MOBILE INSTRUMENT
SERVICE & REPAIR INC.

May 1, 2017

Ms. Carly McWilliams
Mr. John Stone
House Subcommittee on Health
Rayburn Office Building
Washington, DC

Ms. McWilliams and Mr. Stone,

I am writing to you to express opposition to H.R. 2118, Medical Device Servicing and Accountability Act which is scheduled to be discussed on May 2, 2017 at a subcommittee hearing on various proposals to improve regulation of medical technologies.

There is no evidence to suggest that H.R. 2118 will improve public health as intended. According to the only definitive, independent analysis of the FDA's data on adverse events resulting from malfunctioning reusable medical devices, a mere 0.005% of the reportable events were related to servicing regardless of who (manufacturer or independent service organization) performed the service[1]. No objective evidence that has been presented to date through the FDA's multi-year and exhaustive analysis of this subject supports the need for regulation of independent service organizations.

Provider organizations make the choice to use independent servicers every day as thousands of devices are successful and cost-effectively repaired. One reason there are few incidents and providers embrace independent service organizations is that reusable device repair and maintenance is subject to regulatory scrutiny through existing CMS rules on hospital's maintenance programs. This existing framework ensures that devices are maintained according to manufacturer recommendations and is enforced through The Joint Commission and state health departments.

The proposed legislation would do irreparable harm to the independent service industry by imposing rules that were designed for medical device design and manufacture on companies who repair existing devices to their original operating condition. The regulatory burden of the legislation will drive independent servicers from the market resulting in greater market control by manufacturers. The impact will be felt in at least three key areas.

1. Patient Safety. By making repair and maintenance services convenient and accessible, health care providers are more likely to properly maintain their equipment than if they must send it to a manufacturer for service. Independent servicers also provide vital education and advice to clinicians on caring for devices to help improve patient safety.

[1] Refer to the ECRI Institute comments submitted June 1 to FDA located at https://www.regulations.gov/document?D=FDA-2016-N-0436-0126

2. Device Efficacy. When devices are maintained properly, the critical diagnostic and treatment functions performed with the devices are assured and outcomes for patients improve.

3. Cost Control. By providing an alternative to manufacturer service, independent service organizations eliminate the virtual service monopolies that manufacturers operate and reduce the cost of repairs by as much as 50% compared to manufacturer service. Further, when devices are maintained properly, they last longer and reduce the need to buy a replacement.

It is not coincidental that the proposed legislation has been put forward by a consortium of for-profit, medical device imaging system manufacturers. The consortium has much to gain by reducing competition for service and I believe that their motives have more to do with profits than protection of patients. Faced with increased scrutiny of new regulations from the White House, the consortium has turned to Congress to advance its agenda.

Rejecting FDA action and turning to a legislative solution is at best premature. As recently as the Subcommittee hearing on MDUFA IV in March, Dr. Shuren of the FDA stated that agency staff is still collecting information, meeting stakeholders, and analyzing options regarding oversight for independent servicers. In addition, it is not coincidental that the proposed legislation includes an "exemption" for hospital staff who perform services on millions of devices each year. These individuals repair each year would not be subject to oversight even when the work performed is the same as an independent servicer. It seems clear the "exemption" is present so manufacturers can avoid alienating the buyers of their equipment while reducing competition from independent servicers.

Lacking evidence of a problem to be solved, realizing that 0.005% of reportable events involved service activities, and the high likelihood that safety, efficacy, and costs would be adversely impacted, this legislation is neither necessary nor justified. This is an example of manufacturers turning to legislative action to enhance their commercial opportunities. The Subcommittee should reject this legislation and let the FDA perform their statutory responsibilities without external influence.

I would welcome an opportunity to meet with you or members of the Subcommittee to more fully explain our positions and ensure that you have the perspective of independent service organizations as you consider this legislation. I can be reached at 404-518-1486 or danbari@mobilinstrument-ga.com.

Sincerely,

David Anbari
Vice President and General Manager