

# RIGHT TO REPAIR

# TOWN HALL PRESENTATION

By: Chris Nowak and Al Gresch





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## YOUR PRESENTERS:

Al and Chris have decades of experience in the healthcare technology management field. They have each served patients in large scale CE operations and have faced the changing challenges in healthcare and the impacts to managing medical device acquisition, maintenance and disposition.

Today, the pressures of fiscal governance encompasses the entire process of fiscal policy, from planning and budgeting to implementation and oversight. More than ever, the ability to deliver value for the healthcare employer is critical. The ability to control the costs through the entire medical device lifecycle is a key component. As margins for OEM's shrink, they are turning their sights to target service costs as a means to increase the revenue stream and enhance margins.



## WHAT IS THE RIGHT-TO-REPAIR and WHAT DOES IT MEAN TO ME:

The right-to-repair is a movement, not just in healthcare, but also in many other business sectors. It is a movement that is advocating for consumers and third-party repair businesses to have access to the necessary parts, tools, information and software to repair products that they own or decide who they want to service the gear they have purchased. OEM's would rather restrict owners to manufacturer repair or manufacturer-authorized repair centers only. This strategy by the manufacturers has a tremendous impact on business, including healthcare. Lengthy repair times and delays negatively impact patients through canceled or delayed procedures. So not only is the cost of the service more expensive, but also it reduces the revenue for healthcare facilities/providers through the delays or canceled patient diagnostic/therapeutic procedures.

Today, manufacturers are placing “hooks” in medical device software that make servicing more difficult for the owner of the device. This requires medical device owners to purchase expensive service agreements or the “hooks” hamper, rather than hasten the repair time for medical device owner's own staff or the repair staff of the owner's choosing.



## **Breaking News on Right-to-Repair (R-T-R)**

On July 21, Gay Gordon-Byrne, Executive Director of The Repair Association ([www.repair.org](http://www.repair.org)), submitted a letter to the Senate Armed Forces Committee in support of Senate Bill 2209 (<https://www.congress.gov/bill/119th-congress/senate-bill/2209>) which is aimed at guaranteeing our military's right to repair equipment, purchased by taxpayers, that our soldiers rely on.

The military is the largest buyer of tech-enabled products in the world—yet too often, it is locked out of essential repairs because manufacturers withhold access to parts, tools, or diagnostic information. These restrictions slow down readiness, inflate costs, and undermine the very concept of ownership. Repair isn't about copying designs or exposing trade secrets. It's a fundamental right tied to ownership, and it's essential for operational readiness. The Repair Association has seen this issue play out across industries—from agriculture to medical devices—and the same principles apply to defense equipment.



## Where is right to repair today for healthcare?

- Although the movement of R-T-R continues to gain traction, much of those efforts have been in the agricultural industry.
- Several states have passed "Right to Repair" laws, notably New York, Minnesota, and California, requiring access to repair information and parts for electronics, with the only focus in healthcare on electronic wheelchairs.
- Over 40 states have introduced legislation or are considering legislation, but the focus on medical devices has not been the focus. Cars and agriculture continue to be the main focus.
- Medical devices continue to be exempted from the R-T-R legislation “due to the potential risks associated from improper repairs.”
- The debate in healthcare centers around balancing consumer rights to repair with patient safety and the role of the FDA in regulating medical device maintenance.
- The [FDA](#) plays a crucial role in ensuring the safety and efficacy of medical devices. Concerns exist that right-to-repair laws could undermine this oversight, potentially leading to unsafe repairs and adverse events.



## Where is right to repair today for healthcare?

- Medical devices are increasingly connected to the internet, raising concerns about cybersecurity. Unqualified repair personnel could potentially introduce vulnerabilities, [notes MedCity News](#).
- Organizations like AdvaMed® are actively advocating for medical device carve-outs in right-to-repair legislation, emphasizing the need for patient safety.
- Who is AdvaMed: AdvaMed®, The Medtech Association, is a trade association that leads the effort to advance medical technology in order to achieve healthier lives and healthier economies around the world. AdvaMed®'s membership has reached over 600 members and more than 80 employees with a global presence including Europe, India, China, Brazil, and Japan. AdvaMed®'s [member companies](#) range from the largest to the smallest medical technology innovators and companies. The Association acts as the common voice for companies producing medical devices, diagnostic products and digital health technologies.



