SENATE JUDICIARY COMMITTEE
Senator Thomas Umberg, Chair
2021-2022 Regular Session

SB 605 (Eggman)
Version: April 15, 2021
Hearing Date: April 27, 2021
Fiscal: Yes
Urgency: No
AWM

SUBJECT

Medical Device Right to Repair Act

DIGEST

This bill requires 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.

EXECUTIVE SUMMARY

Technological advances, and the increased use of software in a wide range of medical devices, have made it easier for manufacturers to block access to the information, parts, and programs necessary for owners to perform their own maintenance and repairs. Current law does not require manufacturers to make such information, parts, or programs available, meaning manufacturers can effectively block repairs and maintenance by anyone other than their chosen repair representatives. This bill would provide a narrow exception to current law, by requiring manufacturers to make available to hospitals or their chosen independent service facilities, on fair and reasonable terms, the information, parts, and programs necessary for hospitals to perform in-house repairs. The author has agreed to amendments to adopt California's definition of "trade secret" and to clarify the bill's civil penalty provisions.

The bill is sponsored by the American College of Clinical Engineering, the California Public Interest Research Group (CALPIRG), and iFixit, and supported by a wide range of hospitals, medical groups, consumer protection groups, and over 100 individuals. The bill is opposed by a wide range of manufacturing groups. The bill passed out of the Senate Health Committee with a 10-0 vote.

PROPOSED CHANGES TO THE LAW

Existing federal law:

1) Authorizes the Food and Drug Administration (FDA) to regulate and impose performance standards on certain medical devices. (21 U.S.C. §§ 360c-360d.)

2) Requires certain medical device manufacturers to 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. (*E.g.*, 21 C.F.R. §§ 803.10, 806.10.)

3) Requires owners and operators of certain medical devices to provide certain information relating to their devices, including reports on adverse events involving a device. (*E.g.*, 21 C.F.R. § 830.30.)

Existing state law:

1) Establishes the Sherman Food, Drug, and Cosmetic Law, to regulate the manufacture, production, processing, and packing of any food, drug, device, or cosmetic, enforced by the California Department of Public Health (CDPH). (Health & Saf. Code, div. 104, pt. 5, §§ 109875 et seq.)

2) Permits CDPH to 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. (Health & Saf. Code, § 111245.)

3) Requires every manufacturer making an express warranty with respect to certain electronics and appliances to make available to service and repair facilities sufficient service literature and functional parts to affect the repair of a product as follows:
    a) For applicable electronics and appliances with a wholesale price to the retailer between $50 and $99.99, the literature and parts must be available for at least three years after the date a product model or type was manufactured, regardless of whether the three-year period exceeds the warranty period for the product.
    b) For applicable electronics and appliances with a wholesale price to the retailer of $100 or more, the service and parts must be available for at least seven years after the date a product was manufactured, regardless of whether the seven-year period exceeds the warranty period for the product. (Civ. Code, § 1793.03.)

This bill:

1) Establishes the Medical Device Right to Repair Act.

2) States that it is the intent of the Legislature to promote choice and competition for the repair of medical devices by requiring manufacturers of powered medical equipment used in the treatment, monitoring, or diagnosis of a patient, to make available to a hospital and an independent repair provider engaged by the hospital for the purpose of providing medical equipment maintenance and repair, on fair and reasonable terms, the documentation, parts, and tools used to inspect, diagnose, maintain, and repair this equipment.

3) Provides the following relevant definitions:
    a) "Authorized repair provider" is an individual or business who is unaffiliated with an original equipment manufacturer and who has an arrangement with the original equipment manufacturer, for a definite or indefinite period, under which the original equipment manufacturer grants to the individual or business a license to use a trade name, service mark, or other proprietary identifier for the purposes of offering the services of inspection, diagnosis, maintenance, or repair of powered medical equipment under the name of the original equipment manufacturer, or other arrangement with the original equipment manufacturer to offer those services on behalf of the original equipment manufacturer. An original equipment manufacturer who offers the services of inspection, diagnosis, maintenance, or repair of its own powered medical equipment, and who does not have an arrangement with an unaffiliated individual or business for repair, shall be considered an authorized repair provider with respect to that equipment.
    b) "Powered medical equipment" or "equipment" is any powered device approved by the FDA that is used in the treatment, monitoring, or diagnosis of a patient, and including assistive, adaptive, and rehabilitative devices.
    c) "Documentation" is any manual, diagram, reporting, output, service code description, schematic, or other guidance or information used in effecting the services of inspection, diagnosis, maintenance, or repair of powered medical equipment.
    d) "Embedded software" is any programmable instructions provided on firmware delivered with powered medical equipment, or with a part for that equipment, for purposes of equipment operation, including all relevant patches and fixes made by the manufacturer of the equipment or part for these purposes.
    e) "Fair and reasonable terms" may be:
        i. For obtaining a part, tool, documentation, or training course and material: the same costs and terms that are equivalent to the most favorable costs and terms under which an original equipment manufacturer offers the part, tool, documentation, service access method, or training course and materials to an authorized repair

