H.160

Introduced by Representatives Donahue of Northfield, Priestley of Bradford, Marcotte of Coventry, and Tomlinson of Winooski

Referred to Committee on

Date:

Subject: Commerce and trade; consumer protection; right to repair

Statement of purpose of bill as introduced: This bill proposes to require manufacturers of medical devices to make available to hospitals and independent service organizations, on fair and reasonable terms, the documentation, parts, and tools used to diagnose, maintain, and repair medical devices.

An act relating to creating a right to repair for medical devices

It is hereby enacted by the General Assembly of the State of Vermont:

Sec. 1. 9 V.S.A. chapter 106 is added to read:

CHAPTER 106. RIGHT TO REPAIR

Subchapter 1. Medical Devices

§ 4049. DEFINITIONS

As used in this chapter:

(1)(A) "Authorized repair provider" means an individual or business that has an arrangement with the original equipment manufacturer 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 diagnosis, maintenance, or repair of 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.

(B) An original equipment manufacturer that offers the services of diagnosis, maintenance, or repair of its own medical equipment shall be considered an authorized repair provider with respect to such equipment.

(2) "Documentation" means any manual, diagram, reporting output, service code description, schematic diagram, security code, password, or other guidance or information, whether in an electronic or tangible format, used to perform the services of diagnosis, maintenance, or repair of medical equipment.

(3) "Fair and reasonable terms" means making available parts, tools, or documentation as follows:

(A) with respect to documentation required for repair, that documentation is provided by the OEM 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;

(B) with respect to tools, that tools are made available by the OEM at no charge and without requiring authorization or internet access for use or operation of the tool, or imposing impediments to access or use of the tool to diagnose, maintain, or repair and enable full functionality of medical equipment, except that when a tool is requested in physical form, a charge may be included for the reasonable, actual costs of preparing and sending the tool; and

(C) with respect to parts, that parts are made available by the OEM, either directly or indirectly through an authorized repair provider, to independent repair providers and health care facilities at reasonable costs and terms that are equivalent to the most favorable costs and terms under which an OEM offers the part to an authorized repair provider and that:

(i) account for any discount, rebate, convenient and timely means of delivery, means of enabling fully restored and updated functionality, rights of use, or other incentive or preference the OEM offers to an authorized repair provider, or any additional cost, burden, or impediment the OEM imposes on an independent repair provider or health care facility;

(ii) are not conditioned on or imposing a substantial obligation or restriction that is not reasonably necessary for enabling the independent repair provider or health care facility to engage in the diagnosis, maintenance, or repair of medical equipment made by or on behalf of the OEM; and

(iii) are not conditioned on an arrangement described in subdivision (1)(A) of this section.

(4) "Health care facility" means all persons or institutions, including mobile facilities, whether public or private, proprietary or not for profit, that offer diagnosis, treatment, inpatient, or ambulatory care to two or more unrelated persons, and the buildings in which those services are offered. The term shall not apply to any facility operated by religious groups relying solely on spiritual means through prayer or healing but includes all institutions included in 18 V.S.A. § 9432(8), except health maintenance organizations.

(5) "Independent repair provider" means a person operating in this State, who does not have an arrangement with an OEM as described in subdivision (1)(A) of this section, and who is engaged in the diagnosis, service, maintenance, or repair of medical equipment.

(6) "Medical equipment" or "equipment" means any powered device approved by the United States Food and Drug Administration that is used in the treatment, monitoring, or diagnosis of a patient, and includes assistive, adaptive, and rehabilitative devices.

(7) "Original equipment manufacturer" or "OEM" means a business engaged in the business of selling, leasing, or otherwise supplying new medical equipment manufactured by or on behalf of itself.

(8) "Part" means any replacement part, either used or new, made available by an OEM for purposes of effecting the services of maintenance or repair of medical equipment manufactured by or on behalf of, sold or otherwise supplied by, the OEM.

(9) "Tools" means any software program, service key, hardware implement, or other apparatus used for diagnosis, maintenance, or repair of medical equipment, including software or other mechanisms that provision, program, or pair a new part; facilitate access to the equipment's repair and diagnostic functions; calibrate functionality; or perform any other function required to bring the product back to fully functional condition, including any updates.

(10) "Trade secret" has the same meaning as provided in 18 U.S.C. § 1839.

§ 4050. REQUIREMENTS

(a) General requirements. For medical equipment and parts sold and used in this State, the OEM of the equipment or parts or an authorized repair provider shall make available to independent repair providers and health care facilities, on fair and reasonable terms, any:

(1) documentation, parts, and tools, required for the diagnosis, maintenance, or repair of medical equipment and parts for medical equipment, inclusive of any updates to information; and

(2) training courses and materials on the operation, inspection, diagnosis, maintenance, and repair of the equipment that the OEM similarly provides to authorized repair providers.

(b) Security lock access. For medical equipment sold and used in this State that contains an electronic security lock or other security-related function, the OEM of the equipment or parts or an authorized repair provider shall make available to independent repair providers and health care facilities, on fair and reasonable terms, special documentation, tools, and parts required to access and reset the lock or function when disabled in the course of diagnosis, maintenance, or repair of such equipment. The documentation, tools, and parts may be made available through appropriate secure release systems.

§ 4051. LIMITATIONS

(a) This subchapter does not require an OEM to divulge a trade secret to an independent repair provider or health care facility.

(b) This subchapter does not alter the terms of any arrangement described in subdivision 4049(1)(A) of this title in force between an authorized repair provider and an OEM, including the performance or provision of warranty or recall repair work by an authorized repair provider on behalf of an OEM pursuant to such arrangement, except that any provision governing such an arrangement that purports to waive, avoid, restrict, or limit the OEM's obligations to comply with this subchapter is void and unenforceable.

(c) Original equipment manufacturers and authorized repair providers are not liable for damage caused to any medical equipment by independent repair providers or health care facilities that occurs during the course of repair, diagnosis, or maintenance of the equipment.

§ 4052. ENFORCEMENT

(a) A person who violates a provision of this subchapter commits an unfair and deceptive act in trade and commerce in violation of section 2453 of this title.

(b) The Attorney General has the same authority to make rules, conduct civil investigations, enter into assurances of discontinuance, and bring civil actions as provided under chapter 63, subchapter 1 of this title.

Sec. 2. IMPLEMENTATION

This act applies to medical equipment and parts sold or in use in this State on or after the effective date of this act.

Sec. 3. EFFECTIVE DATE

This act shall take effect on July 1, 2025.