



American College of Clinical Engineering
5200 Butler Pike
Plymouth Meeting, PA 19462-1298
(610)625-6067

February 16, 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:

We are writing on behalf of the Board and the members of the *American College of Clinical Engineering* (ACCE).

Our organization represents the clinical engineering profession. As per our definition, "*A Clinical Engineer is a professional who supports and advances patient care by applying engineering and managerial skills to healthcare technology.*" Members of ACCE are employed in virtually all sectors of the healthcare industry. Clinical engineers are employed by hospitals, manufacturers, independent service organizations, regulatory/compliance agencies, and academia. We have no bias toward any particular industry segment. Our interests focus solely on the acquisition, application and support of clinical technologies in a manner that delivers safe and effective patient care.

After examining the positions and reviewing the *pro* and *con* arguments made by manufacturers, their industry associations, by healthcare organizations, and by independent service organizations, **ACCE has decided it is in the best interest of patient safety, service quality and cybersecurity to support 'right-to-repair' legislation (S.180 Fair Repair Act) and the inclusion of medical devices in that legislation.**

Over the past 50 years, as clinical medicine has become increasingly dependent on more sophisticated technologies and the complex equipment associated with it, the clinical engineer, as the name implies, has become the bridge between modern medicine and equally modern engineering and technology. In their work with healthcare providers, clinical engineers seek to ensure the benefits of medical technology are realized by ensuring those technologies are effectively supported throughout their lifecycle.

ACCE believes that medical equipment owner/operators, and the clinical engineers and healthcare technology managers that advise them, should have options that give them the ability to select a source of service offering the appropriate balance of safety, quality, timeliness and cost. ACCE believes that restricting third party service access to service resources (e.g., instructions, training, specialized tools, parts, diagnostic software, passwords, etc.) poses a much greater threat to quality and safety by restricting the medical equipment owner/operator's service choices.

In requiring manufacturers to make available service instructions, training, specialized tools, parts, diagnostic software, passwords and similar materials, ACCE sees no conflict with the Food and Drug Administration (FDA), the Centers for Medicare and Medicaid Services (CMS), state departments of health, the Joint Commission (TJC) or other regulatory and accrediting agencies. Requiring manufacturers to make these service materials available would, in fact, facilitate compliance with the following industry standards:

- ANSI/AAMI EQ56:2013, §7.1.1
- NFPA 99:2012, Section 10.5.3.1
- ANSI/AAMI ES60601-1:2015, Section 7.9.2.13
- TJC Accreditations Manual for Hospitals: 2018, EC.01.01.01 EP3

Thank you for the opportunity to make the *American College of Clinical Engineering's* position on right-to-repair known. Senior representatives of ACCE are available to you to give testimony or answer any questions you may have on the important topic of the safe and effective use and support of clinical technologies.

Respectfully,



Arif Subhan, MS CCE CHTM FACCE
President, ACCE
president@ACCEnet.org



Ilir Kullolli, MS
President-Elect, ACCE
presidentelect@ACCEnet.org



Stephen L Grimes, FACCE FAIMBE FHIMSS
Principal Consultant, SHCTA
SLGrimes@ACCEnet.org

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