Right-to-Repair Efforts Around Medical Devices Gain Traction

The so-called "Right-to-Repair" debate has been ongoing for some time in various industries such as automotive, consumer products and farm equipment, among others. The COVID-19 pandemic focused needed attention on medical equipment, as many hospitals, whether through their in-house teams or chosen third party servicers, found it difficult to secure needed parts, tools and information to service devices essential for the care of COVID-19 patients.

The U.S. Public Interest Research Group (PIRG) recently released a report on how "right-to-repair" considerations impact medical professionals, particularly during the pandemic. Nearly half of the 222 biomedical professionals surveyed for the PIRG report, many of whom work at hospitals, indicated that they had been denied access to necessary parts and information during the pandemic. In May, PIRG delivered a letter signed by 326 biomedical professionals to members of Congress, calling for access to service information including manuals and software access keys.

Restrictions on access to tools, parts and information needed to service and repair medical devices were highlighted during the pandemic, as some original equipment manufacturers (OEMs) were unable to offer parts or on-site support in a timely manner due to hospital restrictions, state or local guidelines or, in some cases, by the OEMs' policy. The resulting gaps often left hospitals and the COVID-19 patients in precarious positions despite of the dedication and efforts of in-house departments and ISOs which work on site.

On August 6th, the Critical Medical Infrastructure Right-to-Repair Act of 2020 (heretofore referred to as Medical Device Repair Act) was introduced in the Senate by Ron Wyden of Oregon and in the House of Representatives by Yvette Clarke of New York. The proposed legislation is designed to lift barriers that prevent healthcare providers from maintaining and repairing their medical equipment they desperately need to care for the COVID-19 and other seriously ill patients. While the proposed legislation is currently tied to the duration of the COVID-19 pandemic, it represents an excellent first step to address at a federal level what has become an increasingly acute problem with respect to medical device repair and maintenance. It is worth noting that the requirement of providing service information has been in existence in

the European Union since 1993 (Medical Device Directive) and will be reiterated in the Medical Device Regulation that will become effective in May 2021. The Centers for Medicare & Medicaid Services (CMS) has recognized the existence of this access problem in the United States.

The **Alliance for Quality Medical Device Servicing** (Alliance), a coalition of six of the country's largest independent service organizations (ISOs), is strongly supportive of the Medical Device Repair Act and applauds Senator Wyden and Representative Clarke for addressing what have been systemic problems in the medical device industry. While the Alliance wants to see the scope of the Medical Device Repair Act become permanent, we fully support bringing this legislation to the forefront. Many healthcare, professional, and advocacy groups, including the National Rural Health Association, American College of Clinical Engineering and Electronic Frontier Foundation, have come out in support of the Medical Device Repair Act.

The Alliance has consistently pointed to the restrictive and often anticompetitive behavior that certain OEMs have perpetuated with respect to medical device service and repair. As suggested by the PIRG survey, we have similarly found that some OEMs frequently restrict or place barriers in front of hospitals and third parties. The following are some of the behaviors we have experienced and reported previously: refusing to provide service manuals to equipment owners or their agents (or requiring license agreements to obtain the service manuals), refusing to provide service training, refusing to sell certain parts, refusing to provide equipment owners or their agents with keys to access software needed for maintenance or repairs, requiring that only OEM service personnel, procedures and parts can be used in servicing medical devices, and pressuring equipment owners not to use ISOs for maintenance or other servicing under unsubstantiated safety and outcome claims.

To be clear, some OEMs have not raised such barriers and have been more supportive of the access rights set out in right-to-repair principles including the Medical Device Repair Act. These OEMs have seen the forest through the trees and have often made information and tools available on commercially reasonable terms. However, such cooperation is often the exception rather than the norm, as many OEMs have taken more restricted approaches and act in an anticompetitive manner to secure the business for themselves. During the pandemic, a few OEMs have lifted temporarily such restrictions when they realized the potential harm to public health and consequential negative publicity; however, they very well may revert to their restrictive policy once the pandemic subsides.

In addition, some in the manufacturing community have painted the current debate as a struggle between ISOs and OEMs. This characterization could not be further from the truth. While ISOs are an important part of the medical device ecosystem, as recognized by the FDA's 2018 report on servicing medical devices[1], many hospitals in the United States do not fully

[1] FDA Report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices, in accordance with Section 710 of the Food and Drug Administration Reauthorization Act of 2017 (FDARA), issued in May 2018.

outsource responsibility for service and repair of their medical devices. Rather, they rely on a combination of dedicated in-house teams, complemented by OEM service contracts and on-demand labor, as well as labor and service arrangements with ISOs. Because the Medical Device Repair Act covers equipment owners, lessees and service providers, these hospital teams would equally reap the benefits of the legislation, as well their chosen service providers.

Manufacturer trade groups have also tried to confuse the matter by suggesting that the current regulatory landscape is a contributing issue. While it is difficult to understand how this question impacts the idea of access set out in the Medical Device Repair Act, device servicers, whether ISOs or in-house teams, are correctly not regulated as manufacturers because they do not design or produce devices. However, these in-house and third party teams must follow all state and federal laws, regulations, and accreditation requirements applicable to their health care provider customers, particularly those issued by the FDA's sister organization, CMS. ISOs that follow an on-site model at hospitals step into the shoes of their hospital customer with respect to compliance with these laws and regulations, including satisfying reporting requirements under the healthcare provider umbrella. Moreover, following a multi-year review and scrutiny of service issues and patient incidents, the FDA concluded in its 2018 Report to Congress that no additional regulatory requirements were needed.

In sum, the Alliance strongly supports the Medical Device Repair Act as well as related initiatives that have as an objective ensuring access to information and tools needed for the support of medical devices and which serve to level the competitive playing field. The Alliance also supports initiatives intended to foster increased dialogue in the industry, such as the collaborative community approach supported by the FDA. This collaborative approach is designed to encourage a broad range of stakeholders to address challenging issues and work together on solutions that benefit the American people. It is unfortunate that some manufacturers and their trade groups discontinued their participation earlier this year, making it difficult to have all stakeholders represented in these important discussions.

About the Alliance

The Alliance for Quality Medical Device Servicing is comprised of six leading independent medical device service organizations throughout the United States. The Alliance consists of TriMedx, 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 fifty states and actively services and maintains millions of medical devices across the country.