

[Normal Priority] - H0612 : [COVID-19] Use of Unapproved Devices or New Applications for Existing Medical Devices to Address COVID-19 Shortages without an EUA May Jeopardize Patient or Staff Safety [ECRI Exclusive Hazard Report]
Medical Device Hazard Report

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Geographic Regions: U.S.

Suggested Distribution: Anesthesia, Clinical/Biomedical Engineering, Critical Care, Emergency/Outpatient Services, Infection Control, Nursing, OR/Surgery, Pulmonology/Respiratory Therapy, Risk Management/Continuous Quality Improvement, Internal Medicine, Staff Education

Problem:

1. The COVID-19 pandemic has created widespread shortages of key medical equipment and supplies.
2. Healthcare facilities have had to be resourceful and may seek novel ways to address these shortages. Some of these solutions involve:
 1. Off-label use of existing devices
 2. Expansion of a device's indications for use
 3. Use of new devices that have not entered the market after formal FDA pre-market review
3. Devices used in this manner, without proper oversight, can lead to patient or healthcare provider harm and may expose the organization to liability risk.

ECRI Recommendations:

1. For solutions that involve either the off-label use of a device or a new device that has not been through formal FDA review, healthcare facilities should:
 1. Check to see whether FDA has granted an Emergency Use Authorization (EUA) for the application. If an EUA was granted, request access from the manufacturer to the user guidance that FDA requires them to post, which should include:
 1. Specific conditions for use
 2. A technology fact sheet
 3. Instructions for how the device is to be used for the application
 2. If the manufacturer does not have an EUA, ask if they applied for one or sought pre-market clearance (e.g., 510(k)).
2. If the EUA is still pending, be aware that you have no assurance that the manufacturer will receive it.
 1. Using the device without the EUA could expose your facility to legal liability.
3. If the manufacturer does not have an EUA and is not planning to pursue one, consider the following before your facility uses the device:
 1. Is there any evidence (e.g., published studies) supporting effective use of the device for the intended application?
 2. Is the manufacturer a company with which your organization has an established relationship and/or is the company well recognized in the medical equipment industry? If the answer to these questions is yes, your facility will likely have more insight into the reputability of the company.
 3. Determine whether the new device or application might introduce new usability or safety concerns, and document what those may be.
 1. The following examples represent some concerns that applied to recent EUAs:
 1. An application involving the use of a sterilizer to decontaminate a single-use device for reuse – Could the process introduce toxic residues or degrade the performance of the device, making it unsafe?
 2. An existing device normally used by staff with a particular specialty is proposed to be used by staff with a different skill set – Could their inexperience with the device lead to patient harm?
 3. A new proposed application calls for the use of a device that is normally intended for home use to be used in a healthcare ICU – Will the device's limited features, unfamiliar labeling, or low alarm volume create safety concerns in an intensive care environment?
 4. If the documented considerations cannot be addressed, it may not be prudent to go forward with the new application.
 5. Assuming that the concerns can be addressed, we recommend that you document how the risks were mitigated.
 1. Share this documentation with your facility's legal counsel and risk management departments to ensure that they agree.
 2. For additional insight on off-label use, see ECRI's guidance article, [Off-Label Use of Medical Products](#) .

Background:

1. Many healthcare facilities are experiencing dire shortages of medical devices and supplies along with a surge of COVID-19 patients, causing the facilities to look for creative solutions.
2. Medical equipment and supply manufacturers are aware of the situation, and may try to address the shortage problems by repurposing

some of their products to help extend or replace the use of affected products that are conventionally used.

1. Under normal circumstances, this would require FDA pre-market review, a process intended to thoroughly investigate questions regarding a product's safety and effectiveness.
 2. As the short supply situation has become a national health crisis, FDA is invoking its use of EUA to help expedite solutions.
 3. FDA grants EUAs after reviewing manufacturer-supplied data that addresses concerns about the safety, usability, and efficacy in the use of the product for a narrow and well-defined application.
 4. Once the crisis subsides, FDA will revoke the EUA and terminate authorization of all applications based on the EUA.
 1. The financial implications of this should be carefully considered, especially when purchasing capital devices under an EUA.
 5. Some manufacturers may try to shortcut or avoid the EUA process altogether, and either introduce new products or expand on the use of existing products without FDA authorization.
3. An EUA is not a guarantee of safety; however, it helps to ensure that critical questions about safety are addressed before these novel solutions are made available.
1. This may provide some facility liability protection compared to independent off-label use decisions, but this protection will vary by jurisdiction and should be discussed with the organization's legal counsel.
4. The EUA will also help to ensure that when adverse events occur unexpectedly, there is a process in place to track them and regulatory oversight.
5. Without the EUA, healthcare facilities are likely assuming full responsibility for assuring that the use of a novel device or application is safe and effective.

References & Source Documents:

1. [FAQs on Emergency Use Authorizations \(EUAs\) for Medical Devices During the COVID-19 Pandemic](#)
2. [Emergency Use Authorization of Medical Products and Related Authorities](#)

Comments:

- This alert is a living document and may be updated when ECRI receives additional information.

Source(s):

- 2020 May 15. ECRI researched report