDA believes it has statutory authority to regulate device servicing

Existing Authorities and Regulations

FDA's Authority and Regulation History

➢ **1987 Compliance Policy Guide (CPG) (7124.28)**

- Reconditioners/rebuilders acquire ownership for resale and restore to OEM Specs.
- These organizations are subject to premarket notification, labeling, GMP, and reporting

➢ **Following the Safe Medical Devices Act of 1990**

- Replace "**quality assurance program**" with "**quality system requirements**"
- This incudes design, purchasing, and servicing controls
- FDA finds data associated with maintenance and repair **provides insight** to device performance
- **Service data must be included by OEMs** to monitor adequacy of design and manufacturing

Existing Authorities and Regulations

FDA's Authority and Regulation History

➢ 1996 FDA Rulemaking Decisions

- The FDA excludes servicers and refurbishers from final QS regulation
- Remanufacturers included in definition of manufacturers and subject to the QS regulation

➢ 1997 FDA Publishes Ruling on Used Device Market

- Covers refurbishers, as-is remarketers, and servicers that do not change a device
- Changing approach do to evolving industry practices and ensure suitable performance
- General controls around quality, labeling, recalls, reporting, and device tracking

➢ 1998 FDA Revokes CPG 7124.28

- Overlapped with and was inconsistent with the 1996 rulemaking

Existing Authorities and Regulations

FDA's Authority and Regulation History

➢ The Electronic Product and Radiation Control Regulation (EPRC)

- Issued under authority of Radiation Control for Health and Safety Act of 1968
- Includes **medical devices that would emit, or does emit, electronic product radiation**
- Some activities covered under EPRC may be considered servicing

➢ Code of Federal Regulations Title 21 (CFR 21)

- Section 800 medical device, section 900 mammography, section 1000 radiation emitting device
- Section 1000 outlines responsibilities of assemblers and manufacturers of x-ray systems
- 21 CFR 1020.30(c) OEM subject to disclosure of information on device performance standards
- 21 CFR 1020.30(g) information disclosure around installation, adjustment, and testing

Existing Authorities and Regulations

FDA's Authority and Regulation History

➢ Medical Device Reporting Regulation

- Requirements apply to **manufacturers, device importers, user facilities**, and some distributors
- OEMs required to report serious, or potential serious adverse events associated with devices
- Malfunctions are reportable when it was **likely to cause or contribute** to a death or serious injury
- User facilities – hospital, ASC, nursing home, and outpatient treatment facilities
- UFs required to report serious adverse events to **the FDA and the manufacturer**
- User facilities required to submit an annual report to the FDA using **form FDA 3500A**
- **No obligation** for user facilities or manufacturers **to notify third party entities**

➢ Challenges of MDR and Servicing of Devices

- Most reports **do not include who, when, how often, parts utilized, and testing completed**
- Lack of information **limits the ability to link** events to servicing
- FDA has **not applied** reporting requirements **to third party servicers**
- Limitations of a passive surveillance system can result in **unreliable reports**

Existing Authorities and Regulations

➢ Centers for Medicare and Medicaid Services (CMS)

- Involved in the regulation of maintenance and repair of medical devices based on COP
- Medical equipment – "intended for diagnostic, therapeutic, or monitoring of a patient by a hospital

➢ The Joint Commission (TJC)

- Accreditation requirements aligned with CMS for deemed status
- New element of performance dictates hospitals maintain service manuals on devices

➢ Federal Trade Commission (FTC)

- Encourages government agencies to consider impact of competition or lack of competition

➢ State Regulations

- Bills proposed to expand access to parts and service manuals
- Several states involved with "Right to Repair" but may not call out medical equipment

March 2016 Request for Comments

➢ Federal Register Request for Comments

- Concerns from interested parties about quality, safety, and effectiveness of service
- Notice sought comments on specific terms of servicing, eval of benefits, and risk
- FDA received **186 comments from OEM, ISO, HDO, HTM professionals, and trade associations**
- Healthcare establishments identified **three leading decision factors: quality, cost, and timeliness**
- Other comments included QMS, training, use of quality parts, and access to service information

➢ Quality Management System (QMS)

- Comments **suggested standards for 3rd parties include ISO9001 or ISO13485**
- Specific aspects – supplier validation, design controls, validated service procedures, documentation
- OEM – Lack of service records can impact root cause, troubleshooting, and device performance
- 3Rd Party and HDO – Lack of instructions and procedures can impact service quality

March 2016 Request for Comments

➢ Training

- All stakeholder's indicated **training is critical** to perform service on certain equipment
- OEMs concerned 3rd Party servicers lack expertise/knowledge required for high quality service
- 3rd Party servicers stated their expertise/knowledge matches or exceeds the OEM
- Limited access to device-specific training and few accredited training programs

➢ Availability and Use of Quality Parts

- Importance of using quality parts but concerns around limited availability

➢ Access to Device-Specific Service Information

- Access to device specifications, required test equipment, and test procedures
- Specific OEM and 3rd Party examples and experiences in providing and receiving service
- **FDA did not confirm the validity of the allegations or investigative findings**

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October 2016 Public Workshop

➢ Presenters and Organizations

- Peter Weems (MITA), David Anbari (Mobile Inst. Service and Repair), Tara Federici (AdvaMed)
- Barbara Maguire (ACCE), Robert Kerwin (IAMERS), Mark Leahey (MDMA)
- Tim McGeath (TriMedx), Katie Ambrogi (FTC), Mary Logan (AAMI)

