



American College of Clinical Engineering
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February 16, 2018

Representative John Hunt
Chair, House Commerce and Consumer Affairs
New Hampshire House of Representatives
107 North Main Street
Concord, NH 03301

Representative Virginia Irwin
Representative David Luneau
Co-Sponsors, HB1733
New Hampshire House of Representatives
107 North Main Street
Concord, NH 03301

Dear Representatives Hunt, Irwin and Luneau:

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 (HB1733: An Act *relative to digital electronic product repair*) 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,



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cc: Members of the House Committee on Commerce and Consumer Affairs