provider, including accounting for factors such as rebates, incentives, or preferences offered to the authorized repair dealer; and the terms may not be conditioned on or impose a substantial obligation or restriction that is not reasonably necessary for enabling a hospital or independent repair provider to engage in the diagnosis, maintenance, or repair of powered medical equipment.

ii. For documentation, including any relevant updates: all the requirements in Part 3.e.i, plus providing documentation and updates at no charge, except that documents requested in printed form may come with a charge for the reasonable actual costs of preparing and sending the copy.

iii. For software tools: all the requirements in Part 3.e.i, plus providing the tools at no charge and without requiring authorization or internet access; without imposing impediments to access or use in the course of the diagnosis or repair, and without impairing the efficient and cost-effective performance of the diagnosis, maintenance, or repair; and enabling full functionality.

iv. For an original equipment manufacturer that does not utilize an authorized repair provider: an equitable price in consideration of the actual cost to the original equipment manufacturer to prepare and distribute the part, tool, service access method, or documentation, exclusive of any research and development costs incurred.

f) "Firmware" is a software program or set of instructions programmed on powered medical equipment, or on a part for that equipment, to allow the equipment or part to communicate within itself or with other computer hardware.

g) "Hospital" is a facility licensed pursuant to Health & Safety Code section 1250(a), (b), or (f).

h) "Independent repair provider" is an individual or business, other than the manufacturer or hospital, that is engaged in the services of inspection, diagnosis, maintenance, or repair of powered medical equipment for purposes of returning it to the safety and performance specifications established by the manufacturer and to meet its original intended use.

i) "Original equipment manufacturer" is a business engaged in the business of selling, leasing, or otherwise supplying new powered medical equipment manufactured by, or on behalf of, itself, to any individual or business.

j) "Part" is any replacement part, either new or used, made available by an original equipment manufacturer for purposes of effecting the services of inspection, diagnosis, maintenance, or repair of powered medical equipment manufactured by, or on behalf of, sold, or otherwise supplied by the original equipment manufacturer.

k) "Tools" is any software program, hardware implement, or other apparatus used in inspection, diagnosis, maintenance, or repair of powered medical equipment, including software or other mechanisms that provision, program, or pair a new part, calibrate functionality, or perform any other function required to bring the product back to fully functional condition.

l) "Service access method" is any password, key, code, software, or token that allows access to medical equipment diagnostics, error logs, or token that allows access to medical equipment diagnostics, error logs, or configuration settings that is necessary to facilitate installation or restoration of medical equipment to normal operation.
m) "Trade secret" is anything tangible or intangible or electronically stored or kept that constitutes, represents, evidences, or records intellectual property including secret or confidentially held designs, processes, procedures, formulas, inventions or improvements, secrets of confidentially held scientific, technical, merchandising, production, financial, business, or management information, or anything within the definition of Section 1839(3) of Title 18 of the United States Code.

4) Provides that, for powered medical equipment, and parts for powered medical equipment, sold or used in this state, an original equipment manufacturer shall make available to a hospital and an independent repair provider by the hospital for the purpose of providing medical equipment maintenance and repair, on fair and reasonable terms:
   a) Any documentation, parts (unless the part is no longer available to the original equipment manufacturer), service access methods, and tools, including any updates to information or embedded software, needed for purposes of inspection, diagnosis, maintenance, or repair of the equipment.
   b) Any training courses and materials on the operation, inspection, diagnosis, maintenance, and repair of the equipment, unless the original equipment manufacturer does not make such a course or material available to an authorized repair provider.

