The Right to Repair Software-Dependent Medical Devices

Health Policy Portal

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Abstract: The "right to repair" movement highlights opportunities to reduce health care costs and promote public health resilience through increased competition in the way in which medical devices are serviced and updated over their lifespan. We review legislative and legal facets of third-party repair of medical devices, and conclude with specific recommendations to help this market function more efficiently to the benefit of patients and health care systems.

Software-dependent medical devices play a large and growing role in health care delivery, spanning medical imaging equipment, ventilators, dialysis machines, and nearly any device with a digital interface. A critical issue for health care institutions managing these devices is ensuring safe and effective use with regular maintenance and updates, usually done through service contracts with the original manufacturer. This article characterizes recent developments aligned with the broader, consumer-driven "right to repair" movement that may expand options for service and repair of medical devices. These changes present potential opportunities for reducing health care costs while advancing other public health goals.

The right to repair movement — a consumer-led advocacy effort aimed at reducing manufacturer repair restrictions — is based on the simple principle that consumers should have the ability to freely choose who repairs products that they own. In many cases, including medical devices, software designers try to block end-users from engaging third-party service providers by encoding "digital locks" within their devices. It then becomes a violation of copyright law, subject to criminal liability under Section 1201 of the Digital Millennium Copyright Act (DMCA), to circumvent these technological protection measures to access software necessary for repair. Every three years, however, the Library of Congress engages in a rulemaking process to add exemptions to the DMCA. For the first time, in October 2021, an exemption was made for medical device repair. In response, industry advocacy organizations Medical Imaging & Technology Alliance and AdvaMed sued the Library of Congress in March 2022 challenging the medical device exemption to the DMCA, in part citing their threatened service revenues under the exemption.

Establishing a safe right to repair for medical devices may promote a

About This Column

Aaron Kesselheim serves as the editor for Health Policy Portal. Dr. Kesselheim is the *JLME* editor-in-chief and director of the Program On Regulation, Therapeutics, And Law at Brigham and Women's Hospital/Harvard Medical School. This column features timely analyses and perspectives on issues at the intersection of medicine, law, and health policy that are directly relevant to patient care. If you would like to submit to this section of *JLME*, please contact Dr. Kesselheim at akesselheim@bwh.harvard.edu.

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competitive medical device repair market, both constraining unnecessary health care costs and promoting public health. Each year, the US spends about $200 billion on medical devices,[1] and over the lifecycle of a device, maintenance typically costs more than procurement.[2] Maintenance contracts with manufacturers amount to approximately 10-15% of a device's original purchase cost annually, while independent and in-house hospital service costs are estimated at 5-8% and 3-5%, respectively.[3] Therefore, assuming third-party service is equivalent in quality, minimizing manufacturer repair restrictions can reduce maintenance costs. This may prove particularly influential in low-resource institutions such as safety-net hospitals, with the potential follow-on effect of improving medical device accessibility.

Manufacturers also benefit from artificially restricting access to necessary repair information and training. They can refuse to publish important repair information and have attempted to use copyright claims to target public databases that provide clinical engineers and technicians a centralized, indexed resource for repair manuals.

How Manufacturers Restrict Repair Competition

Manufacturers attempt to maximize revenue by controlling software-dependent medical device repairs through both internal mechanisms and by gatekeeping crucial information. Technological protection measures are digital locks, such as passwords, service keys, and encryption, that prevent access to copyrighted materials. Manufacturers often use technological protection measures to limit access to diagnostic data, service manuals, and calibration software, all of which are essential to the repair process. These digital obstructions can frustrate even mechanical repairs. For example, imaging equipment often must be calibrated after repairs. But many independent servicers do not have access to the software that completes this process, effectively locking them out of the device until it is reset by the manufacturer. They also have public health implications; software locks meant many ventilators could not be repaired during the COVID-19 pandemic without manufacturer service passwords. In times of scarcity, hospitals may also have to rely on previously decommissioned devices, such that repair restrictions risk obstructing a rapid public health response.

Manufacturers also benefit from artificially restricting access to necessary repair information and training. They can refuse to publish important repair information and have attempted to use copyright claims to target public databases that provide clinical engineers and technicians a centralized, indexed resource for repair manuals. While independent repair services can go through a certification process with the original manufacturer to become an officially authorized service that has access to this information, this training is limited. The U.S. Public Interest Research Group (PIRG) described many of these barriers.[4] General Electric previously required a four-day, in-person training before granting access to ventilator repair information. It subsequently waived the requirement due to pressure from the general public, right to repair interest groups, and a joint statement from several state treasurers. In a separate instance, General Electric was also found to have violated federal antitrust law by denying certification opportunities from competing third-party services. U.S. PIRG's interviews with clinical engineers found that training can also be cost prohibitive, requiring some hospitals to ration training. For other new devices, training programs may not even be offered, narrowing repair services to those provided by the manufacturer alone.

Concerns about Third-Party Repair

Manufacturers may argue that third-party repairs could be lower in quality and therefore risk patient safety. However, in 2018, the FDA reviewed stakeholder presentations, independent studies, and medical device safety reports and servicing complaints submitted to the agency and concluded that manufacturers and third-party services alike "provide high quality, safe, and effective servicing of medical devices" and that "[t]he continued availability of third party entities to service and repair medical devices is critical to the functioning of the U.S. healthcare system."[5] In a 2021 report to Congress, the FTC found "no empirical evidence to suggest that independent repair shops are more or less likely than authorized repair shops to compromise or misuse customer data."[6] Another concern is that manufacturers may increase upfront costs to recuperate lost maintenance and repair revenue, undermining the cost-saving potential of a competitive repair market. But several studies on pricing reform in other areas of the US medical products market suggest that cost-shifting is unlikely.[7]

Right to Repair — Opportunities for Reform

There are several pathways available to minimize manufacturer interference and support a competitive repair market for software-dependent medical devices. The simplest option would be for the Library of Congress to continue to renew the DMCA medical device exemption every three years. However, this triennial uncertainty will make the repair market less desirable for current third-party

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service providers and potential new market entrants.

Alternatively, antitrust law could maximize competitive opportunities for third-party services. This approach is promising, as the FTC has recently oriented much of its focus towards this end. In its 2021 report, the FTC unanimously found that repair restrictions by manufacturers, including those affecting medical devices, unduly stifle competition. The report outlined the agency's goals for increasing enforcement against repair restrictions, including greater scrutiny of potentially pretextual repair restriction justifications, challenging repair restrictions as unfair practices, and after further deliberation, rulemaking to declare overly restrictive practices illegal. To achieve these goals, however, it would be necessary to overcome growing judicial skepticism of administrative authority and any funding limitations that may bar the agency's implementation of right to repair protections.

Finally, Congressional action, while elusive, would provide greater assurance for third-party services that need to circumvent technological protection measures for software-dependent medical device repair. Congress previously exercised its authority to make permanent exemptions from the DMCA in 2012, passing the Unlocking Consumer Choice and Wireless Competition Act and securing the right to circumvent cell phone technological protection measures that prevent consumers from switching wireless carriers after a contrary DMCA ruling. So long as the current exemption proves safe, a similar policy, perhaps supplemented with increased adverse event monitoring by the FDA, could be pursued to make the medical device exemption permanent and support a lasting competitive repair market, decrease medical device spending, and increase availability of software-dependent devices during public health emergencies.

Note

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