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AdvaMed
Advanced Medical Technology Association

February 1, 2021

Honorable Senator Delores G. Kelley
3 East
Miller Senate Office Building
Annapolis, Maryland 21401

Dear Chairwoman Kelley:

The Advanced Medical Technology Association (AdvaMed), the national association of medical technology providers, is concerned about **SB 412**, right to repair legislation, that could require medical technology providers to share design and repair information.

Medical technology servicing and repair by original equipment manufacturers is highly regulated by the FDA and servicing of these devices is sensitive as it relates to patient safety and device system security. Medical technology manufacturers maintain their own devices or provide repair information to authorized third-party servicers they contract with for device servicing.

Federal Oversight of Medical Devices

FDA's Quality Systems Regulations (QSR) CFR 21, Section 820, define requirements addressing repair and maintenance of medical devices. QSR requirements govern methods used for the design, manufacture, packaging, labeling, storage, installation, and servicing of medical devices. The requirements are intended to ensure that devices are designed, manufactured and serviced according to established specifications and that quality is built into the product. Under the QSR, device manufacturers are responsible for establishing protocols for servicing of their devices and are required to analyze adverse events and report them to the FDA. Third-party servicing entities, not contracted with by device manufacturers, are not subject to these same provisions,

Patient Risk

There have been cases where failure to appropriately repair medical devices, or not use approved replacement parts, by non-approved third party servicers has put patients at risk. AdvaMed provided FDA with information on January 2018 from six manufacturers who recorded at least 281 adverse events (also referred to as Medical Device Reports or MDRs) from 2012 to 2017 associated with third-party servicing. For

some devices (e.g., imaging devices), up to 38,500 patients and/or operators were exposed to the potential for harm. These included the following adverse events representing Actual or potential patient and/or operator impacts from these reports include:

> In one example, a serious adverse event occurred after an infusion pump was repaired with a non-approved part, which resulted in an overdose of medication that harmed the patient. In addition, utilizing used 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.

Finally, for devices that rely on computer software, cybersecurity issues could pose a threat from third party non-credentialed service providers especially where untrained staff or volunteers could obtain access to confidential information that could lead to cybersecurity vulnerabilities.

Conclusion

Thank you for considering our perspective on this complicated issue. Our members bear a significant responsibility to the FDA and individual patients that depend on us to protect the safety and security of medical devices, as well as the sensitive data that they contain. We are committed to working with you to promote digital privacy and security, while resisting dangerous interventions that impact patient safety. For those reasons, AdvaMed opposes SB 412.

Thank you for considering our concerns. Please contact me at mbhatt@advamed.org or 303-718-4367 if you have any questions.

Sincerely,

Manthan Bhatt
Director, State Government & Regional Affairs