ACCE
AMERICAN COLLEGE OF CLINICAL ENGINEERING

2024-2025 Educational Webinar Series

Right to Repair: Current Status in the US and Canada

March 13, 2025

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About the Moderator

Dean Skillicorn, BS, CBET, CHTM
St. Luke's Health System

Dean Skillicorn is the Imaging Services Manager for St. Luke's Health System in Boise, ID.

Dean is a member of the ACCE Educational Committee.

Dean is a Certified Biomedical Equipment Technician with a Bachelors Degree in Business from Oregon State University (2020). Dean is also an avid flyfisherman and fishes much of Idaho, Oregon, and Montana.

Logistics

❖All attendees have their microphones muted during the presentation.

❖Questions to the panelists must be submitted via the "Q&A" feature in Zoom at any time. They will be addressed at the Q&A portion.

❖If there is any urgent issue, please use the "chat" feature to communicate with the host/moderator.

❖Please remember to complete the webinar evaluation after attending. A link will be provided at the end.

Session Description

Right to Repair is an issue of increasing importance and urgency in the health technology management (HTM) community. In recent decades, a formerly harmonious relationship between most manufacturers and clinical engineering (CE) & HTM professionals has been strained by some manufacturers' practice of restricting access to parts, tools, documentation and software. Frustration with the resulting equipment downtime and additional costs have caused many CEs and HTMs to join the call for medical device Right to Repair, which has been considered in dozens of states and at the federal level in the US and also in Canada. In this session, we'll discuss the issues at the core of this debate—including concerns about patient safety, remanufacturing, cybersecurity and more—and share updates on the progress of medical Right to Repair legislation in both countries.

Objectives

- Provide a comprehensive review of the Right to Repair movement in general (N Proctor)
- Review the current efforts in the US for medical devices (B Wang)
- Review the current efforts in Canada for medical devices (K Taylor)
- Discuss how attendees can contribute to RtR

About the Speaker

Nathan Proctor
Senior Campaign Director, Right to Repair

PIRG

Nathan Proctor has been a researcher and advocate for the public for the last 17 years. He is the Senior Director of U.S. Public Interest Research Group's (PIRG) Right to Repair campaign.

A graduate of Tufts University. His work has been featured in the New York Times, Wall Street Journal, National Public Radio, and even The Dauly Show.

A member of the Grist 50 "list of emerging leaders from across the US who are working on fresh, real-world solutions to our world's biggest challenges," Nathan lives in Arlington, Mass. with his wife and two children.

About the Speaker

Binseng Wang, Sc.D.
Vice President Program Management
sodexo
QUALITY OF LIFE SERVICES

- Binseng Wang is Vice President, Program Management with Sodexo HTM, an independent service organization
- Previously, Dr. Wang was Director, Quality & Regulatory Affairs for Greenwood Marketing, LLC, as well as Vice President, Quality & Regulatory Affairs, for Sundance Enterprises, Aramark Healthcare Technologies, and MEDIQ/PRN.
- He also worked as a Visiting Scientist at NIH and an Adjunct Professor at the Milwaukee School of Engineering.
- He is a fellow of ACCE and AIMBE. He received the 2010 AAMI CE Achievement Award, the 2015 ACCE Lifetime Achievement Award, and the 2019 AAMI-TRIMEDX Iconoclast Award, and was inducted into the Clinical Engineering Hall of Fame by ACCE in 2017.
- He earned a Doctor of Science (ScD) degree from MIT and is a Certified Clinical Engineer (CCE).

About the Speaker

Kevin Taylor, P.Eng.
Territorial Manager of Biomedical Engineering

NORTHWEST TERRITORIES
Health and Social Services Authority

Kevin Taylor is the Territorial Manager of Biomedical Engineering for the Northwest Territories, Canada.

He is also the co-chair of the Canadian Medical and Biological Engineering Society's Right to Repair committee.

Through his career, he has worked in various health technology management roles within Canada, the US and internationally.

