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New Senate Right to Repair bill to reduce barriers to fixing medical equipment including ventilators

Thursday, August 6, 2020

WASHINGTON -- Sen. Ron Wyden (OR) introduced the Critical Medical Infrastructure Right-to-Repair Act in an online press conference with U.S. PIRG on Thursday. The bill would remove manufacturer-imposed barriers to fixing medical equipment during the COVID-19 pandemic, providing much-needed help to biomedical repair technicians (also known as biomeds).

" There is no excuse for leaving hospitals and patients stranded without necessary equipment during the most widespread pandemic to hit the U.S. in 100 years," Sen. Wyden said. "It is just common sense to say that qualified technicians should be allowed to make emergency repairs or do preventative maintenance -- without having their hands tied by overly restrictive contracts and copyright laws – at least until this crisis is over."

When a ventilator or dialysis machine goes down, coronavirus patients don't have much time to wait. But some manufacturers of medical devices refuse to provide hospital biomeds with what they need to fix these machines. That means on-site biomeds who could make the repair in minutes to hours have to wait hours to weeks for an "authorized" technician to travel to the hospital.

"I've talked to more than a hundred biomeds since the start of the crisis. All they want is to be able to fix broken equipment and protect the patients in their hospitals. By giving these frontline workers access to service materials, Sen. Wyden's bill helps them get their job done," said U.S. PIRG Right to Repair Advocate Kevin O'Reilly.

After pressure from U.S. PIRG and other advocates, some medical device manufacturers have opened up access to repair materials such as manuals and training modules. But problems persist: A recent U.S. PIRG Education Fund report found that 48.8 percent of biomeds surveyed had been denied access to "critical repair information, parts or service keys for medical equipment," since the coronavirus first swept the country in March.

"We continue to hear during the pandemic that manufacturers of imaging equipment have declined to cooperate fully in providing service access information. Regional and rural hospitals depend upon independent servicers when their equipment is in need of repair. We are hoping this legislation will cause greater cooperation," said said Robert Kerwin, General Counsel, the International Association of Medical Equipment Remarketers and Servicers.

"We believe that every organization that purchases or services medical equipment should have the right to get trained and be able to procure parts to repair the equipment they own," said Ilir Kullolli, president of the American College of Clinical Engineering. "This will make health care delivery better, faster, and safer – especially during this pandemic."

"During the pandemic, I have run into problems getting what I need to fix ventilators in my hospital, leading to delays of two to three weeks. That cannot be an acceptable outcome," said Leticia Reynolds, president of the Colorado Association of Biomedical Equipment Technicians. "This bill would make sure that this does not happen to me or any other biomed for the remainder of the emergency."

Right to Repair campaigns around the country, such as Penn PIRG's efforts in Pennsylvania, are advancing reforms that improve access to parts and service information for medical equipment. This bill's introduction in Congress represents growing national support for reforms that address unnecessary repair barriers across multiple industries.

"There is no reason we should tolerate manufacturers putting their own proprietary concerns over patient safety -- especially during the pandemic. Passing this bill is an easy, common-sense way for the Senate to help hospitals in their time of need, and a terrific first step toward a long-term solution to manufacturer-imposed barriers to repair," added O'Reilly.

The bill has attracted support from a wide range of medical and policy groups, including:

- American College of Clinical Engineering (ACCE)
- National Rural Health Association (NRHA)
- National Association of Rural Health Clinics (NARHC)
- International Association of Medical Equipment Remarketers and Servicers (IAMERS)
- Alliance for Quality Medical Device Servicing (AQMDS)
- ISS Solutions Healthcare Technology Management
- The Repair Association
- Electronic Frontier Foundation (EFF)
- Color of Change
- Public Knowledge
- R Street Institute
- Lincoln Network
- Niskanen Center
- Colorado Association of Biomedical Equipment Technicians (CABMET)
- Maine General Medical Center

DCG - Not so sure about this, manufacturers should

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keep legal help on speed dial. If there is a problem they will be held responsible not the entity that repaired the device. Keep good records of all repair work.

Registration and Listing of Medical Devices during the COVID-19 Pandemic

This page provides information for medical device establishments, including owners and operators of places of business (also called facilities for purposes of this page) that are involved in the production (e.g., manufacturing, assembling, or processing) and distribution of medical devices that are authorized by Emergency Use Authorizations (EUA) or that are the subject of one of FDA's COVID-19 guidance documents.

