SENATE JUDICIARY COMMITTEE
Senator Thomas Umberg, Chair
2023-2024 Regular Session

SB 271 (Dodd)
Version: April 12, 2023
Hearing Date: April 25, 2023
Fiscal: Yes
Urgency: No
AM

SUBJECT

Powered wheelchairs: repair

DIGEST

This bill requires an original equipment manufacturer (OEM) of a powered wheelchair to provide, on fair and reasonable terms and costs, documentation, parts, embedded software, firmware, and tools used to inspect, diagnose, maintain, and repair the wheelchair to an owner or an independent repair provider for the purposes of providing service on the equipment in the state. The bill also prohibits the Department of Health Care Services from requiring prior authorization for the repair of a powered wheelchair under Medi-Cal or a treatment authorization request, as specified.

EXECUTIVE SUMMARY

This bill aims to increase accessibility and affordability for wheelchair users by making it easier for consumers to maintain their devices and keep them in good working condition. The bill achieves this by requiring OEMs of powered wheelchairs to provide documentation and necessary tools or parts to consumers and independent repair shops for purposes of serving a powered wheelchair in this state. The bill specifies that a manufacturer is not required to divulge a trade secret, except as may be necessary to comply with the bill's provisions and with other specified exceptions. Colorado enacted a similar law last year. The bill provides enforcement through civil liability that can be enforced by an injured person or the Attorney General, district attorney, county counsel, city prosecutor, or city attorney in the name of the state.

The bill is sponsored by the California Foundation for Independent Living Centers and Consumer Reports and supported by various organizations. The bill is opposed by the National Coalition for Assistive & Rehab Technology and the California Association of Medical Product Suppliers. It passed the Senate Business and Professions Committee on a vote of 13 to 0.

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. (*See* 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. (*See* 21 C.F.R. § 830.30.)

Existing state law:

1) Establishes the Electronic and Appliance Repair Dealer Registration Law (EAR Law) to regulate service dealers and service contracts that address the maintenance, replacement, or repair of consumer goods. (Bus. & Prof. Code § 9800 et seq., 9810.)

2) Establishes the Song-Beverly Consumer Warranty Act (Act), which sets forth standards for warranties that govern consumer goods, and outlines remedies available to purchasers. (Civ. Code § 1790 et seq.)

3) 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 § 109875 et seq.)

4) 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)

5) Requires generally that persons cannot conduct a home medical device retail facility business in California unless they have obtained a license from CDPH. (Health & Saf. Code § 111656)

6) Authorizes CDPH to waive any licensing requirements for a medical device retail facility when, in the opinion of CDPH, a high standard of patient safety, consistent

with good patient care, can be provided by the licensure of a home medical device retail facility that does not meet all of the requirements for licensure as a home medical device retail facility. (Health & Saf. Code § 111656.9)

7) Establishes the Medi-Cal program, administered by the Department of Health Care Services (DHCS), under which low-income individuals are eligible for medical coverage. (Welf. & Inst. Code § 14000 et. seq.)

This bill:

1) Requires an original equipment manufacturer (OEM) of a powered wheelchair, as defined, to provide documentation, parts, embedded software, firmware, and tools used to inspect, diagnose, maintain, and repair the wheelchair to an owner or an independent repair provider for the purposes of providing service on the equipment in the state, on fair and reasonable terms and costs, as defined.

2) Requires an OEM for a powered wheelchair that contains an electronic security lock or other security-related function to provide any documentation, parts, embedded software, firmware, or tools needed to reset the lock or function when disabled in the course of providing services, as specified.

3) Requires an independent repair provider to provide a written notice to a customer before providing repair services, as specified.

4) Exempts from these requirements any trade secret information, as specified.

5) Defines "powered wheelchair" as a motorized wheeled device designed for use by a person with a physical disability.

