Questions and Answers on Third-Party Servicing of Medical Devices

Maintenance and repair of electronic medical devices by third parties has become the subject of increased attention, including state and federal legislation, FDA requests for comments, a public workshop, and a request by Congress for an FDA report on the subject. Following are answers to frequently asked questions on the issue.

1. **Why is there concern with third party servicing of medical devices?**

Electronic medical devices are maintained and repaired (i.e. serviced) by manufacturers, independent servicers, and hospital technicians. Manufacturers may contract with independent servicers to service their equipment, and hospitals may choose to contract with third-parties for device servicing. Manufacturers often even serve as third-party servicers; repairing other manufacturers' devices. Manufacturers ensure that employees and servicers they contract with are properly trained and utilize the appropriate tools, equipment and quality replacement parts. Manufacturers are required to conduct their service activities, and ensure the qualifications of servicers they contract with, under FDA's Quality System Regulations (QSR) and are subject to FDA inspections. However, independent servicers not contracting with manufacturers are not subject to QSR and are not subject to FDA inspections. Thus, there is a risk that servicing is done by inadequately trained personnel or repairs are done with inappropriate replacement parts.

2. Is there any oversight of the activities of independent repair companies working on medical equipment?

No. Medical device manufacturers are regulated by the FDA, hospitals are subject to oversight from the Center for Medicaid and Medicare Services and the Joint Commission, but no agency oversees the activities of independent service providers repairing medical equipment. Independent servicers do not even need to register with the FDA.

3. Is there data demonstrating a patient safety risk that indicates the need for increased federal oversight of third-party servicers?

There is limited data on third-party device servicing because third-party servicers are not required to report adverse events or any other identifiable information to the FDA. This lack of reporting requirement leaves the FDA unaware of the extent of patient injury from third-party servicing. However, there is a risk to patients from servicing being performed by inadequately trained personnel or repairs done with inappropriate parts. There are multiple examples of patients injured from devices serviced by third parties, including receiving excess doses of medication.
Lack of reporting also hinders manufacturers' ability to monitor products in use, issue safety notices, make upgrades and revisions, and identify trends in order to make future improvements, and ensure the safe and effective use of the devices. Adequate regulatory controls (e.g. requiring registration, establishment of a complaint handling system and/or adverse event reporting) are needed to identify and mitigate patient safety risk.

4. What is the process when equipment at a hospital is out of service and needs servicing?

Some portable devices need to be returned to the manufacturer for servicing by specially trained technicians, in which case the manufacturer provides a temporary replacement. With large pieces of capital medical equipment, manufacturers are often able to use advanced diagnostic tools to remotely monitor, diagnose, and repair problems. Manufacturers of large, complex medical equipment often have field technicians available for around the clock on-site maintenance or repairs to get the device back on-line as soon as possible.

5. Can anything be done to improve oversight of third-party servicers?

In 2016, the FDA reviewed issues with servicing, solicited public comments and held a public workshop, and has been considering ways to enhance servicing safety. In addition, under a newly-passed federal law, the FDA report, within 270 days, on how the FDA could:

- regulate servicing and how it could improve such regulation,
- act under current authority to assess servicing, including the size, scope, location, and composition of third-party entities, and
- track adverse events caused by servicing errors.

With the FDA's authority for device regulation and its impending report, further oversight of servicing should occur at the federal level, not as part of state "right to repair" legislation.

6. Won't additional oversight/regulation of third-party servicers increase costs?

Patient safety should be the primary concern with regard to oversight of third-party servicing of medical devices. Requirements to register with the FDA and report data to the FDA are not cost-prohibitive measures and would significantly improve the FDA's ability to ensure appropriate servicing of medical devices and the availability of safe and effective products.

7. For device manufacturers, is this just a matter of them maintaining control?

No, manufacturers are focused on minimizing patient risk and increasing the safety and effectiveness of devices throughout their lifecycle. Manufacturers support the role of third-party servicers and rely on them in many instances. In the interest of patient safety, third-party servicers should have the same level of regulatory oversight as servicing done by manufacturers.

8. If manufacturers shared repair manuals and software with third-party servicers, wouldn't that improve patient care, reduce health care costs, and support small businesses?

Many medical devices are extremely complex. Simply providing tools and service manuals is insufficient to understanding how they work and ensuring they are properly repaired. Proper training is also essential to the performance of servicing activities. Training is an extensive and ongoing process and given the complexity of many medical devices, a high level of training is necessary and needs constant updating to reflect knowledge of the latest technology advancements. In addition, there are cybersecurity risks from having untrained personnel accessing device software systems.