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MEDICAL IMAGING
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January 24, 2018

The Honorable Christopher Pearson
Vermont State House
115 State Street
Montpellier, VT 05633

Re: Opposition to S. 180

Dear Senator Pearson:

As the leading trade association representing the manufacturers of medical imaging equipment and radiopharmaceuticals, the Medical Imaging & Technology Alliance (MITA) opposes S. 180 in its current form and requests a clear exemption for medical devices.

Original equipment manufacturers (OEMs) and their authorized repair providers are regulated by the Food and Drug Administration (FDA) and must adhere to set quality, safety, and regulatory standards, including 21 CFR 820, when performing maintenance and repair. Independent repair providers are not held to the same standards as OEM and authorized repair providers to perform the same maintenance and repair activities. If enacted in its current form, S.180 would require OEMs of medical devices to provide diagnostic and repair information to unregulated repair providers and owners of digital electronic products. This legislation would affect a wide range of sophisticated, medically essential equipment under the classification and oversight of the FDA, including but not limited to magnetic resonance imaging, ultrasound, computed tomography, x-ray, and PET systems.

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Medical Device Servicing

Servicing a medical device is a complex and often difficult activity that poses a range of serious risks to patients and operators if performed improperly. For this reason, satisfactory quality and regulatory performance of servicing activities is dependent on more than possession of proper materials. Suitable training, adherence to a quality system, and compliance with regulatory requirements set by the FDA are essential to proper device servicing.

Not only do manufacturers invest significant resources into the manufacture and design of medical devices, they also invest heavily in development of servicing tools, training and protocols. These proprietary resources are not necessary for the successful servicing of devices. In many cases, one manufacturer may service another manufacturer's device, doing so based on their own know-how and reverse engineering efforts. Many non-OEM servicers also already

make this kind of investment. Independent servicing organizations need to accept the responsibility to ensure the return of the device to safe and effective operation and can do so by adopting appropriate quality systems and developing their own servicing protocols, tools, and training.

Medical imaging device servicing requires the highest level of technical and procedural training. This training needs to be regularly updated to reflect knowledge of the latest products and technologies, including software and hardware, and a deep understanding of and adherence to current best practices. Operating within a regulated quality system ensures that devices consistently meet applicable requirements and specifications.

FDA Regulation

Currently, only OEMs are held to high regulatory requirements by the FDA, including 21 CFR 820. Non-OEM entities are not held to the same consistent quality, safety, and regulatory requirements as are OEMs. In the last year, the FDA has engaged with a variety of stakeholders on medical device servicing. In October 2016, the FDA collected input from medical device servicing stakeholders via a comment period and a public workshop. Based on this input, we expect that the FDA will take action to ensure all servicing activities result in the safe and effective operation of medical devices.

Congress has also recently reviewed and shown concern on medical device servicing and the lack of equivalent regulation among OEM and non-OEM repair providers. The FDA is currently preparing a report to Congress on its findings and planned next steps. Their report will be completed by or prior to May 2018. Given the ongoing consideration at the federal level, MITA believes that a patchwork of state laws would directly conflict with the critical need for consistency in medical device servicing.

Exemption Language

MITA recognizes that §6102 (7) and §6104 (b) in S. 180 attempt to distinguish the unique qualities of medical devices and attempt to remove them from the intended scope of the legislation. MITA recommends the language in §6104 (b) be replaced by the following:

- The requirements of §6103 do not apply to a medical device as defined in the federal Food, Drug, and Cosmetic Act, United States Code, title 21, section 321(h) or a digital electronic product or embedded software found in a medical setting including diagnostic, monitoring, or control equipment.

Conclusion

The MITA position is that all entities engaged in servicing medical devices should be held to consistent minimum quality, safety, and regulatory requirements. Independent service organizations requesting access to repair materials are no exception. It is unfortunate that these discrepancies currently exist and that operators and patients are not guaranteed an equivalent level of quality, safety, and regulation regardless of who services a medical device. For these reasons, we believe that medical devices should be exempted from S.180.

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If you have any questions, please contact Cassandra Ricci at 703-841-3228 or by email at cricci@medicalimaging.org.

Sincerely,

Patrick Hope
Executive Director, MITA

cc: Members of the Senate Committee on Economic Development, Housing and General Affairs
Senator Michael Sirotkin, Chair
Senator Alison Clarkson, Vice Chair
Senator Philip Baruth
Senator Becca Balint
Senator David Soucy

MITA is the collective voice of medical imaging equipment and radiopharmaceutical manufacturers, innovators and product developers. It represents companies whose sales comprise more than 90 percent of the global market for medical imaging technology. These technologies include: magnetic resonance imaging (MRI), medical X-Ray equipment, computed tomography (CT) scanners, ultrasound, nuclear imaging, radiopharmaceuticals, and imaging information systems. Advancements in medical imaging are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. The industry is extremely important to American healthcare and noted for its continual drive for innovation, fast-as-possible product introduction cycles, complex technologies, and multifaceted supply chains. Individually and collectively, these attributes result in unique concerns as the industry strives toward the goal of providing patients with the safest, most advanced medical imaging currently available.