GE Healthcare

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January 29, 2019

The Honorable Edward Butler
New Hampshire State House
107 North Main Street
Concord, NH 03301

The Honorable David Luneau
New Hampshire State House
107 North Main Street
Concord, NH 03301

Re: Opposition to H.B. 462

Dear Chairman Butler and Representative Luneau,

GE Healthcare provides medical technologies and services that are helping clinicians in New Hampshire and around the world predict, diagnose, inform, and treat disease so their patients can live their lives to the fullest.

GE Healthcare manufactures and services highly technical, complex medical equipment, including computed tomography (CT), magnetic resonance imaging (MRI), positron emission tomography (PET), anesthesia delivery systems, and other technology that patients and health care providers rely on every day in life critical situations.

We employ approximately 90 employees in New Hampshire, including equipment service engineers whose responsibility it is to ensure that medical imaging systems and other medical technology serviced by GE Healthcare is performing as intended, safely and effectively, for New Hampshire health facilities and patients. Proper servicing of health care equipment by experienced professionals is critical to help ensure not only patient safety, but also accurate diagnosis of disease such as cancer, heart disease, and dementia.

Both the manufacturing and servicing of medical devices are activities highly regulated by the Food and Drug Administration (FDA). However, currently only Original Equipment Manufacturers (OEMs) such as GE Healthcare are subject to U.S. Food and Drug Administration (FDA) regulation when it comes to servicing. Independent Service Organizations (ISOs) are not subject to the same oversight and regulatory requirements. In the last year, both FDA and Congress have engaged stakeholders to learn more about the gaps in service regulations, and work is ongoing to ensure the highest level of patient safety when it comes to equipment servicing.

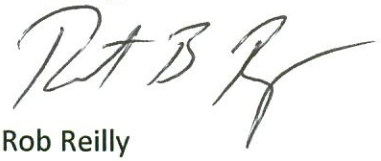
If enacted in its current form, H.B. 462 would require manufacturers of FDA Class I and II medical devices to provide proprietary diagnostic and repair information to unregulated service providers. Class II medical devices include complex equipment such as radiation emitting CT scanners, infusion pumps, and robotic surgery systems. The legislation would exempt Class III medical devices such as Automated External Defibrillators (AEDs), and pacemakers.

Our company invests significant time and resources in the development of servicing tools, processes, employee-training, and service protocols to ensure we meet FDA regulations. GE's equipment comes with our service licensing software, which provides customers with access to all safety, installation, repair and replacement procedures, and all calibrations and tests that are necessary to use the equipment and to carry out ordinary maintenance. Health care providers may purchase a post-warranty license to access more advanced tools, which help to service the equipment more efficiently (e.g., requiring less time or other resources). These proprietary resources, however, are not required for the successful service and maintenance of medical equipment manufactured by GE Healthcare. Likewise, as a multi-vendor service provider, GE Healthcare does not expect or require access to such proprietary technologies and protocols from other manufacturers when we service their equipment.

Requiring manufacturers to make available their proprietary tools, processes, and protocols is not the way to improve patient safety and equipment reliability. Increasing government oversight of all medical equipment servicing activity is a better approach.

GE Healthcare respectfully asks that all medical devices, not just Class III devices, be explicitly exempted from H.B. 462. If you would like to discuss this issue further, please don't hesitate to contact my colleague, Orrin Marcella, at orrin.marcella@ge.com.

Sincerely,



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