5) Provides that any person who knowingly violates the provisions of the bill, or who reasonably should have known that they violated any provision of this article, shall be liable for a civil penalty, assessed and recovered in an action brought in the name of the people of the State of California by the Attorney General or any district attorney, county counsel, or city attorney, in the amount of:
   a) $1,000 per day per piece of equipment for the first violation.
   b) $2,000 per day per piece of equipment for the second violation.
   c) $3,000 per day per piece of equipment for the third and any subsequent violations.

6) Provides that the penalties collected in an action shall be disbursed as follows:
   a) In an action for penalties brought by the Attorney General, half of the penalty collected shall be paid to the treasurer of the county in which the judgment was entered and half shall be paid to the State Treasurer.
   b) In an action for penalties is brought by a district attorney or county counsel, the entire penalty collected shall be paid to the treasurer of the county in which the judgment was entered.

c) In an action for penalties brought by a city attorney or city prosecutor, half the penalty collected shall be paid to the treasurer of the city and half shall be paid to the city.

7) Authorizes the penalties collected by the Attorney General to be expended by the Attorney General, upon appropriation by the Legislature, to enforce the bill's provisions.

8) Provides that an original equipment manufacturer is not required 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.

9) Provides that the bill does not alter the terms of any arrangement between an authorized repair provider and an original equipment manufacturer, including, but not limited to, the performance or provision of warranty or recall repair work by an authorized repair provider on behalf of an original equipment manufacturer subject to an agreement for such work, except that any provision that purports to limit the original equipment manufacturer's obligations to comply with the terms of the bill is void and unenforceable.

10) Provides that the bill's requirements apply to equipment sold or in use after January 1, 2022.

COMMENTS

1. Author's comment

According to the author:

> Though the pandemic brought national attention to the Right to Repair, many critical devices have been left offline for days or weeks waiting for Original Equipment Manufacturer (OEM)–authorized repair technicians, while in-house experts and other third parties who can repair medical equipment immediately at a lower cost are locked out of the process. In addition to saving time and money, in 2018 the FDA found that: "we do not believe that a safety problem exists with the servicing, maintenance, and repair of medical devices by either third-party organizations or OEMs," and, "the continued availability of third party entities to service and repair medical devices is critical to the functioning of the U.S. healthcare system."
>
> COVID-19 has shone a light on many inequities that simply do not need to exist. The grip that OEMs have on repair can cost more money, take more time, and delay care. Allowing for independent repair will enable health care facilities to

quickly service critical medical devices and equipment, preventing delays and improving patient care. SB 605 addresses this by requiring OEMs to provide parts, tools, documentation, and software updates needed for inspection, diagnosis, maintenance, or repair of medical devices to independent repairers and individual owners.

2. Background: the rise of technology and the decline of DIY repairs

As explained in the Senate Health Committee's analysis of this bill—incorporated here by reference—OEMs of a wide range of products have made it increasingly difficult in recent years to repair their products, e.g., by limiting the availability of parts. OEMs also, increasingly, build proprietary software keys into their products: the key is essential to fix the product, but only the OEM and its authorized manufacturer has access to the key, effectively preventing any other party (including the owner) from conducting repairs themselves.[1] The pervasiveness of OEMs inserting proprietary tools into electronic devices has even hampered the United States' Armed Forces' ability to repair its defense equipment and technology.[2] According to the author, OEM-imposed restrictions on repairs lead to higher costs and slower repairs for product owners such as small businesses, farmers, and—saliently for this bill—hospitals.

According to the author and sponsors, the United States Public Interest Research Group (U.S. PIRG) conducted a survey of 222 biomedical repair technicians, clinical engineers, and health care technology management professionals in June 2020—a few months into the COVID-19 crisis—and found that 91.8 percent of respondents reported that they had been denied access to service information for "critical equipment" such as defibrillators, ventilators, anesthesia machines, and imaging equipment; 30.4 percent reported equipment in their facilities could not be used due to restrictions on spare parts and service information; and 68.5 percent said their hospital had to "delay a patient procedure because they were waiting on a manufacturer service representative to fix a device." In a second survey of 129 biomedical personnel during the winter 2020 COVID-19 surge, 76 percent reported being denied access to parts or service materials for critical medical equipment as cases spiked, 80 percent had equipment they could not service because of restrictions to service keys, parts, or other materials, and 90 percent reported that the COVID-19 surge had increased their need to be able to conduct repairs in-house rather than waiting on OEMs or their authorized repair facilities.

