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VT H.160—Medical Equipment Right to Repair

Medical devices are not consumer products. They are FDA-regulated, safety-critical systems involved in patient care. The central question for H.160 is not whether repairs should happen—everyone agrees they should. The question is whether Vermont should mandate broad disclosure of highly technical service materials without establishing an equivalent, enforceable safety-and-accountability framework to ensure devices are returned to original equipment manufacturer (OEM) safety and performance specifications, cyber risks are controlled, and postmarket safety signals are captured.

Myth: "Medical devices are no different than other products under consideration for right to repair such as automobiles, cell phones, home appliances, etc."

Fact: Medical devices are FDA-regulated technologies involved in patient care, including diagnosis, treatment, and management of complex diseases. Repair of these technologies requires extensive training and compliance with strict quality, safety, and regulatory requirements. Improper repair of a medical device can lead to misdiagnosis, patient injury, or even death.

Myth: "H.160 is simply about letting hospitals maintain equipment and it creates no patient safety concerns."

Fact: Safe and effective servicing is not just about access to certain documents or materials—it requires implementing and following policies, practices, and procedures that consistently return the device to safe and effective operation.

Myth: "H.160 restores hospital choice when it comes to device servicing"

Fact: Hospitals already can choose among multiple service models (OEM, independent, hybrid, in-house).

Myth: "OEM and 3rd party servicers are exactly the same."

Fact: OEM servicers are required by the FDA to be appropriately trained and use only qualified parts and processes when repairing a device. 3rd party servicers are not required to meet the same qualifications or credentials.

Myth: "The FDA has found no evidence that hospital or third-party servicing is less safe than OEM servicing—so safety objections are unsupported."

Fact: FDA **did not** conclude there is "no safety issue." FDA concluded the **available objective evidence was insufficient**. Further, FDA identified the need to (1) promote quality management, (2) clarify servicing vs. remanufacturing, (3) strengthen cybersecurity practices, and (4) develop better evidence. That is a call for **more structure and better controls/data**, not for broad "right to repair" mandates.[i]

Myth: "Remanufacturing concerns are solved (FDA issued guidance in 2024), so it shouldn't be part of the H.160 discussion."

Fact: Servicing vs. remanufacturing is *exactly* why this is complex. Servicing entails the maintenance of a device that returns it to safe and effective condition for its intended use. Remanufacturing entails activities that significantly change the safety or performance specifications of a device. Activities can cross the line from servicing into remanufacturing if proper quality, safety, and regulatory controls are not in place. A disclosure mandate that increases uncontrolled distribution of sensitive materials can increase the likelihood of uncontrolled remanufacturing unless paired with strong, enforceable quality and accountability expectations.[ii]

Myth: "Hospitals are already regulated (by CMS/Joint Commission), so oversight is sufficient."

Fact: Healthcare facilities may have to meet certain accreditation requirements under CMS or the Joint Commission, these requirements are very different from FDA medical device regulations. CMS and Joint Commission do not require the same quality management system, training, verification/validation, complaint handling, reporting, or testing procedures as FDA, creating a significant gap when it comes to medical device servicing. Third-party servicers and hospital biomeds are not held to the same quality, safety, or regulatory requirements as OEM servicers.

Myth: "Insufficient access to proprietary materials creates medical device downtime issues"

Fact: Medical device "right to repair" policies are a solution in search of a problem. There is no evidence that care is being delayed because of insufficient access to certain materials.

Myth: "Repair does not affect intellectual property—repair materials never include trade secrets; and the EU has mandated release for years."

Fact: In the medical device context, the materials sought often go beyond what's needed to repair and can include proprietary schematics, service keys, cybersecurity-sensitive materials, and other confidential know-how. [iii]

Myth: "Cybersecurity concerns are overblown; repair technicians have nothing to gain from cyberattacks."

Fact: Cyber risk isn't about motives; it's about **attack surface and control of sensitive access mechanisms** (e.g., software access, service keys, diagnostics). Expanding access pathways and distributing sensitive materials outside controlled agreements can increase risk—even with well-intentioned actors—because credentials and tools can be lost, resold, copied, or misused. FDA itself flagged cybersecurity practices associated with servicing as an area needing strengthening.[iv]

Myth: "Credentialing ensures safety; therefore OEM restrictions are unnecessary."

Fact: Individual credentials are valuable, but patient safety requires system-level controls: validated procedures, qualified parts, calibrated test equipment, documented verification after repair, traceability, and consistent quality management practices. A person can be highly skilled and still be set up to fail if they lack the OEM specifications, validated tools/parts, or a structured QMS environment—or if state policy expands access without requiring those controls.

Myth: "All devices can be repaired if needed."

Fact: Certain devices are intended to be replaced if they break, not repaired. In some cases, devices such as continuous glucose monitors (CGMs) are not repaired. Instead, a new device is issued to the patient. Attempting to repair these devices may have unintended consequences, risking patient safety.

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[i] https://www.fda.gov/media/113431/download
[ii] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/remanufacturing-medical-devices
[iii] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31993L0042
[iv] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cybersecurity-medical-devices-quality-management-system-considerations-and-content-premarket