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February 26, 2018

The Honorable Senator Michael Sirotkin
Chair, Senate Committee on Economic Development,
Housing, and General Affairs
Vermont State House
115 State Street
Montpelier, VT 05633

The Honorable Senator Christopher A. Pearson
Sponsor S.180
Vermont State House
115 State Street
Montpelier, VT 05633

Dear Senators Sirotkin and Pearson:

I am a clinical engineer with over 40 years' experience advising healthcare providers on how to acquire, use, and support their medical technology in a quality, safe and effective manner. My career has included senior positions at large multi-hospital enterprises, independent service organizations, a research institute and as an independent consultant. I have also been active in promoting the medical technology quality, safety and effectiveness through various leadership roles in several professional associations and on standards committees.

I am writing **in support of the pending 'right-to-repair' legislation (S.180 *Fair Repair Act*)** and the **inclusion of medical equipment** in that bill. This legislation is vital to ensure that medical device owner/operators have a an reasonable range of quality and reasonable cost choices in their service options.
Healthcare technology managers want options that give them the ability to select the source of service offering the appropriate balance of safety, quality, timeliness and cost. Restricting 3rd party servicer access to service resources (e.g., instructions, training, specialized tools, parts, diagnostic software, passwords, etc.) greatly limits that technology manager's options. Restricting access to these service resources only serves to limit access to potential quality sources of service in operating in a competitive environment.

I have found the arguments made by manufacturers and their associations (e.g., AdvaMed, NEMA/MITA) against the inclusion of medical devices in 'right-to-repair' legislation to be largely faulty and misleading. Their most common arguments (and my response/counterargument) follow:

Manufacturer Argument #1

There is growing concern with threats to the safety of patients from repairs being done by servicers who do not have adequate training and/or are not using appropriate replacement parts.

Response: *The "concern" that has been raised comes almost exclusively from some manufacturers and their associations. For many years they have been lobbying CMS, FDA, Congress and state legislators to place new restrictions on 3rd party servicers (i.e., in-house service staff and independent service organizations). These restrictions (some recently adopted and some proposed) would limit the ability of 3rd parties to compete effectively with manufacturer servicers. Manufacturers who argue for these restrictions regularly produce the same photographs and stories claiming them to be evidence of widespread servicing problems with 3rd party servicers … but their evidence is anecdotal and neither the photographs nor the stories are accompanied with any details as to the true nature of who was responsible for the illustrated problem and whether there is evidence it represents any kind of a trend.*

There has only been one organization to analyze available data from problem reports taken from the FDA and other sources. ECRI Institute has conducted evidence-based research to determine the frequency of maintenance-related medical device failures occurring in the U.S. ECRI reported that a review of > 2.1M problems reports collected by FDA, ECRI and other sources over 10 years and found an incidence of maintenance-related failures of < 0.005% (including manufacturer, owner/operator and 3rd party repairs). While some manufacturers and their associations have attempted to challenge the ECRI study, no studies have been published, referenced, or presented (including any evidence-based information from manufacturers) to successfully challenge or contradict the ECRI analysis and conclusion that there is no evidence of a problem with servicing that requires a legislative remedy. That was also the 1998 finding by FDA (and by ECRI) when these issues were first raised. The current analysis

shows that the incidence of maintenance-related medical device failures is almost two orders of magnitude LESS than that found in 1998 (0.2% in 1998 versus 0.005% in 2016).

Every year over the past 10 years ECRI Institute has also published a list of the top 10 hazards associated with medical devices. In the past 10 years, no medical device servicing issue has ever made the list.

Manufacturer Argument #2

Inclusion of medical devices in the right-to-repair legislation with its requirement that manufacturers make available service materials (e.g., instructions, training, specialized tools, parts, diagnostic software, passwords, etc.) would open up medical device servicing to unqualified servicers.