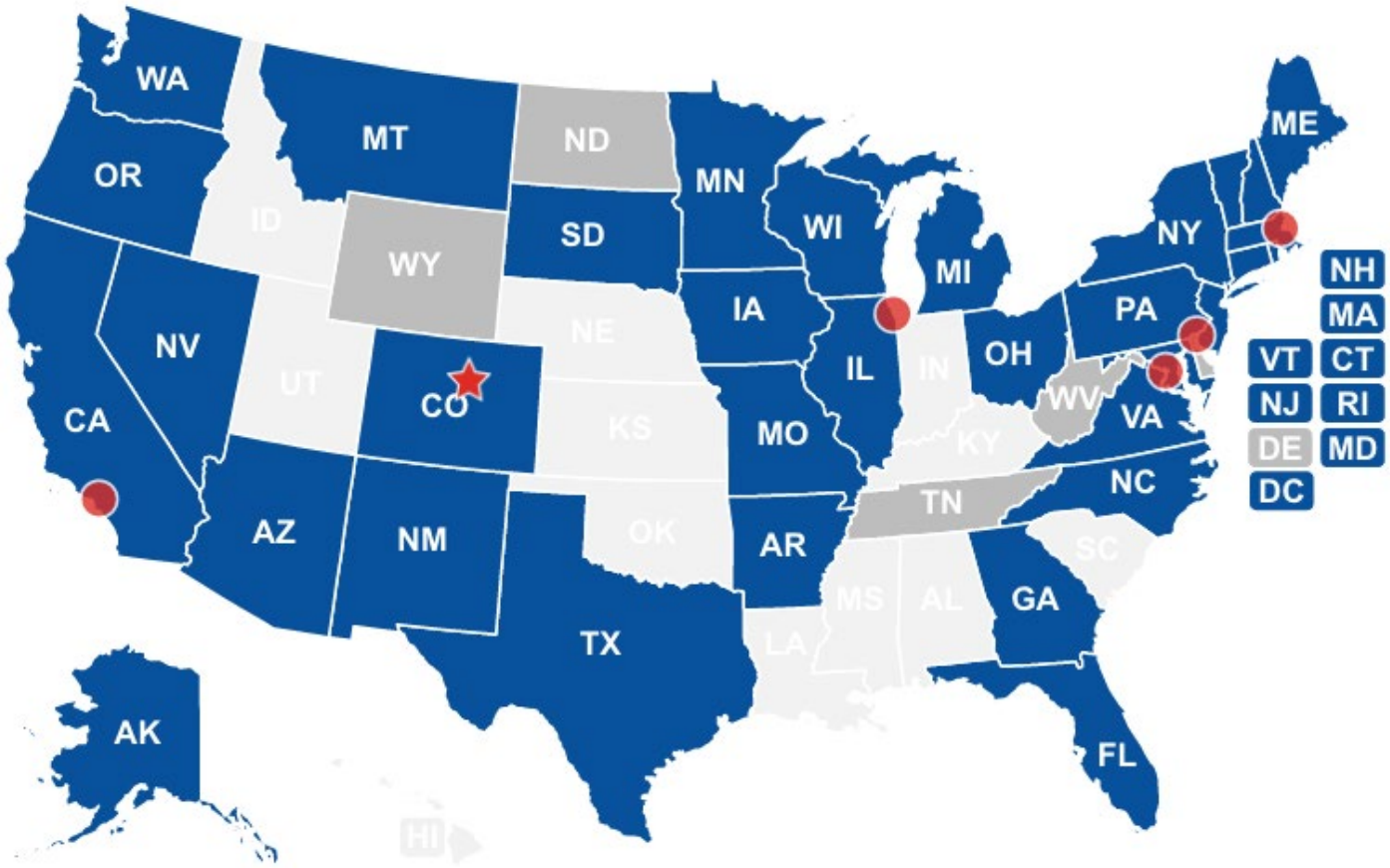
He has had the opportunity to work with others within the Northwest Territories to draft and implement the first health technology Right to Repair policy for a government health system in Canada.

