Third-Party Servicing of Medical Devices

Proper servicing of complex, life-saving and life-sustaining medical devices is vital to their safe and effective functioning and the safety of patients and device users. Original equipment manufacturers (OEMs) dedicate extensive resources to establishing comprehensive servicing programs to ensure that their devices are properly maintained and continue to meet safety and effectiveness standards as determined by FDA.

OEM servicing programs must follow strict requirements set out in FDA's Quality System Regulation, which include specific instructions for training, part and component replacement, documentation of servicing activities, and more. In addition, OEMs and their authorized servicers are subject to numerous other FDA regulations covering reporting of adverse events, recalls, registration with the agency, and many others. This comprehensive set of post-market requirements helps ensure that all servicing done to a medical device is done by properly equipped technicians; that all work is thoroughly documented; and adverse events are reported to the agency.

In addition to servicing their own products, many OEMs also act as third-party servicers to other OEMs and comply with FDA regulations. Some OEMs also rely on contracted third-party servicers to meet their own servicing needs and hold these authorized servicers to the same servicing regulations the OEM is required to meet.

However, there are tens of thousands of unregulated third-party servicers working on complex medical devices — ventilators, imaging systems, infusion pumps, patient monitors, etc. — without proper training and sometimes without appropriate equipment and replacement parts. They are not required to follow the same extensive FDA regulatory requirements as OEMs and their authorized servicers, potentially putting patients and device users at risk. They are not even required to submit basic servicing information to FDA, which means the agency and OEMs are essentially flying blind and cannot ensure devices continue to meet their original standard of safety and effectiveness.

FDA REQUIREMENTS	ORIGINAL EQUIPMENT MANUFACTURERS (OEMS)	THIRD-PARTY SERVICERS
Quality System Regulation (OSR) (21 CFR 820) *Ensures that all servicing operations are carefully controlled and executed.*	✓	✗
Registration (21 CFR 807) *Ensures that FDA knows who is repairing medical devices.*	✓	✗
Medical Device Reporting (MDR) (21 CFR 803) *Ensures that FDA and OEMs know about potentially serious device problems.*	✓	✗
Voluntary Recalls (21 CFR 7) *Ensures that potential device problems are addressed quickly and efficiently.*	✓	✗
Corrections and Removals (21 CFR 806) *Ensures that potential device problems are addressed quickly and efficiently.*	✓	✗

PATIENT HARM FROM UNREGULATED THIRD-PARTY SERVICERS

The lack of regulation of third-party servicers has the potential to harm patients. FDA estimated in May 2018 that there were up to 21,000 companies servicing medical devices. The agency further reported that unregulated third-party servicers were associated with more than 4,300 negative incidents involving medical devices, including 40 deaths and 294 serious patient or device user injuries.

To ensure patient safety, third-party servicers should be required to follow the same regulatory requirements as OEMs — including adverse event reporting, registration to enable FDA inspection, and quality system requirements — so the devices they service continue to meet FDA's high standards of safety and effectiveness.

FALLACY OF "RIGHT TO REPAIR"

Proponents of the so-called "Right to Repair" movement demand that unregulated third-party servicers be given unlimited access to service manuals and other proprietary OEM information. Such a move would only serve to put patients and device users at greater risk. Access to the latest manuals is no substitution for the extensive training, knowledge and expertise provided by the OEM.

Even unauthorized third-party servicers that may have previously worked for an OEM and have knowledge or expertise for earlier models of devices on the market are not equipped to continue to work on these devices. The pace of medical technology innovation is so rapid that these technicians' expertise can quickly become obsolete, rendering their work on newer-model devices potentially dangerous to patients and other device users.