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[1] *E.g.*, Waldman & Mulvany, *Farmers Fight John Deere Over Who Gets to Fix an $800,000 Tractor*, Bloomberg Businessweek (Mar. 5, 2020), https://www.bloomberg.com/news/features/2020-03-05/farmers-fight-john-deere-over-who-gets-to-fix-an-800-000-tractor [last visited Apr. 14, 2021].
[2] Mizokami, *the U.S. Military Has a 'Right to Repair' Problem*, Popular Mechanics (Feb. 11, 2020), https://www.popularmechanics.com/military/weapons/a30859791/us-military-right-to-repair/ [last visited Apr. 16, 2021].

3. This bill requires certain OEMs to make maintenance and repair information and equipment available to hospitals and their chosen repair facilities

This bill would create a limited exemption to the general practice of allowing OEMs to limit who can maintain or repair their equipment, by requiring OEMs to make all necessary tools—information, training, software, access keys, parts, etc.---necessary for maintenance or repairs available to hospitals and their independent service facilities on reasonable terms. Hospitals would thus be able to conduct maintenance and repairs in-house, or using trusted repair facilities, rather than having to rely on the OEMs' repair service or their authorized repair facilities. The bill does not require OEMs to make the necessary tools available for free, but does require the OEMs to make the necessary tools available at the same prices offered to their authorized repair facilities, along with any training materials it offers to its authorized repair facilities. The bill specifies OEM is not responsible for providing tools or training materials that are no longer available to the OEM, and that the OEM need not provide trade secrets except as necessary to permit the hospital or independent service provider to conduct the repairs.

The Senate Health Committee has already heard this bill and considered its implications for health care facilities and patients. This analysis focuses on the issues related to intellectual property, federal law, consumer safety, and civil penalties presented by the bill.

4. This bill does not appear to impose undue risks to OEMs' intellectual property

Opponents of the bill suggest that granting biomedical engineers access to the software and firmware (collectively, software) necessary to conduct repairs could harm their copyright protections in the software. They specifically mention that their software is protected by the Digital Millennium Copyright Act,[3] which ensures that bad actors cannot interfere with the digital rights management tools that manufacturers use to protect their software. Under the terms of the bill, however, it is unclear how manufacturers' copyrights could be at risk. The provision of necessary software or software keys to biomedical engineers authorized under this bill—i.e., providing the software to authorized users—would not have to affect the manufacturers' copyrights; manufacturers could simply provide the keys subject to a limited license or other agreement protecting the copyright. And the provisions of the Digital Millennium Copyright Act would seem to strengthen, not lessen, the manufactures' ability to protect their intellectual property, by specifically prohibiting persons from circumventing copyright holders' technological measures intended to control access to protected works.[4] Hospitals depend on relationships with medical device manufacturers; there has been no evidence provided to this Committee that biomedical engineers are more likely, on an aggregate basis, to misuse OEMs' intellectual property than, e.g., OEMs' authorized manufacturers.

[3] Pub. L. 105-304, 112 Stat. 2860 (1998).
[4] *See* 17 U.S.C. § 1201(a).

Sharing repair information could also implicate OEMs' trade secrets, because the bill does require trade secret information to be shared to the extent necessary for the hospital or its service provider to make repairs. Opponents of the bill have specifically raised concerns about groups that provide "open sourced" repair information online, which they argue could violate their intellectual property interests. While it is unclear how much of the material available online is subject to intellectual property protections, this bill does not prevent OEMs from taking steps to protect their intellectual property by, e.g., requiring recipients of repair information to sign nondisclosure agreements, or placing protections on repair information that would prevent unauthorized use by persons who are not associated with a hospital, such as dual-factor authentication or single-use reset keys. And because the bill limits the required sharing of data to professionals—either those in-house in hospitals or third-party repair service providers—there does not appear to be any specific reason to believe that these persons will be more likely to wrongfully disclose information than any other repair service provider. The author has pledged to continue working with the stakeholders to try and develop specific steps OEMs may take to impose protections on intellectual property and secured data.