Right to Repair Overview

Nathan Proctor

PIRG

PIRG is an advocate for the public interest. We speak out for a healthier, safer world in which we're freer to pursue our own individual well-being and the common good.



On average, Americans dispose of


Parking
Pharmacies
ATMs
DALAHAISHANG VILLAGE
DALAHAIXIACUN
Weikuang Dam
JIAYI KILN
Baotou Huake Rare Earths Weijing Company

Wasting the planet, as well as money and time

- When you can't repair things, and toss them, that causes damaging **electronic waste.**
- When you can't repair things, and have to buy new things, that **wastes money**.
- When you can't repair things, and have to pay for "manufacturer-approved" servicing, they can **charge whatever they want**.
- When you can't repair things, and have to wait for those few "manufacturer-approved" servicers to get all the way down the list to you, that **wastes time.**

Consumers can save big by repairing electronics

$49.6 BILLION

PER YEAR IN AMERICA

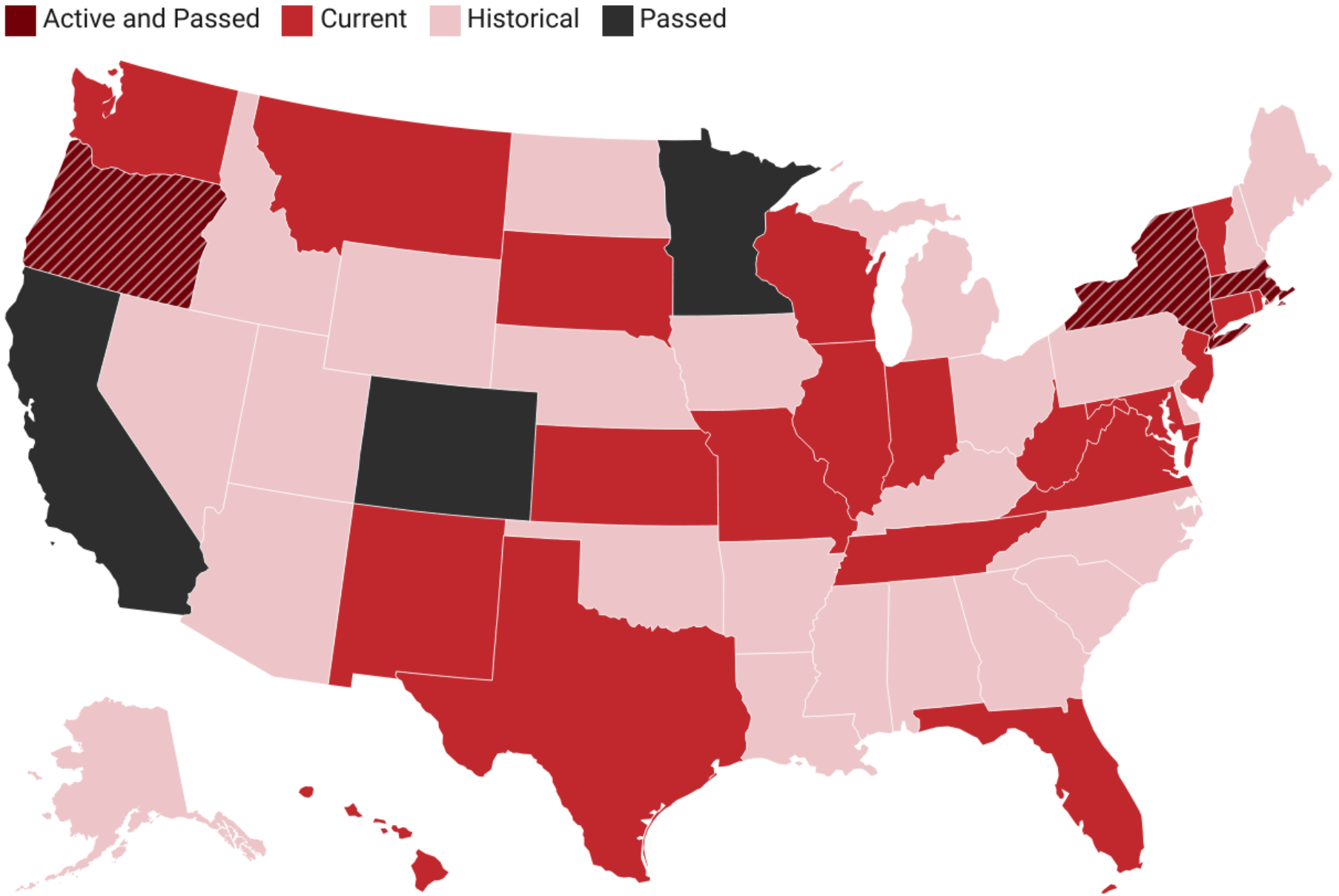
Repair could reduce household spending on electronics and appliances by 22 percent, which would save an average family approximately $380 per year.

