

---

## SENATE COMMITTEE ON APPROPRIATIONS

Senator Anthony Portantino, Chair  
2021 - 2022 Regular Session

---

### SB 605 (Eggman) - Medical Device Right to Repair Act

**Version:** April 29, 2021

**Urgency:** No

**Hearing Date:** May 10, 2021

**Policy Vote:** HEALTH 10 - 0, JUD. 9 - 0

**Mandate:** No

**Consultant:** Shaun Naidu

**Bill Summary:** SB 605 would require manufacturers of powered medical devices to make the documentation, software, and parts necessary to maintain and repair such devices available to a hospital and an independent service organization engaged by the hospital, on fair and reasonable terms, so that the hospital or its engaged repair service can conduct its own maintenance and repairs. It would subject a manufacturer that violates this requirement to a civil penalty, as specified.

**Fiscal Impact:** Unknown, potentially-significant workload cost pressures to the courts to adjudicate alleged violations of this measure. While the superior courts are not funded on a workload basis, an increase in workload could result in delayed court services and would put pressure on the General Fund to increase the amount appropriated to backfill for trial court operations. For illustrative purposes, the Governor's proposed 2021-2022 budget would appropriate \$118.3 million from the General Fund to backfill continued reduction in fine and fee revenue for trial court operations. (General Fund\*)

\*Trial Court Trust Fund

**Background:** Under existing federal law, the Food and Drug Administration (FDA) may regulate and impose performance standards on certain medical devices. Additionally, certain medical device manufacturers must provide certain information to the FDA relating to the devices they manufacture, including reports on adverse events involving a device and reports on repairs or removals of their devices initiated by the manufacturer. Moreover, federal law requires owners and operators of certain medical devices to provide certain information relating to their devices, including reports on adverse events involving a device.

On the state level, the Sherman Food, Drug, and Cosmetic Law, enforced by the Department of Public Health, regulates the manufacture, production, processing, and packing of any food, drug, device, or cosmetic. The department may establish performance standards for devices to provide reasonable assurances of safe and effective performance and, where appropriate, require the use and prescribe the form and content of labeling for the proper installation, maintenance, operation, or use of the device; however, where specified federal laws dictate device performance standards, that federal standard governs in California. Additionally, every manufacturer making an express warranty related to certain electronics and appliances must make available to service and repair facilities sufficient service literature and functional parts to affect the repair of a product, as specified.

**Proposed Law:** This bill would establish the Medical Device Right to Repair Act. Specifically, it would:

- Require an original manufacturer of powered medical equipment used in the treatment, monitoring, or diagnosis of a patient to provide documentation, parts, service access methods, and tools used to inspect, diagnose, maintain, and repair powered medical equipment to a hospital and an independent service organization engaged by the hospital for the purpose of providing medical equipment maintenance and repair, on fair and reasonable terms, as defined.
- Specify that the act does not require an original equipment manufacturer to divulge a trade secret to a hospital or an independent repair provider engaged by the hospital for the purpose of providing medical equipment maintenance and repair, except as necessary to provide documentation, parts, tools, service access methods, and training courses and materials on fair and reasonable terms.
- Make an original equipment manufacturer who knowingly violates any provision of the act, or who reasonably should have known that they violated any provision of the act, liable for a graduated civil penalty as follows:
  - First violation: Up to \$10,000 per piece of equipment.
  - Second violation: \$20,000 per piece of equipment.
  - Subsequent violation: \$50,000 per piece of equipment.
- Allows a civil action alleging a violation of the act to be brought only by the Attorney General, a district attorney, a county counsel, or a city attorney.
- Specify that half of the penalty recovered in an action that is brought by the Attorney General to be paid to the county in which the judgment was entered and half to the state and that penalties collected by the Attorney General may be used to enforce the act
- Specify that all of the penalty recovered in an action that is brought by a district attorney or county counsel is to be paid to the county and that the penalty recovered in an action brought by a city attorney is to be paid half to the county and half to the city.
- Specify that the act applies to equipment that is sold or in use on or after January 1, 2022.

**Related Legislation:** AB 1163 (Eggman, 2019-2020 Reg. Sess.) would have required manufacturers of certain electronic or appliance products making an express warranty for products worth \$50 or more to make available sufficient service literature, at no charge, and functional parts, on fair and reasonable terms, as defined, to owners of the equipment or products, service and repair facilities, and service dealers. AB 1163 was never heard in the Assembly Committee on Privacy and Consumer Protection.

AB 2110 (Eggman, 2017-2018 Reg. Sess.) would have required certain original equipment manufacturers of certain electronic equipment or parts sold and used in the state to, among other things, provide to independent repair providers and owners of the equipment certain parts, tools, and information, including diagnostic and repair information, as specified, for the purpose of providing a fair marketplace for the repair of that equipment. AB 2210 was never heard in the Assembly Committee on Privacy and Consumer Protection.

**Staff Comments:** The fiscal impact of SB 605 to the courts will depend on many unknown factors, including the numbers of violations alleged to have occurred, if parties settle the matter before the filing of an action, and the factors unique to each case. While it is not known how many enforcement actions for alleged violations ultimately

would be filed, it generally costs about \$8,032 (in FY 2020-2021) to operate a courtroom for one eight-hour day. Consequently, if alleged violations of SB 605 lead to the filing of cases by the Department of Justice, district attorneys, county counsels, and city attorneys that, combined, take 50 or more hours of court involvement, the cost pressures of this measure to the courts would surpass the Suspense File threshold. As indicated above, while courts are not funded on a workload basis, an increase in workload could result in delayed services and would create pressure to increase the backfill amount appropriated from the General Fund for trial court operations.

**-- END --**