In general, most facilities that are required to register with FDA are also required to list the devices they manufacture, prepare, propagate, compound, assemble, or process and the activities they perform on such devices. If a device requires premarket approval or notification before being marketed in the U.S., then the owner/operator should also provide the FDA premarket submission number (510(k), PMA, PDP, HDE, De Novo) when they register with FDA. This page answers frequently asked questions about procedures and requirements concerning the registration of facilities and the listing of devices during the COVID-19 pandemic.

Registration and Listing during the COVID-19 Pandemic

Q: Does FDA have any policies or recommendations concerning registration and listing for facilities of medical devices intended for use during the COVID-19 pandemic?

A: During the COVID-19 pandemic, the FDA has taken several steps to help ensure that critical medical devices are available for use. For example, the FDA has issued device-specific guidance documents for certain ventilators and personal protective equipment (PPE) devices that describe the Agency's policies concerning the enforcement of registration and listing requirements for facilities that manufacture, prepare, propagate, compound, assemble, or process these devices during the COVID-19 pandemic. To find the guidance document for a specific device, see COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders.

The FDA has also issued Emergency Use Authorizations (EUAs) for critical devices such as certain infusion pumps, remote monitoring devices, PPE devices, such as N95 respirators, and in vitro diagnostics. To view EUAs for specific devices, see Coronavirus Disease 2019 (COVID-19) Emergency Use Authorizations for Medical Devices. If your device has an EUA, you should review the EUA letter of authorization to determine whether the FDA requires you to register and list.

A facility that registers is required to pay the annual registration user fee prior to registering the facility or listing a device. The process for registering and listing is described at Device Registration and Listing.

Q: How does a facility register and list a device?

A: For step-by-step instructions on how to register and list a device, please see How To Register and List. For tutorials on FDA Unified Registration and Listing System (FURLS) device registration and listing, please see:

The facility is required to pay the annual registration user fee using the Device Facility User Fee (DFUF) website before it can register and list a device. After paying the fee and obtaining the Payment Identification Number (PIN) and Payment Confirmation Number (PCN), the facility will need to complete registration and listing using the FURLS Device Registration and Listing Module (DRLM).

For the annual user fee amount, please see Device Registration and Listing.

Q: Are any waivers of the annual registration user fee available during the COVID-19 pandemic?

A: No. There are no waivers for the annual registration user fee for importers, small business, or any other establishments.

For additional information, see Medical Device User Fees.

Q: What happens if I list a device with a product code that differs from the device description?

A: It is incorrect to list a device with a product code that differs from the device description. If a device has been listed incorrectly and the appropriate product code is known, please deactivate your listing for the incorrect product code and create a new listing for the correct product code.

If you do not know the correct product code, please search the Product Classification Database to determine the correct product code for your device. If you need assistance with determining the appropriate product code, please email the Division of Industry and Consumer Education (DICE) at dice@fda.hhs.gov for assistance.

Confirming Registration and Listing Information

Q: How do I obtain the FDA-assigned number that confirms my facility is registered with the FDA? Where do I find this information?

A: Receiving an assigned owner/operator number, registration number, or FDA Establishment Identifier (FEI) number verifies that your facility is registered.

This information is available on the Establishment Registration & Device Listing database after registration and listing are complete. To view or obtain the assigned numbers, type your facility's name in the Establishment or Trade Name field of the database. If a registration number has been assigned, it will be visible in the Registration or FEI Number field. If a registration number has not yet been assigned, a facility-specific page will open instead. Selecting the facility name hyperlink on this page will open a new page displaying the owner/operator contact information and registration number.

If it has been less than 7 days since you have registered and listed your device, the official correspondent or owner/operator identified on the registration will need to use their Account ID and Password to log into the Online Account Administration site to locate the owner/operator and device listing information. The official correspondent or owner/operator should log in and select the DLRM option to access the DRLM Main Menu, where there is an option to select "View Your Registration and Listing Information." Additional information is available by selecting "View Your Registered Facilities" or "View Your Device Listings."

Q: How long does it take for a facility to receive its registration number once the registration process is complete?