## Where is right to repair today for healthcare?

- In February, Vermont introduced a medical device-specific right to repair bill, which would encourage third party servicers to conduct device repairs at hospitals.
- In March, North Carolina introduced a similar policy, which requires the original manufacturers to give service providers repair information and manuals.
- Peter Pitts, President of the Center for Medicine in the Public Interest and a former FDA Associate Commissioner, said “lawmakers must consider the grave risks associated with dangerously broad right to repair policies and ensure medical device carveouts before it’s too late. Patient safety must come first, always. No exceptions.”
- From Tech Nation article: **Revisit the Right to Repair Movement: Why Medical Equipment Repair Needs More Than Third-Party Action**

Hospital leadership plays a pivotal role in influencing OEM behavior. “If hospital admins want right to repair, it’s far more likely to happen,” Gordon-Byrne said. “Large hospital systems have the leverage of the purchase order.”

Robert Kerwin, general counsel for the International Association of Medical Equipment Remarketers and Servicers (IAMERS), said that HTM professionals should demand service access during procurement.



## Where do we go from here?

- Stay or get involved! Research where your current state legislature is at with regard to R-T-R legislation. Discuss the subject matter in your own hospital/facility. Educate your hospital leaders, c-suite, nursing directors, etc... on R-T-R. Create an awareness on the topic.
- Participate in any regional professional society activities and ensure they are aware of the topic.
- Mike Busdicker, CHTM, FACHEF and Vice President of the Sodexo HTM West Region says, “every organization has a legal counsel or government relations team. They need to understand what’s at stake.”
- Busdicker said state associations must build local political relationships and unify HTM professionals. “Even with ISOs in the mix, we need to work together.”
- Busdicker concluded, “HTM leaders must understand how this impacts patient care, safety, and costs. Education is the first step. Give biomedes the tools they need to take action.”
- Legislators respond to voters. If we break down how lack of repair options increases health costs, we can drive pressure through constituents.”



# Supply Chain Strategies

- Develop Strong Relationships
  - Finance
  - Supply Chain
  - Physician Leaders
  - Clinical Leaders
- Get Involved in the Contracting Process
  - **Purchase Contracts** and Service Contracts
- Engage GPO
  - Premier
  - Vizient
  - Others



# MASTER EQUIPMENT PURCHASE AGREEMENT

This Master Equipment Purchase Agreement, dated for reference purposes as of <insert date> (“Reference Date”) is entered into between <insert Customer Name>., a <Insert State Name> non-profit corporation with its principal place of business at <Insert Business address> <Insert State Name> (“<Customer Name>”), and <Insert Vendor Name>, Inc., a <Insert State Name > corporation with its principal place of business a, <Insert State Name > (“Vendor”).

## RECITALS

A. To improve and ensure patient care and respond to market demands requiring the efficient delivery of health care, <Customer Name> is in the process of standardizing its technology and technology acquisition processes used by <Customer Name> and its Affiliates. To facilitate <Insert Customer Name> effort to standardize the technology used by <Customer Name> and its Affiliates, <Customer Name> is entering into strategic technology alliances with a select group of technology vendors. Pursuant to these alliances, <Customer Name> and its Affiliates will have the right to acquire Products and Services according to pre-established processes, prices and terms.

B. <Insert Customer Name> business objectives to be accomplished through this Agreement, include the ability to (1) lower operating costs, (2) accelerate the process of acquiring technology, (3) capitalize on advances in technology and communications to reduce technology operating costs, (4) improve the collection, storage, exchange and sharing of, clinical and other data, (5) improve patient care, (6) enhance measurement of patient satisfaction and outcomes, and (7) comply with regulatory and accreditation agency reporting requirements.

C. Vendor acknowledges these objectives and represents that it has the Products, Services, expertise and experience to assist <Customer Name> in its achievement of such goals.



# Components of Purchasing Section

- Definitions
- Procurement of Products & Services
  - Available Products
  - Future Products
  - Enhancements
  - Procurement Process
- Pricing
  - Invoicing
  - Savings Reports
  - Payment Terms
  - “Most Favored” Clause
  - Payment Does Not Imply Acceptance



# Components of Purchasing Section (cont.)

- Delivery & Installation
  - Time is of the Essence
  - Documentation
  - Licenses & Permits
  - Installation & Acceptance Tests
    - Failure
    - Acceptance
- Warranties
  - Product
  - Uptime
  - Compliance & Laws
  - Software or Firmware
  - Virus
  - Glassware



# Components of Purchasing Section (cont.)

- Term & Termination
- Limitation of Liability & Damages
- Insurance & Indemnity
- Confidentiality
- Venue



# Components of Services/Pricing Section

- Service Agreement Options
  - Pricing
  - Minimum Repair Hours
  - Non-Obsolescence
  - Response Time
  - Planned Maintenance Parameters
- Time & Materials Coverage
  - Pricing
- Definition of Regular/Overtime/Premium Rates
- Repair Parts
- Vendor Biomedical Training
- Technologist Training
- Licensed Diagnostic Software
- Uptime Warranties



# DISCUSSION

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## Questions and Answers

