DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 14-25-NH
EXPIRED EFFECTIVE: April 28, 2025

DATE: September 2, 2025

ORIGINAL POSTING DATE: May 9, 2014

TO: State Survey Agency Directors

FROM: Director, Survey and Certification Group

SUBJECT: ***EXPIRED:*** Advance Copy – Single Use Device Reprocessing under Tag F441, Revisions to Interpretive Guidance in Appendix PP, State Operations Manual (SOM) on Infection Control

Memo Expiration Information:

Expiration Date: ***04/28/2025***
Expiration Information: ***Refer to F880 in Appendix PP of CMS' State Operations Manual for current infection control requirements and guidance single use devices.***

Memorandum Summary

- **Advance Copy:** The guidance under Tag F441, Infection Control, Preventing Spread of Infection/Indirect Transmission has been revised.
- **Single-Use Device Guidance:** Nursing homes may purchase reprocessed single-use devices when these devices are reprocessed by an entity or a third party reprocessor that is registered with the Food and Drug Administration.
- **Single-Use Device (SUD):** A SUD is a device that is intended for one use on a single patient during a single procedure.
- **Reprocessed SUD:** A reprocessed SUD is an original device that has previously been used on a patient and has been subjected to additional processing and manufacturing for the purpose of an additional single use on a patient.

Background:

The Centers for Medicare & Medicaid Services (CMS) made revisions to the interpretive guidance under Tag F441, Infection Control. In the section, "Preventing Spread of Infection, Indirect Transmission," the current guidance states that: "Single use disposable equipment is an alternative to sterilizing reusable medical instruments. Devices labeled by the manufacturer for single use are never to be reused, even if they are reprocessed." This revised guidance is issued

to be consistent with current Food and Drug Administration (FDA) regulation that allows for the reprocessing and marketing of SUDs under specific conditions (21 CFR §807.92(a)(3)).

The FDA is responsible for reviewing the safety and effectiveness of medical devices before they go to market and ensuring that they remain safe and effective afterwards. In August 2000, FDA released a guidance document on SUDs reprocessed by third parties or hospitals. In this guidance document, FDA states that hospitals or third-party reprocessors will be considered "manufacturers" and regulated in the same manner. A reused SUD will have to comply with the same regulatory requirements of the device when it was originally manufactured. Manufacturers intending to sell medical devices in the United States, including reprocessed SUDs, must register with FDA and provide information listing the devices they

intend to market. FDA considers establishments engaged in reprocessing (that is, any activity needed to render a used SUD ready for use on a subsequent patient) to be the manufacturers of those reprocessed SUDs. Establishments, including reprocessing establishments, are required to update their registrations annually and their device listings twice each year.

Nursing homes may purchase reprocessed SUDs when these devices are reprocessed by an entity or a third party reprocessor that is registered with the FDA. The nursing home must have documentation from the third party reprocessor that indicates that it has been cleared by the FDA to reprocess the specific device in question.

Contact: For questions on this memorandum, please contact Sharon.Lash@cms.hhs.gov

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/
Thomas E. Hamilton

Attachment - Advance copy of updated SOM Appendix PP, 42 C.F.R. §483.65(b), Infection Control, Preventing Spread of Infection.

cc: Survey and Certification Regional Office Management