6) Exempts an OEM from providing any part that would require programmability, calibration, or clinical involvement to ensure appropriate patient seating and positioning, including: batteries, battery chargers, nonprogrammable joysticks, joystick housings or brackets, wheel assembly, non-positioning accessories, antitip devices, armrests, excluding positioning components designed for adjustment by a therapist or assistive technology professional, caster spheres, cosmetic shrouding, floor mats, floor plates, nonpowered leg lowers.

7) Specifies that an OEM is not required to divulge a trade secret, except as necessary to provide documentation, parts, tools, service access methods, and training courses and materials on fair and reasonable terms.

8) Authorizes an original equipment manufacturer to withhold information regarding a component of, design of, functionality of, or process of developing a part, embedded software, firmware, or a tool if the information is a trade secret and the

usability of the part, embedded software, firmware, or tool for the purpose of providing services is not diminished.

9) Provides that an OEM is not liable for faulty or otherwise improper repairs provided by independent repair providers or owners.

10) Provides that an OEM who knowingly violates any of these provisions, or who reasonably should have known that they violated any provision, is be liable for a civil penalty not to exceed $10,000 per piece of equipment for the first violation, and not to exceed $500,000 for each series of related violations.

11) Authorizes a person injured by a violation of the above provisions to bring a civil action for damages or other relief.

12) Authorizes the Attorney General, district attorney, county counsel, city prosecutor, or city attorney may bring a civil action in the name of the state for violation of these provisions.

13) Prohibits DHCS from requiring prior authorization for the repair of a powered wheelchair under Medi-Cal.
    a) Prohibits a treatment authorization request for repair or replacement of a powered wheelchair from requiring a prescription or documentation of medical necessity from the treating practitioner requesting the repair or replacement if the powered wheelchair has already been approved for use by the patient, as specified.

COMMENTS

1. Stated need for the bill

The author writes:

> SB 271, relating to powered wheelchair right to repair, seeks to give consumers and independent repair businesses the ability to repair powered wheelchairs. The bill would require manufacturers to provide information, tools, and replacement parts to an owner or an independent repair provider on fair and reasonable terms and costs. This would increase accessibility and affordability for wheelchair users, making it easier for consumers to maintain their devices and keep them in good working condition. The bill would also ensure that the manufacturers of wheelchairs are held accountable for the accessibility and availability of the necessary information and parts, with violators subject to civil penalties that can be enforced either by the individual injured or by the attorney general, district attorney, or city attorney. The Consumer Wheelchair Right to Repair bill would positively influence the lives of people who use wheelchairs in California by giving them greater control

> over the repair and maintenance of their devices. By making it easier and more affordable to repair wheelchairs, this bill would reduce harmful e-waste and promote sustainability. This legislation reflects a commitment to treating all members of society with dignity and respect, particularly those with disabilities who rely on powered wheelchairs.

2. Background: right-to-repair advocacy

Over the past decade a movement has arisen that advocates for consumer rights to repair products they own or take those products to any repair professional of their choice. Right-to-repair legislation has been introduced in more than 25 states and most recently in Congress under The Fair Repair Act.[1] In 2021, President Biden issued an executive order that allows farmers and motorists the right to repair their own vehicles without voiding warranty protections.[2] Massachusetts passed the Motor Vehicle Owners Right to Repair Act in 2012, which requires auto manufacturers to allow independent mechanics to access diagnostic tools in cars so consumers can have their cars serviced by mechanics of their choice.[3] In 2014, major national auto industry groups signed a memorandum of understanding that made the requirements of Massachusetts Automotive Right to Repair bill a national policy.[4] In 2022, New York passed and the Governor signed the Digital Fair Repair Act providing consumers with the right to repair certain electronic products.[5] Most pertinent to this bill, Colorado passed a bill in 2022 granting powered wheelchair owners the right to repair their own wheelchairs.[6]

3. Wheelchairs are medical devices

The Senate Business and Professions Committee analysis notes:

