FDA Workshop on Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices Performed by Third-Party Entities and Original Equipment Manufacturers - October 27-28, 2016

Viewpoint of the American College of Clinical Engineering

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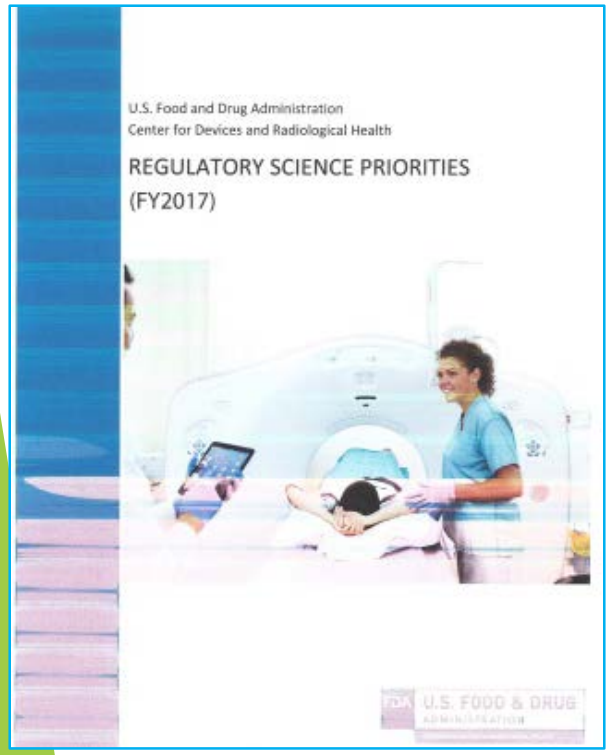
Mission of the ACCE

- To establish a standard of competence and to promote excellence in clinical engineering practice
- To promote safe and effective application of science and technology in patient care
  - Voluntary, not for profit organization founded in 1990 with current membership of over 750
  - Website - ACCEnet.org

Commonsense direction noted in the FDA's 2017 Regulatory Science Priorities



"Leverage real-world evidence and employ evidence synthesis across multiple domains in regulatory decision-making"

"Leveraging real-world evidence can supplement traditional clinical data and inform regulatory decision-making".

With respect to the additional regulation of servicers ….

- The vast majority of servicers are already regulated by the CMS, either directly, through State agencies, or through accrediting organizations such as The Joint Commission.
- Third party entities working within healthcare organizations are able to provide onsite service which improves patient safety at competitive rates
- It is the ACCE's position that additional regulation would be redundant, even counterproductive to our goal of efficiently achieving the highest possible level of equipment-related patient safety.

Rationale for ACCE's Position

1) The "real-world" evidence is that the frequency with which service-related adverse safety events are occurring is not significant - even allowing for potential under-reporting.

2) ACCE believes that the potential benefits associated with additional regulation would not offset the likely downsides.

3) Some of the non-patient-safety arguments from proponents of additional regulation are open to challenge and are not within the jurisdiction of the FDA

Point #1a – The lack of significant real-world evidence …

- Despite a small number of anecdotal reports, there is an insufficient level of evidence of service-related patient incidents to justify any additional regulation.
- The body of available reports:
  - ECRI Institute's MAUDE analysis 1998
  - UK MHRA outcomes of adverse event investigation 2008-2010
  - 2012 TJC survey conducted by AAMI
  - 2013 analysis of TJC sentinel event data
  - 2014 Aramark's decade incident data analysis
  - ECRI Institute's MAUDE analysis 2016
- See docket comments submitted by ACCE for references

Point #1a continued – The actual data

TOTAL EVENTS REVIEWED	CAPITAL EQUIP EVENT RELATED	SERVICE RELATED EVENTS/YEAR	% TOTAL	DATA SOURCE
750,000	137,500	11.76	0.17%	ECRI 1998 (20.5 years)
3,622,000	2,115,523	9.60	0.005%	ECRI 2016 (10 years)

Point #1b – Regarding the allegations of under-reporting

- Several Docket comments allege that the scarcity of data is due to the lack of requirements to report service-related incidents, or near misses.
- However, SMDA'90 and FDA regulations do require user facilities to report incidents, including injury or illness that "necessitates medical or surgical intervention to preclude permanent damage or impairment."
- OEMs are also required by 21 CFR 803.3 to report "… malfunction of the device or a similar device that they market would be likely to cause or contribute to a death or serious injury if the malfunction were to recur."
- Even allowing for a significant level of under-reporting the actual incidence would still be miniscule

Point #1b – Option for improved reporting

Get buy-in from different sector organizations that consistent reporting of service related events on a voluntary basis is better for patient safety and can be a win-win for all sectors.

Point #2b – The likely downsides from additional regulation

- Additional regulation would certainly increase the cost of on-site service support:
  - Reduced levels of on-site support would create delays in repairing devices and therefore in providing patient care. Higher hospital expenses would reduce capital available for acquiring additional devices.
  - Reduced on-site support would reduce other safety-enhancing services provided by on-site support personnel (user training etc.)
- The additional cost burden on third party service providers would diminish the levels of cost-effective third party on-site support currently available to healthcare providers
  - Growth of third-party service is testimony to their perceived value to hospitals who must carefully balance benefits and costs.

Point #2c – The importance and value of on-site technical support

- Important benefits from on-site support
  - Faster response significantly reduces device downtime
  - Can troubleshoot systems with devices from multiple OEMs
  - Can provide user training, support during accreditation surveys, support for capital planning, etc. etc.

Point #3 – Issues that are outside the jurisdiction of the FDA

- "Uneven playing field" is a competitive issue that belongs in the purview of the Federal Trade Commission.
  - OEMs and remanufacturers should recover the costs associated with regulation from device sales, not service
- "Liability imbalance" is a judicial issue that would need to be resolved by the Congress.
  - Plaintiff attorneys sue everyone who has insurance or "deep pockets," not necessarily those who actually caused the injury or loss

In summary

Additional regulation of servicers would be redundant, and evidence does not show that patient safety would be improved.

- No real-world evidence of a significant level of service-related safety problems
- There appears to be no prospect of any significant benefits from additional regulation
- The potential downsides are significant, including the certain risk of increasing the cost of healthcare and the possibility of reducing overall levels of patient safety

Recommendations

- Encourage collaborative activities
  - Education & training
- Encourage community-based initiatives
  - Standardized maintenance documentation
  - Interoperability
  - Voluntary reporting
- Encourage manufacturers to provide better support to users after the sale
- Encourage collaboration between manufacturers and the HTM community
  - Get useful feedback from the field
- Do not impose additional regulations on third party servicers

THANK YOU!

- Please contact us if you have any questions, comments or suggestions
  - ACCE Secretariat, secretariat@accenet.org
- Suggestions, corrections and additional data are always welcome.
- Website: www.accenet.org