GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2023

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HOUSE BILL DRH30264-NH-120

Short Title:	Medical Equipment Right to Repair Act.	(Public)
Sponsors:	Representative Belk.	
Referred to:		

A BILL TO BE ENTITLED

AN ACT TO REQUIRE ORIGINAL EQUIPMENT MANUFACTURERS OF MEDICAL IMAGING EQUIPMENT AND MEDICAL RADIATION THERAPY EQUIPMENT TO PROVIDE EQUIPMENT OWNERS AND REPAIR PROVIDERS ACCESS TO THE SUPPORT DOCUMENTS, TOOLS, AND PARTS NECESSARY TO PERFORM DIAGNOSTIC, MAINTENANCE, AND REPAIR SERVICES ON THE EQUIPMENT.

The General Assembly of North Carolina enacts:

SECTION 1. Chapter 66 of the General Statutes is amended by adding a new Article to read:

"Article 51.

"Medical Equipment Right to Repair Act.

"**§ 66-500. Citation and definitions.**

(a) This Article may be cited as the "Medical Equipment Right to Repair Act."

(b) As used in this Article, the following definitions apply unless context otherwise requires:

(1) Authorized repair provider. – An individual or entity that has contracted with an original equipment manufacturer to offer or perform diagnostic, maintenance, or repair services of the manufacturer's medical imaging or radiation therapy equipment whether operating under (i) a license to use the manufacturer's trade name, service mark, or other proprietary identifier or (ii) an alternative arrangement under which a provider offers to or provides services on behalf of the manufacturer. For purposes of this Article, an original equipment manufacturer that offers or performs diagnostic, maintenance, or repair services of its own medical imaging or radiation therapy equipment is also an authorized repair provider.

(2) Independent repair provider. – An individual or business that offers or performs diagnostic, maintenance, or repair services of medical imaging or radiation therapy equipment without contracting with the original equipment manufacturer.

(3) Medical imaging equipment. – Any device used to view the human body to diagnose, monitor, or treat medical conditions, including products for ultrasound imaging, magnetic resonance imaging, medical X ray, radiography, computed tomography, fluoroscopy, and mammography.

(4) Medical radiation therapy equipment. – Any device that produces high energy-charged particles to provide radiation therapy and related support devices, including signal analysis and display equipment; patient and

equipment supports; treatment planning software; and component parts and accessories.

(5) Original equipment manufacturer (OEM). – An individual or entity that is engaged in the business of manufacturing and selling, leasing, or otherwise supplying medical imaging and radiation therapy equipment to others.

(6) Owner. – An individual or entity that owns or leases medical imaging or radiation therapy equipment.

(7) Part. – Any part made available by the original equipment manufacturer, whether new or used, that is necessary for the maintenance or repair of medical imaging or radiation therapy equipment.

(8) Support documentation. – Any manual, diagram, reporting output, service code description, schematic diagram, security codes, passwords, or other guidance or information necessary to perform diagnostic, maintenance, or repair services on medical imaging and radiation therapy equipment.

(9) Tool. – Any software, hardware, or other apparatus necessary to perform diagnostic, maintenance, or repair services on medical imaging and radiation therapy equipment, including items needed to program or pair new parts, calibrate functionality, conduct software updates, or perform any other function required to bring the product back to fully functional condition.

(10) Trade secret. – Certain information as defined in G.S. 66-152.

"**§ 66-500.1. Duties of original equipment manufacturer.**

Any OEM that manufactures medical imaging equipment or medical radiation therapy equipment that is used in this State is required to do the following:

(1) Make available to any hospital or independent repair provider any support documentation, parts, or tools necessary to perform diagnostic, maintenance, or repair services of the manufacturer's medical imaging or radiation therapy equipment subject to the following terms:

a. Anytime the OEM updates the support documentation for its equipment, the OEM shall automatically send notice of the updated information to all known equipment owners and independent repair providers.

b. An OEM shall provide access to support documentation at no charge to an owner or independent repair provider, however, if the owner or independent repair provider requests a printed copy of a support document, the OEM may charge the owner or independent repair provider the actual costs of printing and shipping the print copy.

c. An OEM shall provide access to tools without requiring authorization, registration, or other such impediment to access or use necessary tools, including impairing the ability to use the tools in an efficient and cost-effective manner. The OEM shall make tools available at no cost to an owner or independent repair provider, however, the OEM may charge an owner or independent repair provider the actual costs of preparing and shipping a tool.

d. An OEM shall provide access to any support documentation or tools needed to access or reset any electronic security lock or any other security-related function.

e. Both OEM and authorized repair providers shall provide access to parts at the same costs and under the same terms as the most favorable agreement between the OEM and any authorized repair provider.

(2) An OEM shall be in compliance with this section if the OEM delegates the requirements of this section to an authorized repair provider and the authorized repair provider satisfies the requirements on behalf of the OEM.

(3) If an OEM offers training courses or training materials on how to properly operate, inspect, diagnose, maintain, or repair its equipment to authorized repair providers, the OEM must offer the same courses or materials to owners and independent repair providers.

"**§ 66-500.2. Limitations and enforcement.**

(a) Any violation of this Article is an unfair or deceptive trade practice for purposes of Chapter 75 of the General Statutes and the violating party is subject to suit thereunder by injured parties and the Attorney General.

(b) Nothing in this Article shall be construed to require an original equipment manufacturer to divulge any trade secret to an owner or independent repair provider.

(c) Any provision of an agreement between an OEM and an authorized repair provider that purports to waive, avoid, restrict, or limit an OEM's obligation to comply with this Article is void and unenforceable.

(d) No OEM or authorized repair provider shall be liable for any damage caused to medical imaging or radiation therapy equipment or injury caused to an owner or independent repair provider which occurs during repair, diagnosis, or maintenance of the equipment."

SECTION 2. This act becomes effective July 1, 2024, and applies to equipment in use on or after that date.