A: It may take up to 90 calendar days for the FDA to assign a registration number to a facility. During this time, a facility can use its owner/operator number and device listing number (if applicable) to import its medical devices into the United States until

the FDA assigns a registration number. After the FDA assigns a registration number, the FDA will send a confirmation email to the official correspondent informing them that a registration number has been assigned to the facility.
Q: Why is my facility not in the registration and listing database?
A: If a facility does not appear in the publicly available registration and listing database, the facility's registration may be inactive or may have only recently been registered. The public registration and listing database is updated weekly.
Q: How does a purchaser verify registration and listing information?
A: If a facility has registered and listed, purchasers may verify the registration and listing status by entering the facility name in the search criteria using the Establishment Registration & Device Listing database. An assigned registration, FEI, or owner/operator number verifies that the facility is registered with the FDA. However, as explained in these FAQs, registration alone does not indicate that FDA has reviewed that facility's device(s). Registration and listing may not be required for some facilities of authorized devices so purchasers may also verify whether specific medical devices have been authorized for use during the COVID-19 emergency by referencing Coronavirus Disease 2019 (COVID-19) Emergency Use Authorizations for Medical Devices.
Q: A facility is claiming to be "FDA Certified" by providing a third-party registration certificate. Does this mean the facility and the devices are certified by the FDA?
A: No. The FDA does not issue any type of device registration certificates to medical device facilities. When a facility registers and lists its devices, the resulting entry in FDA's registration and listing database does not denote approval, clearance, or authorization of that facility or its medical devices.
Purchasers may verify registration status of a facility and the listing status for that facility's medical devices by searching the Establishment Registration & Device Listing database, using the facility's establishment name as the search criterion. Also, purchasers may verify the regulatory status of medical devices, unless the devices are exempt from premarket review, by searching the Premarket Notifications (510(k)s), De Novo, or Premarket Approvals (PMA) databases, using the device trade name as the search criterion.
Q: Does the FDA issue a license to import medical devices?
A: No. The FDA does not issue a license to import medical devices into the United States. The FDA requires importers that meet the definition of an initial importer found in 21 CFR Part 807.3(g) to register with the FDA. When a facility registers as an initial importer, it is required to pay the annual registration user fee using the Device Facility User Fee (DFUF) website. After paying the fee and obtaining the PIN and PCN, the facility can proceed to register using the FURLS and DRLM.
For step-by-step instructions on how to register and list your devices, see Device Registration and Listing page. For help with paying the annual registration user fee, please contact the User Fee Helpdesk at userfees@fda.gov. For additional assistance with completing initial registration, email the CDRH Registration and Listing Helpdesk at reglist@cdrh.fda.gov.
Registration and Listing of Certain Medical Devices for Use During the Emergency
Q: I am an individual, health care organization, or state or municipal government in the United States who wishes to import masks or Personal Protective Equipment (PPE) such as gowns, respirators, and medical gloves into the United States, for my personal use or use in facilities under my control. Do I need to register and list?
A: If the individual, organization or other entity does not own or operate the facility that manufactures masks or PPE, registration and listing is generally not required.
However, if an individual, organization or other entity is importing and selling the masks or PPE, they are likely considered an initial importer and are required to register and list.
Additionally, an entity may be required to register and list as set forth in the device's Emergency Use Authorization (EUA). For an explanation of FDA's policies concerning the enforcement of the registration and listing requirements during the COVID-19 pandemic for some devices, please review FDA's COVID-19 guidance documents, available here: COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders. More information about both of these scenarios are below.
Devices authorized by FDA for emergency use during the COVID-19 emergency:
When imported, these devices should be declared as FDA-regulated with modified entry requirements as allowed by the EUA authorizing your device for emergency use. You must register and list if required by your device's EUA letter of authorization.
FDA's COVID-19 Guidance
These guidance documents describe circumstances during which the FDA does not intend to object to certain device modifications, or the distribution and use of some types of devices, without compliance with certain regulatory requirements as explained in each specific policy. For some of these policies, these regulatory requirements include registration and listing. Please see the guidance that applies to your device, if one has been issued for that device type.
For step-by-step instructions on how to pay the annual registration user fee and register a facility for the first time (initial registration), see Tutorials on the Device Registration and Listing page.

FDA Videos that may be of interest

Go to this link: https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/mdufa-iv-and-beyond-video-reports?utm_medium=email&utm_source=govdelivery

Note: This edition of the Oracle was complied before the election. Does that make any difference, unknown.

Have a good November, in the US a good Thanksgiving.

We in the US are back to 'real' time with our clocks. Good.