



Association of Medical Device Service Organizations

In May of 2018, the FDA released its “Report on the Quality, Safety and Effectiveness of Servicing of Medical Devices,” as required by Section 701 of the Food and Drug Administration Reauthorization Act of 2017 (FDARA).

In arriving at its decision not to impose additional regulation of medical device servicing, the FDA considered numerous inputs. Based upon the available information, FDA concluded:

- *The currently available objective evidence is not sufficient to conclude whether or not there is a widespread public health concern related to servicing, including by third party servicers, of medical devices that would justify imposing additional/different, burdensome regulatory requirements at this time;*
- *Rather, the objective evidence indicates that many OEMs and third-party entities provide high quality, safe, and effective servicing of medical devices;*
- *A majority of comments, complaints, and adverse event reports alleging that inadequate “servicing” caused or contributed to clinical adverse events and deaths actually pertain to “remanufacturing” and not “servicing”; and*
- *The continued availability of third party entities to service and repair medical devices is critical to the functioning of the U.S. healthcare system.*

Although FDA believes that additional formal regulatory action is not warranted, it intends to pursue the following actions:

1. *Promote the Adoption of Quality Management Principles;*
2. *Clarify the Difference Between Servicing and Remanufacturing;*
3. *Strengthen Cybersecurity Practices Associated with Servicing of Medical Devices; and*
4. *Foster Evidence Development to Assess the Quality, Safety and Effectiveness of Medical Device Servicing.*

FDA indicates in the report that stakeholders agree that Patient Safety is at the top of their list of concerns. The FDA suggested the potential creation of a “Collaborative Community” to provide a forum for stakeholders to share information and data. The sharing of information and data between stakeholders, ranging from hospitals and third party independent servicers, to the original equipment manufacturer is critical. The goal of Collaborative Communities is also consistent with the “Right to Repair” legislation pending in several states (e.g., Illinois and Missouri) which would grant non-OEMs access to training, repair manuals, parts at fair and reasonable prices, and all diagnostic repair tools.

AMDSO requires its members to have formal Quality Management Systems and would be supportive of a “Collaborative Community.” AMDSO and its members focus remains steadfastly focused on patient safety. If you would like to see the complete report it can be found on the FDA website at

www.fda.gov/downloads/RegulatoryInformation/LawsEnforcedbyFDA/SignificantAmendmentstotheFDCA/FDARA/UCM607469.pdf.

Sincerely,

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