Right to Repair laws would save U.S. farmers

$4.2 BILLION PER YEAR

Farmers have to go to the dealership for many tractor fixes, leading to inflated repair costs and downtime that can cause crop losses. Right to Repair, which would provide farmers with access to necessary repair materials, would save U.S. farmers $4.2 billion a year.

All 50 States Have Introduced Right to Repair Legislation



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What bills have passed?

- Cars:
  - 2012 Massachusetts law and ballot question
  - 2020 Massachusetts telematic access ballot question
  - 2023 Maine telematic access

- Wheelchairs:
  - Colorado in 2022
  - More limited wheelchair bills in TN and CA in 2024

- Consumer devices:
  - New York in 2022
  - Minnesota in 2023 (which also includes many kinds of industrial equipment)
  - California in 2023
  - Oregon in 2024
  - Colorado in 2024

State	Personal Electronics	Parts Pairing	Appliances	Business / Enterprise	Farm Equipment	Wheelchairs	Car Data
New York	✓	✗	✗	✗	✗	✗	✗
Colorado	✓	✓	✓	✓	✓	✓	✗
Minnesota	✓	✗	✓	✓	✗	✗	✗
Oregon	✓	✓	✓	✗	✗	✗	✗
California	✓	✗	✓	✗	✗	✓	✗
Maine	✗	✗	✗	✗	✗	✗	✓
Massachusetts	✗	✗	✗	✗	✗	✗	✓

COVID PUSHED US TO DO A LOT MORE ON MEDICAL

- Biomeds raised the alarm to us about conditions regarding devices
  - OEM servicers had travel restrictions
  - Additional equipment pressed into service, couldn't get PM kits or other materials
  - Conditions in the hospital were dire
- We surveyed 222 biomeds and HTMs about conditions as part of our report on these issues "Hospital Repair Restrictions"

of respondents reported to have equipment in their facilities which could not be used due to restrictions on spare parts and service information

claimed they had been denied service information for "critical equipment (defibrillators, ventilators, anesthesia machines, imaging equipment, etc.),"

FINDINGS FROM “Hospital REPAIR RESTRICTIONS”

How important is Right to Repair to repair to your work?		
Critical: Right to Repair a top issue facing field	148	67.0%
Very important: Issues around repair restrictions are a persistent problem	56	25.3%
Somewhat important: Right to Repair would improve efficiency and/or provide other benefits	16	7.3%
Somewhat unimportant: Right to Repair provides only slight benefits	1	0.5%
Not important	0	0.0%

DELAYED CARE

Nearly 70 percent of more than 200 medical repair professionals surveyed say that their hospital has had to "delay a patient procedure because [they] were waiting on a manufacturer service representative to fix a device."

70%

CALLING FOR COOPERATION FROM OEMS

engadget

Public interest group tells medical equipment makers to release their repair manuals

The PIRG says that open-sourcing repair documentation could be the difference between life and death.

Daniel Cooper, @danielwcooper
March 19, 2020

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engadget

Ventilator companies are opening up critical repair documents to the public

After being called out by the US Public Interest Research Group.

