

May 2025

Re: Support for Medical Device Right to Repair Legislation

The Alliance for Quality Medical Device Servicing, consisting of TRIMEDX, Sodexo, Crothall, and Agiliti (the "Alliance"), would like to share our support and encouragement for *H.160*, the proposed Medical Device Right to Repair legislation that is being considered by the Vermont State Legislature. The Alliance members are Independent Service Organizations responsible for maintaining millions of medical devices across the United States.

It is the strong opinion of the Alliance that establishing Medical Device Right to Repair legislation is an important factor to ensuring safety, effectiveness and freedom of consumer choice for servicing and maintaining medical devices. Bill H.160 and similar right to repair legislation is necessary to assure fair competition, address ongoing anticompetitive practices by some medical device original equipment manufacturers (OEMs), and ensure and enforce fair access to the materials necessary to maintain medical devices and help contain costs.

Right to Repair legislation centered on medical devices is essential. This position is supported by medical device safety data accumulated over multiple decades that indicates that there is no evidence supporting an argument that the safety of medical devices is negatively affected by who services the device. In May of 2018, the FDA responded to Congress regarding this question in its Report on the Quality, Safety, and Effectiveness of Servicing Medical Devices¹. The report concluded that the evidence actually supports the opposite contention often voiced by some OEMs. The FDA found that there is objective evidence indicating that independent thirdparty service organizations provide high quality, safe and effective service for medical devices, that there is no evidence indicating that there are significant safety issues related to servicing of medical devices, and that additional regulatory changes are not warranted.

The Alliance agrees with these conclusions by the FDA and believes that medical device Right to Repair legislation is an important and necessary step to ensure device safety, cost-effectiveness and a fair and competitive marketplace for all participants. Quite simply, the purchasers of medical devices must have the ability to decide how to best maintain and service their medical equipment without unreasonable restrictions by OEMs.

¹ This report, published in May, 2018, is available at

https://www.fda.gov/downloads/RegulatoryInformation/LawsEnforcedbyFDA/SignificantAmendmentstotheFDCAct/FDARA/UCM607469.pdf