Response: *It is faulty logic to say that requiring manufacturers to provide service material will lead to unqualified servicers. Many servicers employ staff who are (or have been trained by) alumni of manufacturers. Professional servicers need these materials to be fully effective. Manufacturers withholding access of service materials to owner/operators and those 3rd parties otherwise capability of providing these services only limits 3rd parties' ability to provide a fully effective service and gives the manufacturer a service advantage. Withholding access to these materials is also contrary to the following industry standards:*

- *ANSI/AAMI EQ56:2013, §7.1.1*
- *NFPA 99:2012, Section 10.5.3.1*
- *ANSI/AAMI ES60601-1:2015, Section 7.9.2.13*
- *TJC Accreditations Manual for Hospitals: 2018, EC.01.01.01 EP3*

Manufacturer Argument #3

The FDA regulates the repair of medical devices by manufacturers but does not yet regulate repairs by 3rd party servicers.

Response: *The FDA regulations do not actually regulate repairs. Rather the FDA requirements for manufacturers providing repairs and servicing (as per 21 CFR parts 803, 806 and 820) are intended to ensure manufacturers provide post-market support in the form of:*

- *instructions/procedures necessary to verify whether equipment meets specified requirements*
- *statistical and root cause analyses of service reports to determine whether there is evidence of a product or process quality issue that requires manufacturer follow-up (e.g., in the form of recalls, field modifications or additional user guidance) … and that the follow-up is effective*

None of these FDA requirements would be applicable to 3rd party servicers because these servicers are not in a position to

- *know when a device was involved in an adverse event*
- *produce manufacturer service instructions/procedures,*
- *do statistical and root cause analyses on a manufacturer's product line for the purpose providing the manufacturers post-market support.*

See attached graphic.

Manufacturer Argument #4

There is no regulation of the repair of medical devices by 3rd party servicers.

Response: *There are, in fact, regulations and standards requiring medical devices be serviced by qualified servicers. According to existing regulations and standards (CMS State Operations Manual §482.41(c)(2), states' dept of health, TJC, DNV and other accrediting agencies), medical equipment owner/operators can only utilize servicers and staff for whom they have verified their expertise and qualifications. See attached graphic.*

Manufacturer Argument #5

3rd party servicers are not required to report adverse events (medical device failures resulting in serious injury or patient deaths)

Response: *There is a very good reason not to require 3rd party servicers to report adverse events. That is because those 3rd party servicers are working as agents of medical device owner/operators and would normally have no occasion to become aware of which medical device failures did or did not result in an adverse event (i.e., lead to a serious injury or death). The existence of adverse events is generally only known to medical device owner/operators … information they are unlikely to share with their servicer. It is for this reason the FDA requires owner/operators to notify the manufacturer and/or FDA when such adverse events occur … and the manufacturer having been made aware by owner/operators must notify the FDA.*

Manufacturer Argument #6

Medical equipment is too dangerous (often a matter of *life-and-death*) to allow it to be serviced by unqualified third-party servicers

Response: *Two points. First, while some medical equipment is life-critical (as is some consumer equipment like automobiles, guns, home furnaces, smoke alarms, etc.), less than 5% of medical equipment is life-critical. Second, according to existing regulations and standards (i.e., CMS State Operations Manual §482.41(c)(2), states' dept of health, TJC, DNV and other accrediting agencies), medical equipment owner/operators must be able to demonstrate any servicer (manufacturer, in-house or independent service organization) has provided credible evidence of their expertise and qualifications.*

Manufacturer Argument #7

The FDA is scheduled to release a report to Congress in May 2018 on any plans the agency may have to further regulate medical device servicing by manufacturers and 3rd parties.

Response: *Last year manufacturers and their associations lobbied Congress to include an amendment in the FDA Reauthorization Act of 2017 that would require the agency to issue a report by May 2018 detailing the agency's authority to regulate medical device servicing by manufacturers and 3rd party entities and how the agency could improve such regulation. There is no official word available yet about the reports final contents but there is real doubt as whether the FDA will find it necessary to expand its regulations over 3rd party services.*

Manufacturer Argument #8

The FDA's role should not be weakened by state laws that would interfere with its science-based oversight of medical devices, including their maintenance and repair.