Christine Fisher, @cfisherwrites
April 23, 2020

The PIRG says it delivered 43,000 petitions calling for the release of ventilator repair information, and iFixit partnered with the PIRG to catalog ventilator service manuals. While manufactures didn't say whether they modified their policies in response to those petitions, they have made changes. GE is sharing technical reference manuals and service applications without requiring the usual four-day in-person training. Fisher & Paykal are responding to PDF requests, and other companies, like Medtronic, are sharing similar documents in new web portals.

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WHAT PROGRESS HAVE WE MADE?

- Won a copyright exemption under section 1201 of the DMCA for medical device repair.
- Manufacturers eased repair restrictions during COVID … and the sky didn’t fall.
- Introduced legislation in Congress, roughly a dozen other states.
- Protected device servicing as part of the “remanufacturing” debate.

How can you help?

- Get involved. Sign our letter:
- Reach out to us:
  - Nproctor@pirg.org

Current efforts in US for medical devices

- History of Medical Device RtR in the US
- Current Status
- Rebuttal to Claims
- Discussion & Conclusions

Binseng Wang

History of Right to Repair in USA[1]

YEAR	GENERAL RtR	MEDICAL DEVICES
<1996		Most OEMs would collaborate with ISOs to support HDOs in equipment service. Almost anyone could service medical devices
1996		FDA issued the Quality System regulation (21 CFR 820) without requirements on servicers despite OEM objections
1997		FDA issued a Request for Comments on medical device servicing but took no action
2012	Massachusetts passed Automotive Right to Repair Act initiated by the Aftermarket Automobile Industry Association (AAIA)	National Fire Protection Agency (NFPA) revised its NFPA 99 - Health Care Facilities Code to include requirement for manufacturers to provide service manuals
>2012	Other states considered or passed similar automotive RtR legislations	

History of Right to Repair in USA_2

YEAR	GENERAL RtR	MEDICAL DEVICES
2013	Digital Right to Repair Coalition was created, later renamed The Repair Association	
2014	AAIA and other auto repair organizations signed a Memorandum of Understanding (MOU) with the Alliance of Automobile Manufacturers and Association of Global Automakers: manufacturers will provide to owners and independent repair facilities: (1) diagnostic & repair info, (2) repair technical updates and (3) diagnostic repair tools => diagnostic car code reader	
2014	Unlocking Consumer Choice and Wireless Competition Act allowed cellphone owners to unlock it and transfer to another carrier.	
2014	First Digital Right to Repair Bill filed in SD	

History of Right to Repair in USA[3]

YEAR	GENERAL RtR	MEDICAL DEVICES
2016		FDA issued another Request for Comments on medical device servicing but again took no action
2015	Bills filed in New York, Massachusetts and Minnesota	
2016	Bills filed in Nebraska, Iowa, Kansas, Tennessee and Missouri	
2017	Bills filed in Hawaii, New Jersey, New Hampshire	HR 2118 - Medical Device Servicing Safety and Accountability Act introduced in the Congress but did not pass.
2017	US Supreme Court ruled "a patentee's authority to limit licensees does not mean that patentees can use licenses to impose post-sale restrictions on purchasers that are enforceable through the patent laws." (Case: ink-jet cartridges remanufacturing)	HR 2430 (MDUFA IV) section 710 required FDA to investigate and report on the safety of medical device servicing

History of Right to Repair in USA[4]

YEAR	GENERAL RtR	MEDICAL DEVICES
2018	Bills filed in Vermont, Illinois, Washington, Virginia and California	FDA issued the Section 710 (FDARA) report after investigating the safety of medical device servicing
2018	US Copyright Office/LoC issued rule exempting provision of the Digital Millennium Copyright Act (DMCA) that prohibits circumvention of technological measures that control access to copyrighted works… exemption for computer programs that control motorized land vehicles, including farm equipment, for purposes of diagnosis, repair, and modification of the vehicle.	**Alliance for Quality Medical Device Servicing** formed by TriMedx, Sodexo, Crothall, Agiliti, ABM (since acquired by Crothall) and The InterMed Group.
2018		FDA Issued a White Paper on servicing versus remanufacturing for public comment and convened a workshop in Dec to discuss it.
2018		FDA issued a Discussion Paper on cybersecurity

