January 9, 20024

Senator Chip Curry, Chair
Committee on Innovation, Development,
Economic Advancement and Business
100 State House Station
Augusta, ME 04333

Representative Tiffany Roberts, Chair
Committee on Innovation, Development
Economic Advancement and Business
100 State House Station
Augusta, ME 04333

RE: LD 1716
An Act to Establish a Repairability Index for Consumer Electronics - Oppose

Dear Chair Curry, Chair Roberts, and Members of the Committee,

On behalf of the Advanced Medical Technology Association (AdvaMed), AdvaMed Imaging, and the Medical Device Manufacturers Association (MDMA), we write today to express concerns with the right-to-repair legislation LD 1716 in Maine. Our membership comprises the full spectrum of health technology innovators and manufacturers, who work every day to deliver high-quality healthcare for patients worldwide.

Patient safety is our membership's top priority, and this legislation unnecessarily exposes patients to an increased risk of harm or death. Even though the intent of LD 1716 targets certain consumer electronics for residential use only, medical technology is still inadvertently impacted due to use of these products as part of residential home care by nurses, physical therapists, other healthcare providers or the patients themselves. Patients and consumers rely on a technology's accuracy to provide proper diagnosis and maintain safety standards.

As introduced, LD 1716 would require medical technology providers to share proprietary design and repair information with third-party servicers. Often, these providers lack the necessary training to repair complex medical systems. While these tablets or electronic devices are not made by a medical device manufacturer, they become part of the product when approved as a medical device and therefore fall under legal ownership of that medical device manufacturer.

Some examples of medical technology that would fall in the scope of LD 1716:

- portable ultrasound where the transducer is paired with a tablet used exclusively as part of this product,
- patient worn monitors with cellular,
- implantable pacemakers/defibrillators that transmit device status information to clinicians via an ancillary device in the patient's home,
- portable X-ray device that can include a SIM card,
- patient monitors connected to a central station in a hospital.

Original Equipment Manufacturers (OEMs) are subject to strict regulations by the Food and Drug Administration (FDA) to ensure patient safety. These regulations protect the safety and efficacy of medical devices and include registration with the FDA, implementation of quality and safety controls, proper training, and qualification of replacement parts. Independent third-party service providers are not held to the same standards. A 2018 report by the FDA found more than 4,300 adverse events – including 294 serious injuries and 40 deaths – from devices repaired by unauthorized third-party providers.

These complex issues are accounted for in federal legislation known as the Fair Repair Act – a right-to-repair bill that provides a full exemption for medical device manufacturers. Similar exemptions are provided in bills introduced in Minnesota, Washington, and recently signed legislation in New York.

Safety and security are paramount to our members and the patients they serve. We appreciate your consideration of our concerns and are committed to working with the legislature on this critical issue. Feel free to contact any of our organizations with additional questions. Thank you again, and we look forward to working with you.

Sincerely,

Roxy Kozyckyj
Director, State Government and Regional Affairs
AdvaMed

Clayton Hall
EVP, Government Affairs
MDMA

Patrick Hope
Executive Director
AdvaMed, Medical Imaging