Finally, the bill, as currently in print, adopts the Massachusetts and federal definitions of "trade secret." To ensure uniformity of application across California law, and to provide guidance in the form of existing case law interpreting the proper protections for trade secrets, the author has agreed to amend the definition to the one currently in effect in California's Uniform Trade Secrets Act. The amendment is discussed in further detail below.

5. <u>This bill does not appear to pose compliance issues with respect to FDA reporting requirements</u>

The bill's opponents suggest that allowing hospital biomedical engineers or hospitals' chosen third-party repair facilities to repair medical equipment could run afoul of, or run contrary to the purposes of, federal reporting requirements for repairs to certain medical devices. The Senate Health Committee's analysis addresses this issue in greater detail, but in brief, this position does not seem supported by the FDA's most recent guidance on the matter. In 2018, the FDA issued *FDA Report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices*.[5] It concluded that the available evidence did not justify imposing additional, burdensome regulatory requirements on third-party medical device services, and that "the objective evidence indicates that many OEMs and third[-]party entities provide high[-]quality, safe, and effective servicing of medical

[5] *FDA Report on the Quality, Safety, and Effectiveness of the Servicing of Medical Devices, In accordance with Section 718 of the Food and Drug Administration Reauthorization Act of 2017 (Report)*, FDA (May 2018) (*FDA Report*), *available at* https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&ved=2ahUKEwjg1aPewP_vAhUUuZ4KHYb3AIYQFjAAegQIAhAD&url=https%3A%2F%2Fwww.fda.gov%2Fmedia%2F113431%2Fdownload&usg=AOvVaw2Lmdx0sYmRg7OnjOcJlqLr [last visited Apr. 16, 2021].

devices."[6] The FDA further concluded that "the availability of third[-]party entities to service and repair medical devices is critical to the functioning of the U.S. healthcare system."[7] The survey is discussed in greater detail in the analysis of this bill by the Senate Health Committee, which is incorporated here by reference.

As the opponents note, third-party repair services outside the control of the OEMs are currently exempt from the FDA's reporting requirement for medical device repairs. According to the FDA, however, this is by design: the FDA excluded third-party repair services from its regulations because "the nature of servicing involved 'a number of competitive and other issues.' "[8] Thus, to the extent that this bill gives hospitals' in-house or independent repair organizations the right to repair medical equipment without reporting on the repairs to the OEM, this is by design—the FDA has affirmatively declined, at this point, to extend its reporting requirements to third-party repair services. The bill therefore does not appear to run afoul of the FDA's authority to regulate medical devices or thwart any federal scheme to regulate repairs.

The FDA's rules do not prevent the state from imposing additional reporting or record-keeping requirements on hospitals or from requiring other repair organizations to do so. Going forward, the author may wish to consider amending the bill to add specific reporting and recordkeeping requirements relating to repairs by in-house or third-party service organizations.

6. Allowing hospitals' in-house repair providers or independently engaged service organizations does not appear to pose undue risks to consumers of health care

Opponents raise general concerns that allowing medical devices to be repaired by hospitals' chosen repair entities—either in-house biomedical engineers or independent third-party service providers—rather than by the OEM or an OEM-affiliated repair service, could lead to negative consequences for consumers of health care. In particular, they suggest that the results of the repairs could be worse; that the repairs could heighten cybersecurity risks; and that the repairs could compromise patients' private information. These concerns appear based on the impression that in-house engineers or independent repair organizations retained by hospitals are less skilled, or less trustworthy, than OEMs or OEM-affiliated repair services, but the evidence on this point is anecdotal. Regarding the issue of whether independent repair facilities are less competent and pose a risk to patient health, the *FDA Report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices* evaluated device reports going back to 1992 and concluded that three reported deaths could be traced to issues with servicing; however, the report does not identify whether the servicing was performed by an authorized repair facility or a true third-party service provider, and the report excluded servicing performed by OEMs and hospitals.[9] The report therefore does not provide

[6] *Id.* at p. i.
[7] *Ibid.*
[8] *Id.* at p. 5.
[9] *Id.* at p. 22.

evidence one way or the other as to whether allowing hospitals and their chosen service facilities to perform repairs will endanger patient safety. With respect to cybersecurity and privacy concerns, it seems likely that OEMs could implement additional security measures to guard against unauthorized use, such as single-use access keys or dual-factor authentication. To the extent that certain devices may be so complex that they are not susceptible to repairs by anyone other than the OEM, the author could consider amending to more precisely identify what kind of devices are subject to the bill's requirements.

