GENERAL ASSEMBLY OF NORTH CAROLINA SESSION 2023

H HOUSE BILL 752

Short Title	e:]	Medical Equipment Right to Repair Act. (Public
Sponsors:	:]	Representatives Belk, Carney, Cunningham, and Autry (Primary Sponsors).
Sponsors.	-	For a complete list of sponsors, refer to the North Carolina General Assembly web site.
Referred t	to:	Rules, Calendar, and Operations of the House
		April 19, 2023
		A DILL TO DE ENTITLED
IMAC	GING	A BILL TO BE ENTITLED REQUIRE ORIGINAL EQUIPMENT MANUFACTURERS OF MEDICAL EQUIPMENT AND MEDICAL RADIATION THERAPY EQUIPMENT TO
PROVIDE EQUIPMENT OWNERS AND REPAIR PROVIDERS ACCESS TO THE SUPPORT DOCUMENTS, TOOLS, AND PARTS NECESSARY TO PERFORM		
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		TIC, MAINTENANCE, AND REPAIR SERVICES ON THE EQUIPMENT. ssembly of North Carolina enacts:
The Gene		CTION 1. Chapter 66 of the General Statutes is amended by adding a new Article
to read:		
		"Article 51.
"Medical Equipment Right to Repair Act.		
" <u>§ 66-500. Citation and definitions.</u> (a) This Article may be cited as the "Medical Equipment Right to Repair Act."		
<u>(a)</u> (b)		used in this Article, the following definitions apply unless context otherwise
requires:	713	used in this Article, the following definitions apply timess context otherwise
<u>+</u>	<u>(1)</u>	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.
	<u>(2)</u>	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
	(2)	manufacturer. Modical imaging aguinment. Any daviga used to view the human body to
	<u>(3)</u>	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.
	<u>(4)</u>	Medical radiation therapy equipment Any device that produces high
		energy-charged particles to provide radiation therapy and related support



1 devices, including signal analysis and display equipment; patient and 2 equipment supports; treatment planning software; and component parts and 3 accessories. 4 Original equipment manufacturer (OEM). – An individual or entity that is <u>(5)</u> 5 engaged in the business of manufacturing and selling, leasing, or otherwise 6 supplying medical imaging and radiation therapy equipment to others. 7 Owner. - An individual or entity that owns or leases medical imaging or (6) 8 radiation therapy equipment. 9 Part. – Any part made available by the original equipment manufacturer, <u>(7)</u> 10 whether new or used, that is necessary for the maintenance or repair of medical 11 imaging or radiation therapy equipment. Support documentation. – Any manual, diagram, reporting output, service 12 **(8)** 13 code description, schematic diagram, security codes, passwords, or other 14 guidance or information necessary to perform diagnostic, maintenance, or repair services on medical imaging and radiation therapy equipment. 15 Tool. – Any software, hardware, or other apparatus necessary to perform 16 (9) 17 diagnostic, maintenance, or repair services on medical imaging and radiation 18 therapy equipment, including items needed to program or pair new parts, 19 calibrate functionality, conduct software updates, or perform any other 20 function required to bring the product back to fully functional condition. 21 (10)Trade secret. – Certain information as defined in G.S. 66-152. 22 "§ 66-500.1. Duties of original equipment manufacturer. 23 Any OEM that manufactures medical imaging equipment or medical radiation therapy 24 equipment that is used in this State is required to do the following: 25 Make available to any hospital or independent repair provider any support (1) 26 documentation, parts, or tools necessary to perform diagnostic, maintenance, 27 or repair services of the manufacturer's medical imaging or radiation therapy 28 equipment subject to the following terms: 29 Anytime the OEM updates the support documentation for its 30 equipment, the OEM shall automatically send notice of the updated 31 information to all known equipment owners and independent repair 32 33 An OEM shall provide access to support documentation at no charge <u>b.</u> 34 to an owner or independent repair provider, however, if the owner or 35 independent repair provider requests a printed copy of a support 36 document, the OEM may charge the owner or independent repair 37 provider the actual costs of printing and shipping the print copy. 38 An OEM shall provide access to tools without requiring authorization, <u>c.</u> 39 registration, or other such impediment to access or use necessary tools, 40 including impairing the ability to use the tools in an efficient and 41 cost-effective manner. The OEM shall make tools available at no cost 42 to an owner or independent repair provider, however, the OEM may 43 charge an owner or independent repair provider the actual costs of 44 preparing and shipping a tool. 45 An OEM shall provide access to any support documentation or tools <u>d.</u> 46 needed to access or reset any electronic security lock or any other 47 security-related function. 48 Both OEM and authorized repair providers shall provide access to <u>e.</u> 49 parts at the same costs and under the same terms as the most favorable 50 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.

House Bill 752-First Edition