History of Right to Repair in USA_5

YEAR	GENERAL RtR	MEDICAL DEVICES
2019	Bills filed in West Virginia, Oregon, Indiana, North Dakota and Georgia (total 20 states)	HR 7956 - Critical Medical Infrastructure Right-to-Repair Act of 2020 introduced but was not voted
2021		FDA issued a Draft Guidance on Remanufacturing of Medical Devices and invited comments
2021	US Copyright Office (Library of the Congress) issued the final rule "Exemption to Prohibition on Circumvention of Copyright Protection Systems for Access Control Technologies"	
2022	NY State passed the Fair Repair Act for consumer electronics	California's RtR bill for medical devices was approved unanimously by the Health Committee, it "disappeared" in the Finance Committee
2022		HR 7253 - Clarifying Remanufacturing to Protect Patient Safety Act introduced by some OEMs but was not incorporated into MDUFA V

History of Right to Repair in USA[6]

YEAR	GENERAL RtR	MEDICAL DEVICES
2022-24	Several states approved RtR for personal electronics, appliances, and farm equipment	Colorado passed the Consumer Right To Repair bill but only for powered wheelchairs (HB22-1031)
2023	The White House convened a discussion the RtR on Oct 24, 2023, with participation of administration officials and state legislative leaders. Participants included: White House staff, FTC chair, EPA, Apple, state legislators from CA, CO, MN, etc.	
2024	US PIRG and iFixit petitioned the FTC to initiate a rulemaking "to protect consumers' right to repair products they have purchased." Comments were due Feb 02, 2024, and 1685 comments were received from individuals and companies. Most company comments were not posted online due to "sensitive information."	Many device servicers, including the Alliance, submitted comments to the FTC.

History of Right to Repair in USA[6]

YEAR	GENERAL RtR	MEDICAL DEVICES
2024		A Medical Device RtR bill was drafted by Alliance (TriMedx, Sodexo, Crothall, Agiliti, Elite, and Avante) and presented to several congressional representatives and their staff. While several House Representatives showed interest in supporting it, none were willing to formally sponsoring it
2024		FDA issued on 5/9/2024 the final guidance on "Remanufacturing of Medical Devices" to clarify distinction between servicing and remanufacturing despite of comments on its impractical applicability
2024		California passed on 9/28/2024 a RtR bill for power wheelchairs (SB 1384) that went into effect in 01/2025
2024		A RtR provision within the National Defense Authorization Act was **removed** after AdvaMed met with House and Senate committees on Armed Services

2024 AdvaMed Annual Report

(extracted from page 16) [my emphasis in color/color]

RIGHT TO REPAIR … PREVENTED

- *AdvaMed successfully prevented the inclusion of a "right to repair" provision in the final **National Defense Authorization Act** (NDAA), safeguarding the integrity of medical devices.*
- *To achieve this outcome, the Federal Affairs team met with key staff from the House Armed Services Committee (HASC) and the Senate Armed Services Committee (SASC) to emphasize the risks of unauthorized repairs to device safety and thus to patients. This advocacy effort was particularly impactful, as few others were actively advocating against the provision.*
- *Ensuring that only authorized repairs are permitted protects patient safety from risks associated with improperly maintained or modified medical devices. This is especially crucial for life-supporting and high-risk technologies that require precise maintenance to function safely and effectively*

Current RtR Efforts

- Federal level
  - Alliance continues to reach out to house representatives and senators to seek sponsor(s) for a medical device RtR bill
  - Alliance also trying to re-establish contact with FDA and other federal agencies
  - Alliance seeking partnerships with other healthcare industry groups
- State level
  - Vermont is considering a RtR bill that includes medical devices
  - Almost every state has a RtR bill covering other consumer and professional products (but not medical devices)

REBUTTALS TO CLAIMS$_1$

Some OEMs and their trade associations have made sweeping claims against 3rd-party servicers. Here are some examples of such claims and rebuttals prepared by the Alliance for Quality Medical Device Servicing (my emphasis in **color**).

