Compliance Flash

Topic: Single Use Devices – May 2022

What is a Single-Use Device?

According to the Federal Food, Drug, and Cosmetic Act, a single-use device, also referred to as a disposable device, is intended for use on one patient during a single procedure. It is not intended to be reprocessed (cleaned, disinfected/sterilized) and used on another patient.

What is the cost of non-compliance?

- Dr. Donald Woo Lee sentenced in $12 Million Medicare Fraud and Device Adulteration Scheme. In addition to other allegations, Dr. Lee re-packaged used and contaminated catheters for re-use on patients. These catheters had been cleared by the FDA for marketing as single-use only. The re-use of these devices put patients at risk of infection and other bodily injury. Dr. Lee was sentenced to 93 months in prison, three years supervised release, and ordered to pay more than $4.5 million in restitution to Medicare.

- DOJ Files Complaint Against Medical Device Manufacture and its Owner for Training Providers to Improperly Reuse Disposable Items. It has been alleged that The Prometheus Group caused health care providers to bill Medicare for services in which the providers improperly re-used single-user rectal sensors and single-use catheters on multiple patients, which may put patients at risks of serious bacterial, fungal and viral infections. The FDA cleared the device as a single-user device and the catheter as a single-use device.

Reprocessing of Reusable Medial Devices

What is a Reusable Device?

Reusable medical devices are devices that health care providers can reprocess and reuse on multiple patients.

What are the three categories of Reusable Devices?

- Critical Devices come into contact with blood or normally sterile tissue.
- Semi-critical Devices come into contact with mucous membranes.
- Non-critical Devices come into contact with unbroken skin.

Critical and Semi-Critical Devices must be designed and labeled for multiple uses, and they need to be reprocessed by thorough cleaning and high-level disinfection or sterilization between patients. Reprocessing instructions are reviewed during the FDA Premarket Clearance/Approval process.

For more information, please review the FDA Final Guidance for Industry on Reprocessing and Labeling.

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