Moreover, hospitals have numerous incentives to hire competent, trustworthy people to repair their medical devices. Hospitals are required to perform regular maintenance on devices and ensure equipment is maintained at an acceptable level of safety and quality as conditions of receiving Medicare funds.[10] A poorly repaired medical device could lead to tragic patient outcomes and substantial liability for the hospital. Reports of poorly maintained equipment could lead to bad publicity and a loss of public confidence in the institution. Absent specific evidence that hospitals' chosen repair services are less competent than OEMs' authorized service providers, this bill does not appear to pose a significant risk to consumers of health care.

7. <u>This bill provides civil penalties for violations of the bill but requires amendments to be sufficiently clear</u>

As currently drafted, the bill provides a per-day civil penalty for violations of the act, in the following amounts:

- $1,000 per day per piece of equipment for the first violation.
- $2,000 per day per piece of equipment for the second violation.
- $5,000 per day per piece of equipment for the third and any subsequent violations.

The penalties are recoverable in a civil action that may be brought in the name of the people of the State of California by the Attorney General or by any district attorney, county counsel, or city attorney in any court of competent jurisdiction.

While an enforcement mechanism is a logical component of this bill—*ubi jus ibi remedium*[11]—the bill is currently vague as to how, exactly, the "per day per piece of equipment" penalty would be applied. In order to ensure a consistent and reasonable application of a civil penalty, the author has agreed to amendments to create a per-violation penalty that triggers upon violation, rather than increasing on a daily basis: $10,000 per piece of equipment for the first violation, $20,000 per piece of equipment for the second violation, and $50,000 per piece of equipment for the third and any

[10] Director, Survey and Certification Group, Center for Medicare and Medicaid Services, *Memorandum re Hospital Equipment Maintenance Requirements*, Ref. S&C: 14-07-Hospital, Department of Health and Human Services (Dec. 20, 2013).
[11] "Where there is a right, there is a remedy." (Black's Law Dict. (11th ed. 2019) p. 2020.)

subsequent violation. The civil penalty remains recoverable only by the Attorney General or any district attorney, county counsel, or city attorney.

As currently drafted, the bill does not provide a direct means by which a hospital or a hospital's chosen independent repair service can seek review of an OEM's refusal to provide repair information on reasonable terms. The author is continuing to work with stakeholders on possible remedies, which could include authorizing actions for injunctive relief following an OEM's refusal.

8. Amendments

As discussed above, the author has agreed to amendments to adopt California's definition of "trade secret," to ensure consistency of application, to clarify the enforcement mechanisms of the bill, and to make technical, nonsubstantive changes.

Amendment 1

On page 3, in line 13, strike out "including" and insert "includes"

Amendment 2

On page 5, strike out lines 38 to 40, inclusive; on page 6, strike out lines 1-5, inclusive, and insert

"(m) "Trade secret" means information, including a formula, pattern, compilation, program, device, method, technique, or process, that meets both of the following:
(1) Derives independent economic value, actual or potential, from not being generally known to the public or to other persons who can obtain economic value from its disclosure or use.
(2) Is the subject of efforts that are reasonable under the circumstances to maintain its secrecy."

Amendment 3

On page 7, in line 21, strike out "Any person" and insert "An original equipment manufacturer"

Amendment 4

On page 7, in line 24, strike out "one thousand dollars ($1,000) per day" and insert "ten thousand dollars ($10,000)"

Amendment 5

On page 7, in lines 25 and 26, strike out "two thousand dollars ($2,000) per day" and insert "twenty thousand dollars ($20,000)"

Amendment 6

On page 7, in line 27, strike out "five thousand dollars ($5,000) per day" and insert "fifty thousand dollars ($50,000)"

9. Arguments in support

According to bill sponsors American College of Clinical Engineering, CALPIRG, and iFixit:

