ALLIANCE
FOR QUALITY MEDICAL DEVICE SERVICING

Servicing Medical Devices

Preparing America for the Next Crisis by Learning from the COVID-19 Pandemic Experience

The COVID-19 crisis has created many challenges for the health care system and has raised some opportunities for improvements. One area of improvement is related to the servicing of medical devices, namely in increased collaboration and improved access to the parts, manuals, training and other materials necessary to maintain the devices. Some of these enhanced collaboration and access in response to the public health crisis may, unfortunately, be only temporary. Prior to COVID-19, the policy by some Original Equipment Manufacturers ("OEMs") of restricting access to data, parts and the training requisite for proper servicing of hospitals' medical equipment was common practice. This led to longer time to complete repairs and made medical devices unavailable for use, inflated costs, limited the number of trained technicians and endangered our national health care system defenses.

When some of these barriers were lifted in response to the COVID-19 crisis, Independent Service Organizations ("ISOs") and in-house teams were empowered to work autonomously and in tandem with OEMs, assisting hospitals in caring for COVID-19 patients by safely and effectively servicing medical equipment and ensuring its availability for use when needed. Examples of this amazing collaboration between the OEMs, ISOs and in-house teams include the dramatic response to the national need for ventilators, selfless coverage for technicians infected with the COVID-19 virus and unprecedented, unified support of our medical first responders in ICUs and emergency rooms. Health care facilities of all sizes, locations and economic status were covered by the considerably increased legion of qualified medical equipment technicians. It is vital to ensure the lesson from these experiences is not lost.

The Right to Repair legislation currently under consideration in many state legislatures provides a timely opportunity to eliminate restrictive and unfair business practices, comply with existing requirements and ensure that recalcitrant OEMs make available the information and parts needed to service the equipment. This legislation will not increase risk as evidenced by the Food and Drug Administration's ("FDA's") own assessment and conclusion that third parties "provide high-quality, safe and effective servicing of medical devices" as part of a year-long study about safety of service performed by third parties. Such legislation will also not diminish an OEM's ability to profitably create and sell next-generation medical devices, nor will it eliminate an OEM's role as the ultimate source for knowledge and maintenance of those products, while still offering choices to health care providers on how to service their medical devices. It will, however, immediately create more available working medical equipment to

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meet demand, promote more competitive servicing prices and reduce response times without lowering quality standards, equipment effectiveness or safe patient care.

While state Right to Repair legislation is one means to address the issue of restrictive practices and to ensure access to service materials, there are other important, complementary avenues. For example, FDA and the Centers for Medicare & Medicaid Services ("CMS") play critical roles in establishing and enforcing standards concerning medical device servicing and availability of service materials. Some OEM's regularly restrict access to such materials, creating barriers for health care providers and their chosen service teams. In addition, the Federal Trade Commission ("FTC") can act to prevent anti-competitive practices in this area. Notably, the FTC began looking at repair restrictions generally when it hosted a "Nixing the Fix" workshop in 2019. Each of these agencies plays a key role in the overall objective of ensuring that restrictive barriers lifted during the COVID-19 crisis do not again fall back into place.

We believe it is time to address the facts without bias and to strengthen our national health care system and its ability to respond to future health crises that are all but certain to reoccur. The collaboration generated by the COVID-19 crisis can and should be an example for a new standard.

The Alliance for Quality Medical Device Servicing was formed in 2018 and is composed of six leading independent medical device service organizations throughout the United States. The Alliance consists of TriMedx (which now includes the former Aramark Healthcare Technologies business unit), Sodexo, Crothall, ABM, Agiliti and The InterMed Group.

The Alliance represents the largest participants in the ISO segment of the U.S. medical device service industry. The Alliance employs tens of thousands of employees across all 50 states and actively services and maintains millions of medical devices across the country. The Alliance members, as ISOs, serve as a truly independent voice and advocate for health care providers, offering not only safe and effective service, but also an equipment agnostic perspective focused on improving safety, reliability and efficiency.

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