> Wheelchairs are considered a medical device under FDA standards. Depending on the complexity of the wheelchair, the device can be classified in Class I, II, or III. Class III requires the most rigorous approval in terms of safety and effectiveness on the part of manufacturers, while Class I require the least rigorous approval. According to the FDA, powered wheelchairs are most often in Class II of medical devices.[7] When considering whether to grant FDA approval, most powered

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[1] H.R. 4006 (2021-22).
[2] Exec. Order No. 14036, 86 FR 36987 (July 9, 2021), available at https://www.federalregister.gov/documents/2021/07/14/2021-15069/promoting-competition-in-the-american-economy.
[3] Mass. Gen. Laws Ch. 165 (2013).
[4] *Industry trade groups sign R2R info agreement*, Tire Business, (Jan. 23, 2014), available at https://www.tirebusiness.com/article/20140123/NEWS/140129947/industry-trade-groups-sign-r2r-info-agreement.
[5] NY Asm. Bill 7006B (2022).
[6] Colo. H.B. 22-1031 (2022).
[7] *Learn if a Medical Device Has Been Cleared by the FDA for* Marketing, FDA, Dec. 29, 2017, https://www.fda.gov/medical-devices/consumers-medical-devices/learn-if-medical-device-has-been-

wheelchairs must demonstrate they are "substantially equivalent" to another device that has already been through FDA's pre-market approval and pre-market notification processes. Companies themselves also subject powered wheelchairs to significant crash testing, etc. to ensure their safety for consumers. While some wheelchairs are generic and can fit most people's needs, some are customized to a patient's body and specific needs.[8]

4. This bill enacts a right to repair for powered wheelchairs

This bill requires OEMs of a powered wheelchair (equipment) to make available to an independent repair provider or owner of a powered wheelchair, any documentation, parts, embedded software, firmware, or tools that are intended for use with the wheelchair or any part, including updates to documentation, parts, embedded software, firmware, or tools. If the equipment contains an electronic security lock or other security device the OEM must make any documentation, parts, embedded software, firmware, or tools needed to reset the lock or function when disabled to function, an original equipment manufacturer available to independent repair providers and owners of the equipment on fair and reasonable terms and cost. The bill requires these things to be provided on fair and reasonable terms and costs, i.e. in a similar manner to authorized repair providers. The bill provides that these requirements do not apply to powered wheelchairs subject to Medi-Cal provisions related to rehabilitative services for a physically or cognitively impaired patient that would require programmability, calibration, or clinical involvement to ensure appropriate patient seating and positioning. An OEM is not liable for faulty or otherwise improper repairs provided by independent repair providers or owners.

The bill provides enforcement through civil liability, making an OEM who knowingly violates any these provisions, or who reasonably should have known that they violated any of these provisions, liable for a civil penalty not to exceed $10,000 per piece of equipment for the first violation, and not to exceed $500,000 for each series of related violations. The bill authorizes a person injured by a violation of these provisions to bring a civil action for damages or other relief or the Attorney General, district attorney, county counsel, city prosecutor, or city attorney to bring a civil action in the name of the state for any violation. The bill additionally provides that an OEM who violates a court order or injunction issued pursuant to this chapter is to be liable for a civil penalty not to exceed $10,000 per violation.

The bill's requirements do implicate trade secrets as the bill requires a manufacturer to divulge a trade secret except as necessary to provide documentation, parts, tools, service access methods, and training courses and materials on fair and reasonable

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cleared-fda-marketing#:~:text=Class%20II%20%E2%80%93%20Most%20medical%20devices%20are%20considered,43%25%20of%20medical%20devices%20fall%20under%20this%20category.

[8] Sen. Bus. & Prof. Comm. analysis SB 271 (2023-24 reg. sess.) as amended April 12, 2023 p. 5.

terms. The bill allows an OEM to redact trade secrets from the documentation before providing access to the documentation if the usability of the redacted documentation is not diminished. Additionally, an OEM can withhold information regarding a component of, design of, functionality of, or process of developing a part, embedded software, firmware, or a tool if the information is a trade secret and the usability of the part, embedded software, firmware, or tool for the purpose of providing services is not diminished.

