THE SENATE
THIRTY-SECOND LEGISLATURE, 2023
STATE OF HAWAII

S.B. NO. 1172

JAN 2 0 2023

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**

MEDICAL DEVICE RIGHT TO REPAIR ACT

§ -1 Purpose; short title. (a) 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 the equipment.

(b) 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 intellectual property arrangement with the original equipment manufacturer. "Authorized repair provider" includes an original equipment manufacturer who offers to provide inspection, diagnostic, maintenance, or repair services for powered medical equipment manufactured by or on behalf of, or sold or otherwise supplied by, an original equipment manufacturer, and who does not have an intellectual property arrangement with an unaffiliated individual or business.

"Documentation" means any manual, diagram, reporting output, service code description, schematic, or other guidance or information use in effecting the provision of inspection, diagnostic, maintenance, or repair services for powered medical equipment.

"Embedded software" means any programmable instructions provided on firmware delivered with powered medical equipment, or with an applicable part thereof, for purposes of equipment operation. "Embedded software" includes all relevant patches and fixes to powered medical equipment, or any part thereof,

made by the original equipment manufacturer for purposes of equipment operation.

"Fair and reasonable terms", with respect to:

(1) Obtaining a part, a 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 the original equipment manufacturer offers the part, tool, documentation, or training course and materials to an authorized repair provider that:

(A) 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 that the original equipment manufacturer offers to an authorized repair provider, or any additional cost, burden, or impediment that the original equipment manufacturer imposes on an independent repair provider;

(B) Are 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

(C) Are not conditioned on the existence an intellectual property arrangement;

(2) Documentation requested in physical printed form, including any relevant documentation updates, means only the reasonable actual costs of preparing and sending physical documentation;

(3) Documentation not requested in physical printed form, including any relevant documentation updates, means at no charge; and

(4) Obtaining software tools, means at no charge and without:

(A) Requiring authorization or internet access to perform, or imposing impediments to access or use during, the diagnosis, maintenance, or repair; and

(B) 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 any part thereof, to allow the equipment or part to communicate within the equipment or part or with other computer hardware.

"Independent repair provider":

(1) Means, with respect to an original equipment manufacturer, an individual or business operating in the State, that:

(A) Is engaged in the services of inspection, diagnosis, maintenance, or repair of powered medical equipment;

(B) Does not have an intellectual property arrangement with the original equipment manufacturer of the subject powered medical equipment; and

(C) Is not affiliated with any individual or business having an intellectual property arrangement with

the original equipment manufacturer of the subject powered medical equipment; and

(2) Includes an original equipment manufacturer or an individual or business that:

(A) Has an arrangement with that original equipment manufacturer or is affiliated with an individual or business that has an arrangement with that original equipment manufacturer; and

(B) Engages in the provision of inspection, diagnostic, maintenance, or repair services for powered medical equipment that is not manufactured by or on behalf of, or sold or otherwise supplied by, that original equipment manufacturer.

"Intellectual property arrangement" means an arrangement between an original equipment manufacturer and an authorized repair provider 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 to provide diagnostic, maintenance, or repair services for digital electronic equipment manufactured by

or on behalf of, or sold or otherwise supplied by, an original equipment manufacturer.

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

"Owner" means an individual or business that owns or leases powered medical equipment.

"Part" means any new or used replacement part made available by an original equipment manufacturer for purposes of effecting the provision of inspection, diagnostic, maintenance, or repair services for powered medical equipment manufactured by or on behalf of, or 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 thereof, that is used in the treatment, monitoring, or diagnosis of a medical patient.

"Tools" means any software program, hardware implement, or other apparatus used in the provision of inspection, diagnosis,

maintenance, or repair of powered medical equipment, including software or other mechanisms that provide, program, or pair a new part; calibrate functionality; or perform any other function required to bring the powered medical equipment back to fully functional condition.

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

§ -3 Requirements. (a) Each original equipment manufacturer shall make available to each applicable owner and independent repair provider, on fair and reasonable terms:

(1) Documentation, parts, and tools, including any updates to information or embedded software, used in the inspection, diagnosis, maintenance, or repair of the applicable equipment; provided that nothing in this paragraph shall be construed as requiring an original equipment manufacturer to make available a part that is no longer available to the original equipment manufacturer; and

(2) Training courses and materials regarding the operation, inspection, diagnosis, maintenance, and repair of the powered medical equipment.

(b) For powered medical equipment containing an electronic security lock or other security-related function, the original equipment manufacturer shall make available to each applicable owner and independent repair provider, on fair and reasonable terms, any special documentation, tools, and parts needed to reset any lock or function that is disabled during the inspection, diagnosis, maintenance, or repair of the equipment; provided that the original equipment manufacturer may make available the special documentation, tools, and parts through appropriate secure release systems.

(c) If the original equipment manufacturer makes an express warranty with respect to powered medical equipment, the wholesale price of which is equal to or greater than $100, the original equipment manufacturer shall provide during the warranty period all applicable parts, tools, and documentation necessary to enable the repair of the equipment at an equitable price and terms providing for convenient delivery and enabling of functionality; provided that, in determining the price and terms provided for herein, the original equipment manufacturer shall take the following into consideration:

(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 by the original equipment manufacturer;

(2) The ability of the owner of independent repair provider to pay for 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 chapter.

§ -5 Limitations. Nothing in this chapter shall be construed as:

(1) Requiring an original equipment manufacturer to divulge a trade secret to an owner or independent repair provider, except as necessary to provide

documentation, parts, and tools on fair and reasonable terms; and

(2) Altering the terms of any intellectual property arrangement in force between an authorized repair provider and an original equipment manufacturer, including the performance or provision of warranty or recall repair work by an authorized repair provider on behalf of an original equipment manufacturer pursuant to the arrangement; provided that any provision in the 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 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. 1172

Report Title:
AG; Medical Devices; Right to Repair; Powered Medical Equipment

Description:
Requires manufacturers of powered medical equipment to make available to powered medical equipment owners and independent repair providers parts, equipment, tools, documentation, and training courses and materials. Requires manufacturers to provide tools to repair equipment having a cost greater than or equal to $100. Creates a right of action by the Attorney General for certain violations of the State's medical device right to repair laws.

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