

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

SB 1384 (Dodd)
Version: March 21, 2024
Hearing Date: April 2, 2024
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 this state, with certain exceptions. 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.

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 in 2022. This bill is substantially similar to SB 271 (Dodd, 2023) except that it does not include a prohibition on the Department of Health Care Services (DHCS) from requiring prior authorization for the repair of a powered wheelchair under Medicaid if the repair was not greater than \$1,250. SB 271 passed this Committee, but was ultimately vetoed by the Governor citing his concerns with the prohibition on prior authorization. This bill passed the Senate Business, Professions and Economic Development Committee on a vote of 12 to 0. The bill is author sponsored and supported by various entities and organizations that advocate for those who may need the use of wheelchairs and iFixit, an organization that advocates for the right to repair. The Committee has received no timely opposition.

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 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.)
- 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 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)
- 4) 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)
- 5) Establishes the Right to Repair Act, which requires manufacturers of an electronic or appliance product, as defined, with a wholesale price to the retailer of not less than \$50 to make available, on fair and reasonable terms, sufficient service documentation and prescribed functional parts and tools to owners of the product,

service and repair facilities, and service dealers for specified timeframes, as provided and with certain exceptions.

- a) A violation of the Right to Repair Act subjects a person to civil liability that can be enforced by the Attorney General, a district attorney, county counsel, city prosecutor, or city attorney.

This bill:

- 1) Requires an original equipment manufacturer (OEM) of a powered wheelchair, as defined, to make available 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 make available 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.
 - a) Provides an OEM is not required to make available a part if the part is no longer available to the OEM.
- 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 of up to \$2,500 per powered wheelchair, not to exceed \$250,000 for a first violation.
 - a) Provides a three-day right to cure in the case of a first violation before a civil penalty is imposed if an OEM did not knowingly violate these provisions.
 - b) Any subsequent violation by an OEM subjects the OEM to liability in the amount of \$10,000 per powered wheelchair, not to exceed \$250,000 for each series of related violations.
- 11) Provides an OEM is not subject to the above penalties if the OEM fails to provide a part because it is out of stock and unobtainable so long as the OEM does both of the following:
 - a) informs the customer or independent repair provider that the part is out of stock, and, consequently, they are unable to obtain the part; and
 - b) Makes the part available within three business days of that part becoming available.
- 12) Authorizes a person injured by a violation of the above provisions to bring a civil action for damages or other relief, as provided.
- 13) Authorizes the Attorney General, district attorney, county counsel, city prosecutor, or city attorney to bring a civil action in the name of the state for violation of these provisions, as provided.
- 14) 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.
- 15) Specifies that these provisions are not to be construed to exempt an original equipment manufacturer from a products liability claim that is otherwise authorized by law.
- 16) Specifies that the above provisions only apply to powered wheelchairs sold or in use on or after January 1, 2025.

COMMENTS

1. Stated need for the bill

The author writes:

The California Senate Bill 1384, 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 or district 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 a consumer's 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 After several attempts, last year California enacted a Right to Repair Act for consumer products in SB 244 (Eggman, Ch. 704, Stats. 2023). 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

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).

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 Connecticut introduced two somewhat similar bills in 2023, but they were not enacted.⁷ Hawaii has a bill currently pending that would provide a right to repair for powered wheelchairs in that state.⁸

3. Wheelchairs are medical devices

The Senate Business and Professions Committee analysis for SB 1384 (Dodd, 2024) 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.^[9] When considering whether to grant FDA approval, most powered 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.¹⁰

According to an article published on Harvard Health Blog, a survey of 533 wheelchair users with spinal cord injuries reported: out of pocket costs ranging from \$50 to \$620; experiencing adverse consequences from the breakdown ranging from two to 17 days;

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 Conn. H 6702 (2023); Conn. H 6083 (2023).

⁸ Hawaii SB 1172 (2023).

⁹ *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-cleared-fda->

[marketing#:~:text=Class%20II%20%E2%80%93%20Most%20medical%20devices%20are%20considered,43%25%20of%20medical%20devices%20fall%20under%20this%20category.](https://www.fda.gov/medical-devices/consumers-medical-devices/learn-if-medical-device-has-been-cleared-fda-marketing#:~:text=Class%20II%20%E2%80%93%20Most%20medical%20devices%20are%20considered,43%25%20of%20medical%20devices%20fall%20under%20this%20category.)