Response: *There is absolutely nothing in the proposed 'right-to-repair' legislation that would interfere with any existing FDA regulations or any reasonably conceivable future FDA regulation. There is nothing in the proposed 'right-to-repair' legislation that is intended to regulate service by anyone on any type of equipment … let alone interfere with other legislation that is intended to provide such regulation of servicers.*

I hope the above information may serve to bring some proper perspective to the arguments being made.

In summary, I believe including medical devices in the proposed 'right to repair' legislation is an important step to ensuring medical device owner/operators retain the ability to select the service option that represents the best balance of safety, quality, timeliness and cost.

Thank you for your consideration. If I can provide any further information, please do not hesitate to contact me directly.

Sincerely,

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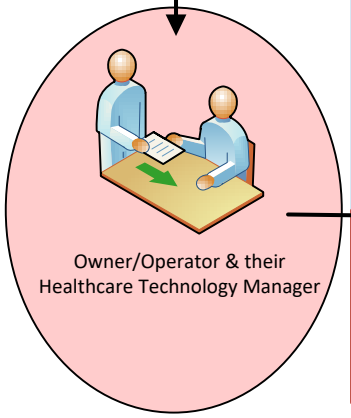
How Current Regulations/Standards Impact Medical Equipment Owner/Operators, Manufacturers and Servicers and the Purpose of those Regulations/Standards

Healthcare Technology Managers role (in-house staff or contracted): *Maintain inventories, service histories, and typically manage compliance, updates/recalls, service contracts, etc.*

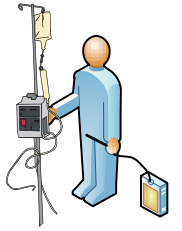


Owner/Operator & their Healthcare Technology Manager

If service is required, the owner/operator typically works with their healthcare technology manager to select the best option for medical equipment service based on safety, quality, availability and cost. They are required by CMS, department of health regulations and accreditation standards to select a qualified source of service and to verify those qualifications. Their options generally include the device manufacturer in-house service or independent service organization.

A Medical Equipment Servicer operates under direction of Owner/ Operator (in coordination with Healthcare Technology Manager)

Relevant Regulations/Standards:
CMS State Operations Manual §482.41(c)(2), States' Dept of Health, TJC, DNV and other accrediting agencies

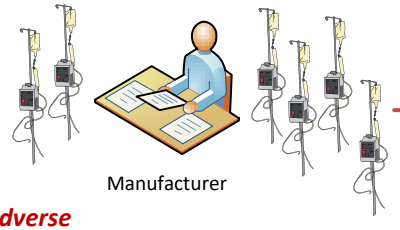


Medical Equipment Servicer
(may be Manufacturer, In-house Staff or Independent Service Organization)

If an adverse event occurs involving death of a patient (or if subsequent occurrences of event could result in patient death), the owner/operator is required by regulation to report to the FDA

If an adverse event occurs involving serious injury to patient, the owner/operator is required by regulation to report to the manufacturer

Relevant Regulations:
21 CFR Parts 803, 806 and 820



Manufacturer

Recalls, field modifications, additional user guidance provided by manufacturer to owners in order to address problems identified by owner/operator and/or FDA reports

Manufacturers must analyze reports of patient deaths or injuries to determine what manufacturing changes, updates (recalls or field modifications) or instruction changes may be necessary. Implementation plan for all corrections must be reported to FDA

FDA

The FDA informs Manufacturers of owner/operator reported patient deaths (or events that could cause death if reoccuring) and requires the manufacturer analyze and report back on any corrective measures taken

NOTE: As can be seen from this illustration, ***medical equipment service*** and the ***reporting of adverse events*** are both currently regulated but by different authorities. The FDA regulates *manufacturing practices*, *post-market support* (e.g., making design changes, planning field corrections, conducting recalls, or providing instruction updates) and *adverse event reporting*. CMS and state Departments of Health (DoH) regulate quality of *maintenance services* and accrediting agencies (TJC, DNV, etc.) ensure compliance. The FDA regulations and the CMS/DoH regulations serve different purposes. Applying FDA-like regulations to Servicers would provide no additional patient safety benefit because Servicers are not in the loop to know when a device has been involved in an adverse event nor are they in business of making design changes, planning field corrections, conducting recalls, or providing updated user guidance.

2/22/2018