➢ Stakeholder and Panel Discussion Summaries

- OEM concerns - 3rd Party service activities, no mandatory event reporting, incomplete service history
- OEM concerns – Service by untrained personnel, utilization of non-approved parts
- 2016 ECRI report no evidence of issues with independent servicing entities
- **Most servicers are regulated through CMS** and other agencies and no need for more regulation
- Availability of independent servicing entities are **necessary and important for the healthcare ecosystem**
- **Increased collaboration** on training, parts, and manuals is necessary to preserving cost and quality
- **Market competition impacts lower cost, improved access, and better service quality**
- April 2016 Presidential Executive Order requires the government to promote competitive markets

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Summary of Evidence - Medical Device Servicing

➢ Number of Service and Repair Entities

- Precise number of medical device servicing firms in the U.S. is unknown
- Dun and Bradstreet SIC codes estimated 4,791 servicing firms
- Sample group and independent statistical analysis – 16k to 21k medical device service companies

➢ January 2018 FDA Literature Review

- No quantitative evidence to support an evaluation of quality, safety, or effectiveness of servicing

➢ ECRI Institute Analysis

- FDA's MAUDE database 2006-2015 (2,114,303 records)
- ECRI Health Device Alerts database 2006-2015 (528 Records)
- ECRI confidential contracted accident investigations 2006-2015 (692 investigations)
- Only included capital devices and focused on servicing, repair, and maintenance of medical devices
- **Percentage of reports related to servicing was insignificant (96 out of 2,115,523)**

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Summary of Evidence - Medical Device Servicing

➢ Medical Device Reports

- Several hundred thousand MDRs received by the FDA each year
- Used to monitor device performance and potential device related safety issues
- All reports since March 1992 were evaluated, 4,301 reports mentioned only 3rd party service
- **Included 40 deaths, 294 serious injuries, 3,791 malfunction reports, 176 classified as other**
- 4,240 from OEMs, 16 from distributors, 25 from user facilities, and 20 from voluntary sources
- **3 deaths linked to servicing: FSE with CT scanner, FSE with MRI, patient lift rail incorrectly installed**
- Fourth death related to malfunction of remanufactured imaging system without FDA approval
- **FDA determined no conclusive relationship between 3rd party servicers and adverse events**

➢ Regulatory Misconduct Reports (Complaints) to CDRH

- Searched all reports since 2009 mentioning device servicing
- 68 total relevant complaints with 28 of those related to remanufacturing
- Remaining 40 included lack of service manuals, critical parts, training, and falsifying records
- 29 reports of OEM service issues and 10 complaints of ISO service issues

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Summary of Key Issues and On-going Activities

➢ Promote the Adoption of QM Principles by Servicers

- Quality management principles help identify, prevent, track, and monitor safety hazards
- FDA intends to work with entities to identify essential elements of a voluntary framework
- This approach is **more conducive than mandating adoption** of FDA QS regulations

➢ Clarify the Differences Between Servicing and Remanufacturing

- Significant portion of **complaints and allegations pertain to remanufacturing**, not servicing
- FDA has and will continue to regulate remanufacturing as manufacturers.
- FDA intends to publish guidance to ensure more consistent interpretation and categorization
- This will allow FDA to focus on the area with the greatest impact on quality, safety, and effectiveness

➢ Strengthen Cybersecurity Practices Associated with Servicing

- FDA has issued guidance for manufacturers to follow throughout product lifecycle
- Non-OEM service creates servicer challenges like access to tools, materials, diagnostics
- FDA has clarified requirements but many OEMs, 3rd Party, and HDOs, lack required expertise

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Summary of Key Issues and On-going Activities

➢ Foster Evidence Development to Assess Quality, Safety, and Effectiveness

- Collection of evidence on number, rate, and type of servicing errors would be valuable
- Factors impacting collection: underreporting, lack of processes, failure to recognize, poor documentation
- Extending MDR or FDA registration to 3rd party entities would not alone yield desired results

➢ Clarify the Differences Between Servicing and Remanufacturing

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FDA May 2018 Report - Conclusion

- **Evidence is not Sufficient to Conclude a Public Health Concern**
- **No Justification for Additional/Different Regulatory Requirements**
- **FDA Intends to Pursue the Following Actions**
  - Promote adoption of quality management principles
  - Clarify the difference between servicing and remanufacturing
  - Strengthen cybersecurity practices associated with servicing of medical devices
  - Foster evidence development to assess quality, safety, and effectiveness of servicing
- **CDRH Commits to Establishing "Collaborative Communities"**
  - Continuing forum for public and private sector to work together in solving shared problems
  - Participants work in an environment of trust and openness to communicate concerns
  - Focus on delivering high quality, safe, and effective servicing of medical devices

Medical Device Servicing Community (MDSC)

➢ MDSC Steering Committee

- Initial meeting in 2019 at AAMI
- AAMI is a neutral convening organization
- Virtual meetings held every month
- MDSC Charter approved July 2020
- Shared documents on the AAMI website

- MDSC Website:
  https://mdsc.mypagecloud.com/

- Linkedin:
  https://www.linkedin.com/groups/12529335/

➢ MDSC – Current Members

- Assoc. Medical Device Service Organizations
- Steris, Baxter, Siemens, and GE Healthcare
- The Ohio State University Medical Center
- Intermountain Health and Kaiser Permanente
- Defense Health Agency and CommonSpirit
- Arkansas Children's Hospital and VHA/VA
- McLaren Healthcare and Sharp Healthcare
- Norton Healthcare and Massachusettes Hospital
- Mobile Instrument Repair and Block Imaging
- TriMedx, InterMed Group, Crothall, and Nuvolo
- DNV, TJC, ACCE, ECRI, IAMERS and AORN
- Public Interest Research Group
- FTC, FDA, CDRH, and AAMI

Questions?
Answers?
Dad Jokes?
Good Stories about John Krieg?

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Thank You!