THE SENATE
THIRTY-FIRST LEGISLATURE, 2021
STATE OF HAWAII

S.B. NO. 760

JAN 22 2021

A BILL FOR AN ACT

RELATING TO MEDICAL DEVICES.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:

SECTION 1. The Hawaii Revised Statutes is amended by adding a new chapter to be appropriately designated and to read as follows:

"CHAPTER

§ -1 Purpose; short title. The purpose of this chapter is to promote choice and competition for 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 independent repair providers and device owners, on fair and reasonable terms, the documentation, parts, and tools used to inspect, diagnose, maintain, and repair such equipment. This chapter shall be known and may be cited as the "Medical Device Right to Repair Act".

§ -2 Definitions. As used in this chapter:

"Authorized repair provider" means 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 such 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 described in this definition with an unaffiliated individual or business, shall be considered an "authorized repair provider" with respect to such equipment.

"Documentation" means 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.

"Embedded software" means any programmable instructions provided on firmware delivered with powered medical equipment, or with a part for such equipment, for purposes of equipment

operation, including all relevant patches and fixes made by the manufacturer of such or part for these purposes.

"Fair and reasonable terms", in the context of obtaining any part, tool, documentation, or training course and materials means at costs and upon terms that are equivalent to the most favorable costs and terms under which an original equipment manufacturer offers the part, tool, documentation, or training course and materials to an authorized repair provider that:

(1) Accounts for any discount, rebate, convenient means of delivery, means of enabling fully restored and updated functionality, rights of use, or other incentive or preference the original equipment manufacturer offers to an authorized repair provider, or any additional cost, burden, or impediment the original equipment manufacturer imposes on an independent repair provider;

(2) Is not conditioned on imposing a substantial obligation or restriction that is not reasonably necessary for enabling the owner or independent repair provider to engage in the diagnosis, maintenance, or

repair of powered medical equipment made by or on behalf of the original equipment manufacturer; and

(3) Is not conditioned on an arrangement as described in the definition of "authorized repair provider";

provided that, with respect to obtaining any documentation including any relevant updates, "fair and reasonable terms" means at no charge, except that when the documentation is requested in physical printed form, a charge may be included for the reasonable actual costs of preparing and sending the copy; and provided further that, with respect to obtaining software tools, "fair and reasonable terms" means at no charge and without requiring authorization or internet access, or imposing impediments to access or use, in the course of effecting the diagnosis, maintenance, or repair and enabling full functionality of powered medical equipment, in a manner that impairs the efficient and cost-effective performance of any of those activities.

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

"Independent repair provider" means an individual or business operating in this State, who does not have an arrangement described in the definition of "authorized repair provider" with an original equipment manufacturer, and who is not affiliated with any individual or business who has such an arrangement, and who is engaged in the services of inspection, diagnosis, maintenance, or repair of powered medical equipment, except that an original equipment manufacturer or, with respect to that original equipment manufacturer, an individual or business who has such an arrangement with that original equipment manufacturer, or who is affiliated with an individual or business who has such an arrangement with that original equipment manufacturer, shall be considered an "independent repair provider" for purposes of those instances in which it engages in the services of inspection, diagnosis, maintenance, or repair of powered medical equipment that is not manufactured by or sold under the name of that original equipment manufacturer.

"Original equipment manufacturer" means 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.

"Owner" means an individual or business who owns or leases powered medical equipment purchased or used in the State.

"Part" means 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.

"Powered medical equipment" or "equipment" means any powered instrument, apparatus, implement, machine, contrivance, implant, or other article, including a component part or accessory, that is used in the treatment, monitoring, or diagnosis of a patient.

"Tools" means 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.

"Trade secret" has the same meaning as in section 482B-2.

§ -3 Requirements. (a) For powered medical equipment sold or used in the State, an original equipment manufacturer shall make available, for purposes of inspection, diagnosis, maintenance, or repair of such equipment, to any independent repair provider, or to the owner of powered medical equipment manufactured by or on behalf of, or sold or otherwise supplied by, the original equipment manufacturer, on fair and reasonable terms, documentation, parts, and tools, inclusive of any updates to information or embedded software. Nothing in this subsection requires an original equipment manufacturer to make available a part if the part is no longer available to the original equipment manufacturer.

(b) For powered medical equipment sold or used in this State, an original equipment manufacturer shall make available to any independent repair provider, or to the owner of powered medical equipment manufactured by or on behalf of, or sold or otherwise supplied by the original equipment manufacturer, on fair and reasonable terms, training courses and materials on the operation, inspection, diagnosis, maintenance, and repair of powered medical equipment.

(c) For equipment that contains an electronic security lock or other security-related function, the original equipment manufacturer shall make available to the owner and to independent repair providers, on fair and reasonable terms, any special documentation, tools, and parts needed to disable the lock or function, and to reset it when disabled in the course of inspection, diagnosis, maintenance, or repair of the equipment. Such documentation, tools, and parts may be made available by means of an appropriate secure system.

(d) When the original equipment manufacturer has made an express warranty with respect to powered medical equipment and the wholesale price of the equipment is $100 or more, the manufacturer shall provide such parts, tools, and documentation as to enable the repair of the equipment during the warranty period, at an equitable price and convenience of delivery and of enabling functionality, in light of:

(1) The actual cost to the original equipment manufacturer to prepare and distribute the part, tool, or documentation, exclusive of any research and development costs incurred;

(2) The ability of owners and independent repair providers to afford the part, tool, or documentation; and

(3) The means by which the part, tool, or documentation is distributed.

§ -4 **Enforcement by Attorney General.** Violation of any of the provisions of this chapter is an unlawful practice under section 480-2. All remedies, penalties, and authority granted to the Attorney General by chapter 480 shall be available for the enforcement of this section.

§ -5 **Limitations.** (a) Nothing in this chapter shall be construed to require an original equipment manufacturer to divulge a trade secret to an owner or an independent service provider, except as necessary to provide documentation, parts, tools, and training courses and materials on fair and reasonable terms.

(b) No provision in this chapter shall be construed to 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 pursuant to such arrangement,

except that any provision in such terms that purports to waive, avoid, restrict, or limit the original equipment manufacturer's obligations to comply with this chapter shall be void and unenforceable.

§ -6 Applicability. This chapter shall apply with respect to equipment sold or in use on or after the effective date of this Act."

SECTION 2. This Act shall take effect upon its approval.

INTRODUCED BY: 

S.B. NO. 760

Report Title:
Medical Devices; Repair; Powered Medical Equipment

Description:
Creates the Medical Device Right to Repair Act. Requires manufacturers of powered medical equipment to make parts, equipment, tools, and documentation available to independent repair providers and purchasers of such equipment. Requires manufacturers to provide tools to repair equipment that costs $100 or more. Creates a right of action for violation of the chapter enforceable by the Attorney General.

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