House Energy and Commerce Subcommittee on Health

2125 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Burgess and Committee Members:

Re HR 2118 Medical Device Servicing and Accountability Act

About Repair.Org

Repair.Org is a 501(c) 6 non-profit trade association representing the industry repair industry for technology-enabled assets such as computers, communications, consumer electronics, and technology enabled medical equipment. Our members include companies in the business of independent medical equipment repair, hospitals, and Biomedical Engineering Technicians (BMET).

HR 2118 will increase, rather than decrease OEM Repair Monopolies

Our primary concern with HR 2118 is the impact this bill will have on independent repair businesses and the health care facilities that hire them. Currently, competition for repair services is being destroyed for high-tech medical equipment by manufacturers that refuse to provide access to the basic information and materials necessary for repair, including directly to their customers. These are true repair monopolies and have been determined as such as recently as April 27, 2017 where GE was found in violation of anti-trust law for monopolizing repair of anesthesia equipment.[1]

Repair businesses only operate under the supervision of regulated hospitals, physicians, and BMETs. These are the parties responsible for patient care, not the repair business. These users are not demanding more regulation of repair and are seeking our help driving legislation to improve competition for repair services.

It appears to us that the primary impetus behind HR 2118 is to help OEMs reduce their exposure to competition for repair as a business. We know these OEMS are in opposition to state legislative efforts to expand access to modern repair, and it does not surprise us to see attempts to use the FDA and Congress to achieve their aims.

[1] See Red Lion Medical v GE https://www.law360.com/cases/54f64405a09caa5024000001

Registration Requirement will Kill Jobs and Damage Patient Care

Repair businesses are nearly all small business – and the financial burdens of registration alone will cause many to go out of business. Thousands of repair technicians that support older equipment will lose their jobs, and hospitals will lose the option of keeping older equipment in use. Patients will have less access to technology enabled medical services as fewer and fewer facilities will be able to afford equipment.

Driving competition out of business is a benefit to the OEMs that can sell new equipment to replace unsupported models and command arbitrary labor rates and parts prices.

Purpose of Registration:

We have heard the theory that independent repair businesses are not subject to the same rules as OEMs. This is framed as a matter of fairness – which would be reasonable if the two businesses were the same. They are not. Repair and Manufacturing are two totally separate industries. It happens that some OEMS engage in both manufacturing and repair, but repair businesses are not manufacturers.

Independent repair providers do not, and cannot, fix problems that originate with the manufacturer – such as poor design or buggy software. The FDA requires registration from OEMS because they are responsible for oversight of patient safety and can demand corrections from OEMS. We agree that if repair providers engage in manufacturing they should be required to register – but without a manufacturing function there is nothing for the FDA gain through registration.

Reporting Requirement is Duplicative:

The requirement to require independent repair providers to report on patient outcomes will not improve information flow to the FDA. Repair technicians, both OEM and ISP, are called on to repair a specific product and following completion return the equipment to the user for return to service. Service technicians are not privy to patient records and would not have any knowledge of patient outcomes. Only the user (hospital, supervising physician, or BMET) would be able to report on patient outcomes to the FDA.

Common Misconceptions about Repair:

Repair is restoration of equipment to full function using the documentation, tools, and parts designed by the OEM for the purpose of repair. Repair is not tinkering, customization, or modification. If repair information is hidden or blocked – the business of repair is monopolized to the OEM.

OEMs write service documentation and diagnostics so that technicians can quickly identify the hardware failure, remove the failed part, insert a spare, and re-run diagnostics to confirm the repair is complete. This process is identical regardless of if the technician is employed by the OEM, ISP, or a hospital (BMETS). The only difference between OEM and ISP repair is availability of the information intended to be used for repair.

Incomplete Repair:

Technically, it is difficult to consider any device repaired if it does not “fully execute” its original diagnostics. This has been the standard for digital electronics repair for decades and eliminates any guesswork based on the relative skills of the technician. It may take a poorly trained tech longer to complete a repair, but the repair itself is just as complete once the unit successfully executes its diagnostics.

Projections of patient harm due to incomplete repair are therefore suspect.

Post-Repair Problems:

Following repair, some devices may undergo further processing, such as sterilization, before patient use. These services may be provided by independent providers, but these services are not repair. Issues of improper handling for invasive surgical procedures should not become an excuse to further monopolize repair.

We welcome the opportunity to work with all stakeholders to make sure that all care facilities have access to the highest quality repair services.

Thank you for your consideration.

Sincerely

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