



The University of Vermont

February 13, 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

Re: S.180, Chapter 152, Vermont Fair Repair Act

Dear Senators Sirotkin and Pearson:

The University of Vermont Technical Services Partnership (TSP) is a non-profit, university department which has provided healthcare technology education, management and technical services to a majority of hospitals, clinics and other healthcare organizations throughout Vermont since 1973. TSP is a World Health Organization Collaborating Center for Health Technology Management – *the only such center in the United States*. We have a staff of over 50 professionals located at various sites including our main office at UVM, a dozen at UVM Medical Center, resident staff in community hospitals, or other locations throughout Vermont, New York and New Hampshire. TSP Staff include nationally Certified Clinical Engineers, Certified Biomedical Equipment Technicians, and Certified Healthcare Technology Managers through the American College of Clinical Engineering and the Association for the Advancement of Medical Instrumentation.

A significant part of our services are directed toward the quality assurance, preventative maintenance and repair of the 70,000 medical devices in our contracted inventories. Our quality systems include a complete database of all maintenance, recalls, and other actions throughout the life of the device, a robust set of calibration equipment to verify device quality, staff orientation, training and certification requirements, and policies and procedures conforming to national standards including:

- ANSI/AAMI EQ56:2013 *Recommended Practice for Medical Equipment Management Program*
- ANSI/AAMI EQ89:2015 *Guidance for the Use of Medical Equipment Maintenance Strategies and Procedures*
- NFPA 99 (2012) *Health Care Facilities Code (adopted by Vermont CMS and requires complete service documentation)*
- AAMI/ANSI ES60601-1:2005 (R)2012 *Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance (adopted by the FDA)*
- The Joint Commission *2018 Hospital Accreditation Manual (in conformance to CMS regulations and requires hospitals to have complete service documentation)*

TSP

TECHNICAL SERVICES PARTNERSHIP

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Trusted medical technology for superior patient care

The Technical Services Partnership at UVM endorses bill S.180. Here are some factors supporting the bill related to medical devices:

- **Cost:** With the rapid growth in the number of microprocessor-based medical devices, some manufacturers may deny access to critical service information, service parts and tools to medical equipment owners and third-party servicers. The effect is a lock-out of manufacturers' service competition, leaving medical equipment owners with no choice but to accept a higher cost and often less convenient service offered by the manufacturer. History shows annual service by manufacturers typically represents 10-14% of the acquisition cost of the medical equipment. When healthcare technology managers and clinical engineers have service options and the ability to select between manufacturer, third-party and in-house servicers they generally are able to maintain the overall average annual service costs to between 4 and 6% of the medical equipment acquisition cost. For equipment in the TSP inventory **this represents an estimated savings of \$12-32 million when the service is not provided by the manufacturer.**
- **Safety:** Scientific evidence suggests those who claim that offering service materials - including manuals, instructions, software, access codes, and parts for medical equipment would compromise patient safety - are wrong. A recent study done by the highly respected ECRI Institute of 2.1 million device failure reports made to the FDA over the past 10 years found only 0.005% of failures could be attributed to service or maintenance issues. ECRI Institute concluded there was no evidence to date that a patient safety problem exists with "Servicing of Medical Devices Performed by Third-Party Entities and the Original Equipment Manufacturers."

Also, hospitals are responsible for devices they own and are highly regulated related to medical device quality and safety by CMS and its accreditation agencies such as the Joint Commission, FDA, FCC, NRC, OSHA, and more. Regarding S.180, section 6104. EXCLUSIONS (b) – As it is our understanding that federal rules override state rules in all cases, we don't feel it is necessary to include medical devices as a specific exclusion. Federal agencies who have responsibility for certain appliances, devices or motor vehicles would also override Vermont actions.

Other advantages to qualified, non-manufacturer service providers requiring complete service documentation, tools, and training include:

- *necessarily prompt service by local or resident staff especially for emergent problems to ensure equipment is available promptly for patient care,*
- *integrated, networked systems from multiple manufacturers require resources from multiple manufacturers to resolve any "system-related" problems that may occur,*
- *hospital and TSP healthcare technology management departments have complete histories of all failures and causes, and*
- *qualified healthcare technology managers such as those at TSP employ a rational maintenance strategy to provide direct service only on devices which we can service with quality and have manufacturers service the highly complex and expensive systems such as MRI, CT Scanners, robotic surgery systems and the like.*

Requiring medical device manufacturers to make service instructions, parts, software and other service tools available to medical device owners and third-party servicers is critical to healthcare's ability to ensure medical devices are maintained in a safe, cost-effective, competent and timely manner.

Thank you for the opportunity to express the position of Technical Services Partnership at the University of Vermont on S.180. I am available for questions at (802)656-0070 or Michael.Lane@uvm.edu.

Best Regards,



Michael W. Lane, MBA, CHTM, CMQOE
Director

CC: Members of the Senate Committee on Economic Development, Housing and General Affairs