> Hospitals have three choices for maintaining the medical equipment they use: contracting with the OEM [original equipment manufacturer], hiring a third-party repair service, or using in-house technicians. When performed under a manufacturer contract, service can cost as much as 10-15 percent of the device. Compare that to 5-8 percent for an independent service organization or 3-4 percent for hospital-employed biomeds [biomedical engineers]. Given that a new MRI machine can cost as much as $3 million, those differences can lead to a much higher [repair] bill.
>
> Anecdotes from biomeds across the country demonstrate these increased costs. During a webinar hosted by CALPIRG, [biomed of the California Medical Instrumentation Association Nader] Hammoud gave an example of a simple repair that needed only a replacement part costing around $80, but he was told by the OEM that their repair technicians would need to come in and make the repair for the cost of $4,000. "And then we wonder why the healthcare is expensive," he added…
>
> As California and the country battled a winter surge of COVID-19, U.S. PIRG surveyed biomeds about the status about the status of their hospitals' equipment and the impacts of the pandemic on repair. The findings, released in February, include:
>
> - 76 percent of biomeds were denied access to parts or service for critical medical equipment by the manufacturer as cases spiked.
> - 80 percent of biomeds at the time of their response had equipment that they could not service because of restrictions to service keys, parts, or other service materials.
> - 90 percent of respondents reported that the surge of COVID-19 cases has increased their need for Medical Right to Repair…
>
> SB 605 would allow hospitals and other healthcare providers to deliver quick, quality care to patients at a lower price. The pandemic has underscored the need for these reforms; if passed, this bill would be the first in the country to guarantee the Right to Repair medical equipment.

According to bill supporter California Hospitals Association:

> Hospitals are responsible for making certain that patients have access to life-saving medical equipment. This requires regular testing, maintenance, and repair of a wide range of technology and equipment. Unfortunately, manufacturers are often unable to service equipment in the timeframe needed, and the hospital's team must decide between taking a machine that is due for regular maintenance offline or not having it meet its maintenance schedule.
>
> If manufacturers of this equipment were to provide the information and repair parts to hospitals' teams to make these repairs, then these delays could be avoided. This would make potentially life-saving medical technology more available to patients…
>
> Going forward, Senate Bill (SB) 605 (Eggman) would help to avoid these unnecessary delays and allow capable hospital teams to repair the medical equipment that they own by creating a right to repair, thus making these technologies more accessible to the patients they serve.

According to twelve intellectual property law professors who wrote in support of the bill:

> Facilitating the repair of medical devices is consistent with federal copyright law and policy. SB-605 is in no way preempted by the Copyright Act, which merely prohibits states from enacting exclusive rights "equivalent" to those provided under federal law. 17 U.S.C. § 301(a). Nor does SB-605 conflict with [section] 1201 of the Copyright Act. Some devices are not yet subject to an exemption permitting the circumvention of technological protection measures for repair purposes. But SB-605 does not require, authorize, or even contemplate circumvention. To the extent those activities are unlawful under federal law, they will remain so after the enactment of SB-605…
>
> Nor does SB-605 jeopardize manufacturers' trade secret rights insofar as it would enable access to information, replacement parts, or tools. SB-605 specifically exempts most trade secrets. Manufacturers must disclose information only "as necessary to provide documentation, parts, tools, and training courses and materials on fair and reasonable terms." Since repair parts and tools are often generally known within the industry, they can't be considered secrets. And the information necessary to enable repair would not extend to manufacturing schematics and other documents that would expose production processes. The sort of repair information the bill would require manufacturers to disclose is frequently shared with authorized repair providers, who may or may not be under any legal obligation to maintain its secrecy. Even if such information is secret, the legislature is entitled to craft exceptions to trade secret law in order to safeguard the public's interest in repair…

> Finally, there is no reason to believe that SB-605 exposes manufacturers to any additional risks that their products will be counterfeited or otherwise reproduced. Determined counterfeiters already have access to devices, either on the open market or directly from device makers' own suppliers. The idea that a bill designed to enable repair and increase competition would contribute to the problem of counterfeiting in any material way is implausible.

