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The Fallacy of Right to Repair for Medical Devices

Fact: The Risk to Patient Safety is Too High

Proponents of the Right to Repair movement demand that unregulated, third-party servicers be given unlimited access to service manuals and other proprietary Original Equipment Manufacturer (OEM) information, while skirting any meaningful oversight of quality and safety standards. Legislative proposals establishing Right to Repair policies for medical devices can significantly compromise patient safety and erode existing standards that protect the quality, effectiveness, and innovation patients rely on.

Common Myths on the Right to Repair Medical Devices

MYTH

OEMs Charge More to Maintain Devices

FACT

Any discounts unregulated third-party servicers may provide come from not having to comply with FDA's patient safety regulations. The cost for servicing depends on the sophistication of the device, which could range from simple blood pressure cuffs to a computerized tomography (CT) scan machine which requires longer and more complex training. Trainings that provide customer service tools for use after the training, like the manufacturer's intellectual property, are also more costly.

MYTH

Study Shows that OEM Servicing Does Not Make Devices Safer

FACT

Proper service and repair of complex medical technology is often a life-or-death matter for patients. Proponents of Right to Repair legislation often cite a flawed Emergency Care Research Institute (ECRI) study while failing to provide critical information from the FDA. The FDA's report to Congress on the Quality, Safety, and Effectiveness of Servicing of Medical Devices found 4,301 adverse events associated with inadequate third-party device repairs and replacement parts, including 40 deaths and 294 serious injuries. This evidence was gathered despite third parties not being required to report any adverse events during or resulting from their repairs.

MYTH

More Options for Repair Reduces Equipment Downtime

FACT

There is no substitution for the extensive training, knowledge, and expertise of an OEM or an authorized third-party repair. In fact, an OEM is often called in after a third party has attempted and failed to repair a machine. Many OEM replacement parts are highly specialized and precise in design and function, with some devices requiring more than 90 custom tools for servicing. Most third-party services cannot replicate the caliber or quality necessary to properly service a device, which can negatively impact the device's safety and lead to possible injury or death of the patient.

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MYTH

The FDA Does Not Want to Regulate Third Party Medical Device Service Repair

FACT

Third parties do not submit Medical Device Reports (MDR), so there is insufficient evidence for FDA to make a determination. The full quote from the 2018 FDA study actually states: "The currently available objective evidence is not sufficient to conclude whether or not there is a widespread public health concern related to servicing, including by third party servicers of medical devices that would justify imposing additional/different, burdensome regulatory requirements at this time."

MYTH

All Technical Material Must Be Available to Service Medical Devices Properly

FACT

Authorized service entities and medical technology manufacturing competitors can and do expertly repair medical devices, after the proper training from an OEM, without access to intellectual property. Right to Repair advocates falsely claim that they need this proprietary information to properly repair medical devices. Preventing OEMs from determining who may have access to service manuals, replacement parts, specialized repair equipment, or programming software may result in additional unsafe and ineffective devices compromising patient safety.

MYTH

Third Parties Are Already Regulated

FACT

The claim that third parties are regulated or undergo any comparable level of scrutiny and oversight is false. The Centers for Medicare and Medicaid Services (CMS) and The Joint Commission (TJC) policies only establish minimum requirements on hospitals for the maintenance of equipment, not servicers, and the requirements do not apply to all facilities or clinics. TJC provides accreditation for some, but not all hospitals, and the prerequisite to meet an accreditation equipment maintenance requirement is not the same as a universal requirement for all healthcare equipment servicers to be regulated by the FDA.

Bottom Line

Tens of thousands of unregulated third-party servicers work on complex medical devices without proper training and sometimes without appropriate equipment and replacement parts. OEMs and their authorized servicers recognize that — despite the additional cost— compliance with FDA regulations is vital to helping companies fulfill their commitment to patient safety. OEMs believe any service or repair on complex medical technology should be done only by trained and authorized servicers to ensure continued adherence to the highest levels of effectiveness and patient safety.