¹⁰ Sen. Bus. & Prof. Comm. analysis SB 1384 (2023-24 reg. sess.) as introduced Feb. 16, 2024 p. 5.

and that 27 percent reported being stranded in their homes, 12 percent were stuck in bed, and 9 percent were stranded outside their home.¹¹

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

This bill is substantially similar to SB 271 from last year, except that it does not include the prohibition on prior authorization language. SB 271 was vetoed by Governor Newsom who stated:

This bill would outline right to repair requirements for businesses that repair complex rehabilitation technology (CRT) powered wheelchairs and would prohibit the Department of Health Care Services (DHCS) from requiring prior authorization for the repair of a CRT powered wheelchair if the cost of the repair does not exceed \$1,250.

While I appreciate the author's efforts to increase accessibility and affordability for CRT wheelchair users, prior authorization is a key safeguard for cost containment and prevention of abuse in the Medi-Cal program. Further, setting a monetary threshold for prior authorization in statute creates an additional barrier, should the amount need adjustment in the future.

While I am unable to sign this bill, I am directing DHCS to review the current treatment authorization request policies for complex rehabilitative technology powered wheelchairs and make any necessary adjustments administratively.

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.

¹¹ Lisa I. Iezzoni, MD, MSc, *Millions rely on wheel chairs for mobility, but repair delays are hurting users*, Harvard Health Publishing (July 21, 2022), available at <https://www.health.harvard.edu/blog/millions-rely-on-wheelchairs-for-mobility-but-repair-delays-are-hurting-users-202207212785>.

The bill provides enforcement through civil liability by 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 up to \$2,500 per piece of equipment, not to exceed \$250,000 for a first violation. For subsequent violations, an OEM may be liable or a civil penalty up to \$10,000 per piece of equipment, not to exceed \$250,000. The bill provides that an OEM who does not knowingly violate these provisions may be provided a three-day right to cure the violation before a civil penalty is imposed. If an OEM fails to provide a part because it is out of stock and unobtainable, the OEM is not subject to these penalties so long as the OEM: (1) informs the customer or independent repair provider that the part is out of stock; and (2) makes the part available within three business days of it becoming available. An OEM is also not required to make a part available if the part is no longer available to the OEM. 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 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 law¹² and there is no federal preemption issue under the federal Defend Trade Secrets Act.¹³ 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

The California State Council on Developmental Disabilities (SCDD) writes in support stating:

¹² 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.").

¹³ See 18 U.S.C. § 1838.

Powered wheelchairs are crucial to the well-being and independence of many Californians with a wide variety of medical conditions and mobility issues. However, the shortage of licensed repair shops in the state and long wait times for repairs can cause serious difficulties for individuals who rely on their powered wheelchairs for most activities in their daily lives. Additionally, manufacturers are not currently required to provide information or replacement parts directly to consumers or independent repair businesses for power wheelchairs. Without access to a functioning chair, consumers are unable to attend health appointments, unable to travel to work or school, and overall, can negatively impact their quality of life.

SCDD's mission is to advocate, promote and implement policies and practices that achieve self-determination, independence, productivity, and inclusion in all aspects of community life for Californians with developmental disabilities and their families. SB 1384 aligns with SCDD's mission and ensures people have access to resources they need to preserve their independence and quality of life without facing any unnecessary obstacles or costs.

SUPPORT

Association of Regional Center Agencies
California Foundation for Independent Living Centers
California State Council on Developmental Disabilities
IFixit
LeadingAge California
National Multiple Sclerosis Society
Yolo County In-home Supportive Services Advisory Committee

OPPOSITION

None received

RELATED LEGISLATION

Pending Legislation: None known.

Prior Legislation:

SB 244 (Eggman, Ch. 704, Stats. 2023) enacted right-to-repair legislation for consumer products, except as specified.

SB 271 (Dodd, 2023) was substantially similar to this bill but it also included a prohibition on 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. SB 271 was vetoed by the Governor. *See* Comment 4 for Governor's veto statement.

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 2110 died in the Assembly Privacy and Consumer Protection Committee.

PRIOR VOTES

Senate Business, Professions and Economic Development Committee (12 Ayes, 0 Noes)
