



The Issue:



MEDICAL DEVICES & RIGHT TO REPAIR

States across the nation have introduced bills that aim to give consumers more options on how they repair the products they own. Known as "right to repair," these bills would require manufacturers to provide device instructions as well as parts and tools to independent repair shops and consumers. While this may work for some farming equipment and personal consumer devices, extending right to repair to medical devices could have severe consequences on individuals health and wellbeing. These are complex, intricate machines that require expert training and federal oversight to conduct repairs.

Without precision, patient safety could be at risk.

NOT ALL PRODUCTS ARE CREATED EQUAL

Repairing life-saving medical equipment has a much higher risk-factor than the personal devices that are the focal point of many right to repair bills. There is a fundamental difference between fixing a phone screen and repairing highly sophisticated medical devices, like MRI machines and CT scanners.



MANDATES THREATEN HIGH STANDARDS OF REPAIR

Unlike original equipment manufacturers (OEMs), third-party servicers are not required to follow the U.S. Food and Drug Administration's Quality System Regulations for servicing equipment, and importantly, not required to report when repairs go wrong, known as "adverse event reporting." These strong federal regulations are in place for one reason: patient safety. A gap in oversight puts patients at risk, especially if we enact one-size-fits-all legislation that gives broad access for third party servicers.



MANDATES CREATE VULNERABILITIES & STIFLE INNOVATION

Not holding all servicers to the same level of accountability increases the likelihood of defective repairs, along with the risk of cybersecurity vulnerabilities. Properly trained servicers know the particulars of both the hardware and software of these devices, mitigating the risk of a data breach. Right to repair mandates could also limit technological innovations among manufacturers designs in favor of standardization.