It is unclear how much of the information required to be divulged under the bill would be a trade secret. Moreover, the Legislature has the power to create exceptions to state trade secret law[9] and there is no federal preemption issue under the federal Defend Trade Secrets Act.[10] The public policy of allowing consumers the right to repair equipment they own or by repair facilities of their choosing may outweigh the potential and/or tangential effects on an OEM's trade secrets.

5. Statements in support

Consumer Reports, a sponsor of the bill, writes:

> Millions of Americans rely on wheelchairs, and this bill would save Californians time, money, and prevent injury by giving them more options to repair these essential products. For example, consumers have been charged hundreds of dollars for wheelchair parts that could be purchased much more cheaply from an independent source. Tactics that interfere with repair rights force consumers to rely on the manufacturer, or the manufacturer's handpicked servicer, to fix these products. The manufacturer is then free to charge whatever it wishes, or even to refuse to repair the product and force the consumer to throw it away and buy a new product.
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> Manufacturers and their representatives have worked to defeat Right to Repair legislation, often by using spurious arguments about safety and security. On the contrary, this bill would better ensure the safety of products, and without sacrificing consumer choice. Independent repair technicians would have to meet whatever certification requirements are set by state law, just like authorized repair technicians. This bill would ensure that they have the same access to proper instructions that are vetted for safety.

[9] *See* 38 Cal.2d. 396, 398 (court held that "[o]ne legislative body cannot limit or restrict its own power or that of subsequent legislatures and, therefore, the act of one legislature does not bind its successors.").
[10] *See* 18 U.S.C. § 1838.

6. Statements in opposition

The National Coalition for Assistive & Rehab Technology is opposed unless amended writing:

> As the bill was amended on April 12th, we have made significant progress with addressing barriers to timely service repairs by removing burdensome and outdated prior authorization requirements. Amendments were also taken to ensure that clinical items that require professional medical staff do not fall under the bill. […]
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> However, with the bifurcation of clinical items and non-clinical items, we believe enforcement must be dealt with in a sensitive manner in order to not place undue harm on our members for unintentionally violating these new provisions of law. Currently, SB 271 would place a fine for a first-time offense at $10,000 per piece of equipment, and up to $500,000 if they knowingly OR "who reasonably should have known that they violated any provision of law". With thousands of components to a CRT powered wheelchair, we believe basing a fine per piece of equipment on a first offense is excessive. […]
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> In order to avoid unintended consequences for our members, we believe the first violation should be limited to that single violation, and not per piece of equipment. We also believe the legal standard for civil penalties should be limited to if someone "knowingly violates the law" as "reasonably should have known" is a vague and subjective standard in law. (Emphasis in original)

SUPPORT

California Foundation for Independent Living Centers (sponsor)
Consumer Reports (sponsor)
Association of Regional Center Agencies
California Commission on Aging
California Senior Legislature
Californians Against Waste
California Public Interest Research Group (CALPIRG)
Communities Actively Living Independent and Free
Democrats of Rossmoor
IFixIT
LeadingAge California
National Federation of Independent Business
National Health Law Program
State Council on Developmental Disabilities
South Bayside Waste Management Authority
Yolo County In-home Supportive Services Advisory Committee

Yolo Healthy Aging Alliance

OPPOSITION

California Association of Medical Product Suppliers
National Coalition for Assistive & Rehab Technology

RELATED LEGISLATION

Pending Legislation: SB 244 (Eggman, 2023) enacts right-to-repair legislation for consumer products, except as specified. This bill is pending in the Senate Appropriations Committee.

Prior Legislation:

SB 983 (Eggman, 2022) was substantially similar to this bill. SB 983 died in the Senate Appropriations Committee.

SB 605 (Eggman, 2021) would have required 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. SB 605 died in the Senate Appropriations Committee.

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 and functional parts, on fair and reasonable terms 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) 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 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 Business and Professions Committee (13 Ayes, 0 Noes)

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