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:


§ 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.