## GENERAL ASSEMBLY OF NORTH CAROLINA SESSION 2025

H HOUSE BILL 460

Short Title	e: M	Sedical Equipment Right to Repair Act.	(Public)
Sponsors:		Representatives Belk, Carney, Cunningham, and Buansi (Primary Sponsors).	
•		For a complete list of sponsors, refer to the North Carolina General Assembly well	
Referred to	o: R	ules, Calendar, and Operations of the House	
March 20, 2025			
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:	SEC.	1101 1. Chapter 60 of the General Statutes is affended by adding a flev	v Article
"Article 52.  "Medical Equipment Right to Repair Act.  "§ 66-503. Citation and definitions.			
<u>(a)</u>			
<u>(b)</u> requires:	As us	sed in this Article, the following definitions apply unless context o	tnerwise
<u>roquiros.</u>	(1)	Authorized repair provider. – An individual or entity that has contract an original equipment manufacturer to offer or perform diamaintenance, or repair services of the manufacturer's medical image radiation therapy equipment whether operating under (i) a license to manufacturer's trade name, service mark, or other proprietary identificant alternative arrangement under which a provider offers to or services on behalf of the manufacturer. For purposes of this Arroriginal equipment manufacturer that offers or performs diamaintenance, or repair services of its own medical imaging or therapy equipment is also an authorized repair provider.	agnostic, aging or o use the er or (ii) provides ticle, an agnostic,
	<u>(2)</u>	Independent repair provider. – An individual or business that of performs diagnostic, maintenance, or repair services of medical im radiation therapy equipment without contracting with the original equipment with the origi	aging or
	<u>(3)</u>	manufacturer.  Medical imaging equipment. – Any device used to view the human diagnose, monitor, or treat medical conditions, including produltrasound imaging, magnetic resonance imaging, medical	ucts for X ray,
	<u>(4)</u>	radiography, computed tomography, fluoroscopy, and mammography Medical radiation therapy equipment. – Any device that produce energy-charged particles to provide radiation therapy and related	ces high



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. 12 Support documentation. – Any manual, diagram, reporting output, service **(8)** 13 code description, schematic diagram, security codes, passwords, or other 14 guidance or information necessary to perform diagnostic, maintenance, or 15 repair services on medical imaging and radiation therapy equipment. 16 Tool. – Any software, hardware, or other apparatus necessary to perform (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 "§ 66-503.1. Duties of original equipment manufacturer. 22 Any OEM that manufactures medical imaging equipment or medical radiation therapy 23 equipment that is used in this State is required to do the following: 24 (1) Make available to any hospital or independent repair provider any support 25 documentation, parts, or tools necessary to perform diagnostic, maintenance, 26 or repair services of the manufacturer's medical imaging or radiation therapy equipment subject to the following terms: 27 28 Anytime the OEM updates the support documentation for its <u>a.</u> 29 equipment, the OEM shall automatically send notice of the updated 30 information to all known equipment owners and independent repair 31 providers. 32 An OEM shall provide access to support documentation at no charge <u>b.</u> 33 to an owner or independent repair provider, however, if the owner or 34 independent repair provider requests a printed copy of a support 35 document, the OEM may charge the owner or independent repair 36 provider the actual costs of printing and shipping the print copy. An OEM shall provide access to tools without requiring authorization, 37 <u>c.</u> 38 registration, or other such impediment to access or use necessary tools, 39 including impairing the ability to use the tools in an efficient and 40 cost-effective manner. The OEM shall make tools available at no cost 41 to an owner or independent repair provider, however, the OEM may 42 charge an owner or independent repair provider the actual costs of 43 preparing and shipping a tool. 44 An OEM shall provide access to any support documentation or tools <u>d.</u> 45 needed to access or reset any electronic security lock or any other 46 security-related function. 47 Both OEM and authorized repair providers shall provide access to <u>e.</u> 48 parts at the same costs and under the same terms as the most favorable

49

agreement between the OEM and any authorized repair provider.

<u>(3)</u>

2 3 4

1

(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.

5 6 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.

6 7 8

## "§ 66-503.2. Limitations and enforcement.

9 10 11 (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.

12 13

(b) Nothing in this Article shall be construed to require an OEM to divulge any trade secret, as defined in G.S. 66-152, to an owner or independent repair provider.

14 15 (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.

16 17

(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."

18 19 20

21

**SECTION 2.** This act becomes effective July 1, 2025, and applies to equipment in use on or after that date.