CLAIM #1 - SAFETY: services provided by third parties are unsafe for patients.

a) In its 2018 report to Congress, FDA stated "… the objective evidence indicates that many OEMs and third party entities provide **high quality, safe, and effective** servicing of medical devices." Further, The FDA Report highlighted an ECRI Institute analysis indicating a statistically insignificant number of issues related to service and repair of medical devices.

b) Onsite staff provided by third parties can respond swiftly, while waiting for offsite service technicians may impede timely patient care, as clearly evidenced during the COVID-19 pandemic.

REBUTTALS TO CLAIMS$_2$

CLAIM #2 - REGULATORY OVERSIGHT: 3rd parties are not regulated by the FDA and, thus, pose risks to public health.

a) Third parties are contracted by hospitals, which are licensed by respective states and required to comply with the Conditions of Participation (CoPs) enforced by CMS through state agencies and accrediting organizations. Those requirements are typically transferred by the hospitals to the third parties, so effectively the third parties are indirectly regulated by FDA's sister agency, CMS.

b) The 2018 FDA Report emphasized that "…**the currently available objective evidence is not sufficient … that would justify imposing additional/different burdensome regulatory requirements at this time.**"

c) Several OEMs also provide services on equipment manufactured by other OEMs (aka multivendor service – MVS) thereby blurring the differentiation between OEMs and third party service providers.

REBUTTALS TO CLAIMS$_3$

CLAIM #3 - INTELLECTUAL PROPERTY (IP): providing service materials (technical specifications, service manuals, diagnostic and calibration software access, proprietary parts and test tools, etc.) would require OEMs to reveal trade secrets and IP.

a) We are not aware of any third party service providers interested in securing IP to produce competitive products. Servicers are focused on safely and effectively servicing devices, not manufacturing.

CLAIM #4 - CYBERSECURITY: providing access to equipment diagnostic and calibration software would allow servicers to introduce malware and, thus, pose cyber risks.

a) Most cyber-attacks are perpetrated by hackers or persons seeking monetary gains. Servicers have nothing to gain from ransomware attacks. Furthermore, third party servicers are required by hospitals to monitor and address promptly cyber vulnerabilities and attacks being onsite and in close contact with the equipment.

REBUTTALS TO CLAIMS$_4$

CLAIM #5 - REMANUFACTURING: servicers often exceed the limits of servicing and ended up remanufacturing devices, thus violating FDA regulations.

a) The 2018 FDA Report found a small number of cases involving complaints related to device remanufacturing and FDA has committed to issue a guidance to clarify the distinction between servicing and remanufacturing, with input from many stakeholders including the Alliance. It is possible that some of those remanufacturing activities were committed due to the lack of access to device specifications and service materials.

b) Since **1993**, OEMs are required by the European Union to release "… **all the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed** to ensure that the devices operate properly and safely at all times." In contrast, such requirements only exist in the US for medical lasers (21 CFR 1040.10) and for assembly, installation, adjustment and testing of diagnostic X-ray systems (21 CFR 1020.30).

DISCUSSION & CONCLUSIONS

- Nothing to do with patient safety or wellbeing.
  IT'S ALL ABOUT MONEY!
- So this will be a long and arduous war, not a battle
- Best (or perhaps the only) hope: imitate the automobile repair groups, i.e., get enough state bills passed and some bills introduced in the Congress to convince OEMs to come to the table for a Memorandum of Understanding (MOU) on access to service material (manuals, parts, softkey, remote diagnostics, etc.)
- In essence, paraphrasing former American congressman John Lewis:
  Get in good trouble, necessary trouble, and help everyone around the world to get the Right to Repair!

DISCUSSION & CONCLUSIONS (cont.)

