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Concerns with
State Right to Repair Legislation

Right to Repair legislation, introduced this year in Massachusetts and several other states, would require manufacturers of electronic equipment, including medical devices, to provide product owners and independent repair entities with diagnostic and repair information, including technical updates and software. Medical devices should not be included in this legislation since the manufacture, use, and maintenance of devices is regulated by the Food and Drug Administration (FDA). In addition, the Centers for Medicare and Medicaid Services (CMS), as well as the Joint Commission, which accredits hospitals, have rules for health care facilities relating to the maintenance and repair of devices.

Further, the FDA is currently conducting an inquiry into patient safety issues with medical device servicing by third-party entities. While the Massachusetts legislation would exclude Class III medical devices from the legislation, all medical devices should be excluded from the legislation since many medical devices, beyond Class III would be impacted by this legislation. The inclusion of medical devices in this legislation would conflict with federal oversight and create confusion for providers and manufacturers and could pose risks to patient safety. Also, inclusion of medical devices in the legislation is inappropriate while the FDA is considering additional regulation of medical device servicing.

Medical Equipment
This legislation would impact a wide range of life-saving and life-enhancing medical equipment, including magnetic resonance imaging, mammography machines, ultrasound, computed tomography, laboratory equipment, robotic surgery, medical lasers and x-ray machines. Most electronic medical equipment is classified by the federal Food and Drug Administration (FDA) as either Class II or Class III because of the potential risk to patients and may require post-approval oversight.

The medical device industry's primary concerns with state Right to Repair legislation is that they could result in maintenance and repairs of medical devices being performed by untrained personnel, and that inappropriate replacement parts may be used. Already, there have been reports of serious adverse events linked to failures to appropriately repair medical equipment or use of replacement parts not recommended by the original manufacturer. Further, if these technologies are not maintained properly, the original manufacturer could be liable for damages. Medical device manufacturers currently provide repair information and manuals to third-party repair entities that they contract with for device servicing. However, it would be inappropriate, and pose a potential patient safety risk, for medical device manufacturers to be required to provide repair information to untrained repair entities that may use unapproved replacement parts.

FDA Regulations
The FDA's Quality Systems Regulations (QSR) CFR 21, Section 820, defines requirements that address repair and maintenance of medical devices:

- The QSR requirements govern the methods used for the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished medical devices. The requirements are intended to ensure that finished medical devices are designed and manufactured according to established specifications and that quality is built into the product.

- Under the QSR, it is the responsibility of device manufacturers to establish methods and procedures to help ensure that their products consistently meet applicable quality system requirements. Unfortunately, those QSR requirements do not apply to third-party servicing entities.

- Under QSR Subpart N, finished medical device manufacturers are responsible for establishing instructions for servicing of their devices, and are also required to analyze service reports and report them, as applicable, to the FDA as medical device reports (MDRs). Those third-party servicing entities not contracted with by device manufacturers would not be subject to these same provisions,

In the Federal Register, on March 4, 2016, the FDA announced an inquiry into issues around patient safety and medical device effectiveness as the result of third-party servicing of medical devices. The FDA solicited written comments from stakeholders and announced a public forum to be held later in the year. The notice indicated that issues arising from improper servicing of devices could include ineffective recalls, device safety features being disabled, and improper or unexpected device operation. Significant comments were submitted at the Public Workshop (10/27-28, 2016). During a Congressional hearing, in early May of this year, Dr. Jeffrey Shuren, director of FDA's Center for Device and Radiological Health, indicted that the FDA is continuing to gather information on the issue.

CMS Regulations
Beyond the FDA's oversight, the Centers for Medicare and Medicaid Services (CMS), have requirements that relate to device maintenance and servicing. To safeguard patients, federal regulations (42 CFR 482.41-(c)) impose requirements on medical device maintenance in hospitals. CMS has issued guidance to hospitals requiring that they strictly adhere to manufacturers' maintenance specifications for some types of equipment, including new technologies, imaging machines, radiological equipment, and medical lasers. For some equipment, other federal laws, or regulations promulgated by another agency, may establish maintenance requirements that are even more stringent than the manufacturers' specifications.

The Joint Commission
In recognition of the potential risks to patient safety from inappropriate equipment maintenance and repair, the Joint Commission, which accredits more than 20,000 health care organizations, has issued elements of performance (EPs), which align its equipment maintenance requirements with the CMS guidance document.

Patient Safety Concerns
It is difficult to quantify the potential impact to patient safety from maintenance or repairs being done by improperly trained personnel or from the use of unapproved parts. In cases involving potential, or actual harm, to patients it may not be obvious how the unauthorized repair contributed

to the event. However, there have been cases where the failure to appropriately repair medical devices, or not using approved replacement devices, has put patients at risk. One example of a serious adverse event occurred after an infusion pump was repaired with a non-approved replacement part, which resulted in the pump delivering a dangerously high dose of medication that resulted in harm to the patient.

Other Concerns

- Utilizing used or significantly changed X-ray tubes in imaging procedures, such as computerized tomography (CT) and in interventional cardiology may no longer meet manufacturer specifications or may not meet FDA approval requirements;

- Improper repairing of scopes with insufficient resealing may result in the failure of the device to perform after certain sterilization methods and may result in poor image quality;

- For devices that rely on computer software, cybersecurity issues could pose a threat from third-party non-credentialed service providers;

- Third parties may not have the necessary training or equipment to do the maintenance or repair properly and do not have to comply with the QSR; and

- There is legitimate concern that device manufacturers would be required to disclose technical and design intellectual property information that is proprietary. Currently, disclosure of this information to contracted service providers is protected by confidentiality nondisclosure agreements.

Conclusion

Federal regulations and accrediting bodies impose requirements on the proper service, repair, and maintenance of medical equipment. The FDA's inquiry of third-party servicing could result in changes to how they are regulated by the federal government. The inclusion of medical devices in state "Right to Repair" legislation would conflict and interfere with the federal requirements and cause confusion for manufacturers and health care facilities and threaten patient safety. For these reasons, medical devices should not be included in the "Right to Repair" legislation.

About AdvaMed

The Advanced Medical Technology Association (AdvaMed) is the world's largest trade association representing medical device and diagnostics manufacturers. AdvaMed's member companies produce the innovations transforming health care through earlier disease detection, less invasive procedures and more effective treatments. AdvaMed has more than 400 member companies, ranging from the largest to the smallest medical technology innovators and manufacturers.