10. Arguments in opposition

According to a coalition of opponents comprised of Advanced Medical Technology (AdvaMed), Biocom California, California Life Sciences Association, National Coalition for Assistive & Rehab Technology (NCART), and TechNet:

> On behalf of the hundreds of manufacturers and businesses our organizations represent, we respectfully Oppose SB 605, which would compromise patient safety and cybersecurity in our health care system by improperly forcing medical technology providers to enter into unfair contracts to share design and repair information with unlicensed, unregulated independent repair providers who do not have to meet any known standards or comply with US Food & Drug Administration (FDA) Quality System Regulations.
>
> Medical technology servicing and repair by original equipment manufacturers is highly regulated by the FDA and servicing of these devices is sensitive as it relates to patient safety and device system security. Medical technology manufacturers maintain their own devices or provide repair information to authorized repair providers for device servicing under contract. Medical technology companies are generally supportive of voluntary contractual agreements with third party servicers and repair entities, provided they follow consistent quality, safety and regulatory requirements.

According to a coalition of opponents comprised of AdvaMed, the Air Conditioning, Heating, and Refrigeration Institute, the Association of Home Appliance Manufacturers, the Consumer Technology Association, the Entertainment Software Association, the Information Technology Industry Council, the Internet Coalition, the Medical Imaging & Technology Alliance, the National Electronic Manufacturers Association, NetChoice, PRBA—The Rechargeable Battery Association, Repair Done Right, and the Security Industry Association:

> Manufacturers make significant investments in the development of products and services, and the protection of intellectual property is a legitimate and important aspect of sustaining the health of the vibrant and innovative technology industry. However, SB 605 puts at risk the intellectual property that manufacturers have developed.

Consumer electronics' on-board software (i.e., firmware) are key to the functioning and operation of the hardware it is embedded in, and firmware helps protect against unauthorized access to other software and applications. That software is subject to copyright under federal law, and Section 1201 of the Digital Millennium Copyright Act, a related federal law, ensures that bad actors cannot tamper with the digital rights management that copyright owners use to protect this software. The problem is that making repairs to hardware components may require the circumvention of digital rights management and leave the software in an unprotected state—harming the copyright owners of the software.

Firmware controls many other product functions, and opening it up for repair purposes exposes other more sensitive functions, such as security features, to potential tampering. Given the scope of products covered and what must be provided under the legislation—including diagnostics, tools, parts, and updates to software—it is highly likely that some of the information would be proprietary. Providing unauthorized repair facilities and individuals with access to proprietary information without the contractual safeguards currently in place between OEMs and authorized service providers places OEMs, suppliers, distributors, and repair networks at risk.

SUPPORT

American College of Clinical Engineering (co-sponsor)
CALPIRG (co-sponsor)
iFixit (co-sponsor)
101 individuals
American Federation of State, County, and Municipal Employees (AFSCME) California
Association of California Healthcare Districts
Association of Medical Device Service Organizations
Association of Regional Center Agencies
California Alliance for Retired Americans
California Black Health Network
California Health Advocates
California Hospital Association
California State Rural Health Association
Californians Against Waste
Cedars Sinai
Consumer Action
Consumer Reports
Dignity Health
Electronic Frontier Foundation
EP Radiological Services
Fixit Clinic
French Hospital Medical Center
International Association of Medical Equipment Remarketers and Servicers, Inc.

MultiMedical Systems
National Stewardship Action Council
Renovo Solutions LLC
SecuRepairs.org
Sodexo Clinical Technology Management
Sutter Health
Tech Knowledge Associates
The Repair Association
The Story of Stuff Project
Upstream
Washington Hospital Healthcare System

OPPOSITION

Advanced Medical Technology Association
Air Conditioning, Heating, & Refrigeration Institute
Association of Home Appliance Manufacturers
Civil Justice Association of California
Consumer Technology Association
CTIA
Entertainment Software Association
Information Technology Industry Council
Internet Coalition
Medical Imaging & Technology Alliance
National Coalition for Assistive & Rehab Technology
National Electronic Manufacturers Association
NetChoice
One individual
PRBA—The Rechargeable Battery Association
Repair Done Right
Security Industry Association
Siemens Healthineers North America.
State Privacy & Security Coalition
Technet
Telecommunications Industry Association
Varian Medical Systems

RELATED LEGISLATION

Pending Legislation: None known.

Prior Legislation:

AB 1163 (Eggman, 2019) 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 died in the Assembly Privacy and Consumer Protection Committee.

AB 2110 (Eggman, 2018) The bill 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 died in the Assembly Privacy and Consumer Protection Committee.

PRIOR VOTES:

Senate Health Committe (Ayes 10, Nos 0)

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