- Right to Repair (RtR) for medical devices is not for saving money but for improving patient safety and care quality and timeliness
- RtR is also essential for reducing toxic wastes and climate change
- RtR has been mandated in other countries (EU, UK, China, etc.) for years with little, if any, negative impact on OEM intellectual property, revenue or profit margin
- RtR is not a "free for all" but responsible maintenance and management of healthcare technology
- Everyone in the healthcare industry must work together to achieve a safe, balanced, equitable solution for all, **particularly the patients** (ALL OF US!).

Current efforts in Canada for medical devices

Kevin Taylor

Canadian Right to Repair Overview

- General Right to Repair Legislation Changes in 2024
  - Bill C-244 Received Royal Assent
    - An act to amend the copyright act to allow TPMs to be bypassed for the purposes of service.
  - Bill C-294 Received Royal Assent
    - An act to amend the copyright act to allow TPMs to be bypassed for the purposes of inter-operability.
  - Amendments to the Competition Act – Enhanced Refusal to Deal Provisions
    - Ensure that the provision can apply to refusals to provide diagnostic or repair information or related products.
      - This change will help independent firms that provide repair services get access to the information and parts they need to repair products.

The Canadian Medical and Biological Engineering Society

CMBES/SCGB

- CanRepair (https://www.canrepair.ca/) – a grass roots general technology Right to Repair organization formed and making a difference.

The Canadian Medical and Biological Engineering Society
CMBES/SCGB

CMBES Right to Repair Work

- Provided Letter of Support for Bill C-244 both to Parliament and Senate.
  - Met with Member of Parliament who sponsored the bill
- Met with a major Canadian Group Purchasing Organization's leadership
  - Assisted them in drafting and implementing procurement clauses
    - Allow members to identify vendors who are and aren't compliant with Right to Repair
- Met with ECRI on their Product Comparison System
  - Asking them to enhance Product Comparison System questions around provision of key service elements
- Added Right to Repair Updates to CMBES eBulletins
- Recommended its members submit voluntary Health Canada sentinel events
  - Where manufacturers blocking the ability to repair a device caused or may have caused a delay in patient care and consequently impacted patient safety

The Canadian Medical and Biological Engineering Society

CMBES/SCGB

CMBES Position Statement

Health Technology Right to Repair Position Statement

Canadian Medical and Biological Engineering Society (CMBES) is committed to supporting the Right to Repair movement through awareness, education, and advocacy.

In order to provide safe and effective medical equipment management, biomedical engineering professionals within Canada's healthcare system require access to service training, documentation, tools, software, and parts.

CMBES is committed to encouraging our members to work together with manufacturers to ensure the functionality and availability of Canada's medical technology to support safe and timely healthcare delivery.

https://www.cmbes.ca/clinical-biomedical-engineering/publications-resources/position-statements/right-to-repair

Panel Discussion/Q&A

#1

How attendees can contribute to RtR?

From Nathan Proctor/PIRG: You may add your support to RtR by signing the Biomedical RtR support letter:

To enter your support, please go to https://tinyurl.com/BiomedR2R

Biomedical Right to Repair support letter

As biomedical professionals, we are committed to advancing the best practices in clinical engineering, and promoting the safe and effective application of science and technology in patient care.

In order to provide the most effective medical equipment management, skilled biomedical engineering professionals require access to the full range of materials created to conduct safe and effective repairs, including all service training, documentation, tools, software and parts.

Therefore, to ensure patient care and safety, we support the Right to Repair for health technology, through collaboration with manufacturers, as well as awareness, education, and advocacy.

Signed by the following organizations and biomedical engineering professionals:

#2

Will right to repair movement influence vendors to change their practices?

#3

What deliverables encompass the right to repair?

#4

Explain how right to repair does not infringe on intellectual property

Questions from attendees

Any question?

Please type your questions to the Zoom Q&A window

Thank You

Please complete the online evaluation form at
https://www.surveymonkey.com/r/session7_03-14-25