

GENERAL ASSEMBLY OF NORTH CAROLINA  
SESSION 2023

H.B. 752  
Apr 18, 2023  
HOUSE PRINCIPAL CLERK

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HOUSE BILL DRH30264-NH-120

Short Title: Medical Equipment Right to Repair Act.

(Public)

Sponsors: Representative Belk.

Referred to:

1 A BILL TO BE ENTITLED  
2 AN ACT TO REQUIRE ORIGINAL EQUIPMENT MANUFACTURERS OF MEDICAL  
3 IMAGING EQUIPMENT AND MEDICAL RADIATION THERAPY EQUIPMENT TO  
4 PROVIDE EQUIPMENT OWNERS AND REPAIR PROVIDERS ACCESS TO THE  
5 SUPPORT DOCUMENTS, TOOLS, AND PARTS NECESSARY TO PERFORM  
6 DIAGNOSTIC, MAINTENANCE, AND REPAIR SERVICES ON THE EQUIPMENT.

7 The General Assembly of North Carolina enacts:

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

10 "Article 51.

11 "Medical Equipment Right to Repair Act.

12 "**§ 66-500. Citation and definitions.**

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

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

- 16 (1) Authorized repair provider. – An individual or entity that has contracted with  
17 an original equipment manufacturer to offer or perform diagnostic,  
18 maintenance, or repair services of the manufacturer's medical imaging or  
19 radiation therapy equipment whether operating under (i) a license to use the  
20 manufacturer's trade name, service mark, or other proprietary identifier or (ii)  
21 an alternative arrangement under which a provider offers to or provides  
22 services on behalf of the manufacturer. For purposes of this Article, an  
23 original equipment manufacturer that offers or performs diagnostic,  
24 maintenance, or repair services of its own medical imaging or radiation  
25 therapy equipment is also an authorized repair provider.
- 26 (2) Independent repair provider. – An individual or business that offers or  
27 performs diagnostic, maintenance, or repair services of medical imaging or  
28 radiation therapy equipment without contracting with the original equipment  
29 manufacturer.
- 30 (3) Medical imaging equipment. – Any device used to view the human body to  
31 diagnose, monitor, or treat medical conditions, including products for  
32 ultrasound imaging, magnetic resonance imaging, medical X ray,  
33 radiography, computed tomography, fluoroscopy, and mammography.
- 34 (4) Medical radiation therapy equipment. – Any device that produces high  
35 energy-charged particles to provide radiation therapy and related support  
36 devices, including signal analysis and display equipment; patient and



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

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

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

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

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

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

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

21 **"§ 66-500.1. 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  
27 equipment subject to the following terms:

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

32 b. An OEM shall provide access to support documentation at no charge  
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.

37 c. An OEM shall provide access to tools without requiring authorization,  
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 d. An OEM shall provide access to any support documentation or tools  
45 needed to access or reset any electronic security lock or any other  
46 security-related function.

47 e. Both OEM and authorized repair providers shall provide access to  
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.

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

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

8 **"§ 66-500.2. Limitations and enforcement.**

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

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

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

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

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