AMDSO
Association of Medical Device Service Organizations

February 22, 2018

The Honorable Senator Michael Sirotkin
Chair, Senate Committee on Economic Development, Housing, and General Affairs
Vermont State House
115 State Street
Montpelier, VT 05633

The Honorable Senator Christopher A. Pearson
Sponsor S.180
Vermont State House
115 State Street
Montpelier, VT 05633

Dear Senators Sirotkin and Pearson,

I am writing on behalf of the Board and members of the Association of Medical Device Service Organizations (AMDSO). AMDSO represents Independent Service Organizations (ISOs) engaged in the service, repair and education of reusable medical devices.

For years there has been debate regarding the service and repair of surgical devices. Questions such as: If the FDA does not regulate ISOs can their repairs be trusted? Should a health system utilize the Original Equipment Manufacturer (OEM) or an Independent Service Organization (ISO) for the maintenance and repairs of the device for its full life cycle? Is there a difference in quality of repair, parts, technicians and/or warranties?

Many manufacturers would imply that because the FDA does not regulate service of devices, a company other than the OEM who provides service is somehow not of equal quality or puts the hospital at risk. The reality is that to date the FDA has declined the need for regulation of repairs by ISOs and also the OEMs. The FDA governs manufacture of equipment and assures it meets standards when sold as new. As long as the repair does not alter the original use and function of the device, the FDA approval is still in place. Some manufacturers use scare tactics to discourage the use of other companies in the repair and maintenance of their equipment, however many of the largest hospital systems in America utilize and depend on 3rd party repair companies to achieve their financial and operational objectives.

Numerous independent service providers voluntarily expend significant resources to ensure their repairs are high quality and maintain original function by certifying operations according to the International Organization for Standardization. These companies commit to these standards because of their unwavering attention to promote quality, safety and continued effectiveness. It is not uncommon for an ISO to indemnify the hospital against claims resulting

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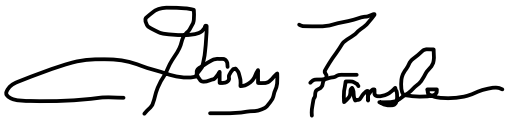
from their failure, provide warranties on the parts/service equal to or greater than that of an OEM, invite you to tour their facilities, provide loaners and perform other value-adding activities to afford healthcare providers confidence in their decision.

While it is true that not all repairs are the same, the determining factor regarding quality is not whether the servicer manufactured the device or not but rather the processes, commitment and focus of the company providing that service. When you hear terms like “manufacture approved”, “factory trained” and “unauthorized” remember that these are used to exclude competition, not ensure quality of repair. If the objective of the manufacturer is to ensure quality of repair, they will offer approved parts, factory training classes and certification to other companies that hospitals select to provide service.

AMDSO supports ‘right to repair’ legislation (S.180 Fair Repair Act) and the inclusion of medical devices in that legislation.

Respectfully,



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