



Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 14-25-NH

DATE: May 9, 2014

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

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

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 reproducers 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

CMS Manual System

Pub. 100-07 State Operations

Provider Certification

Department of Health &
Human Services (DHHS)
Centers for Medicare &
Medicaid Services (CMS)

Transmittal

Date: **Month XX ---2013**

SUBJECT: Revisions to Appendix PP – “Interpretive Guidelines for Long-Term Care Facilities F tag 441 Infection Control”

I. SUMMARY OF CHANGES: This instruction updates the guidance at F tag 441, Infection Control, Preventing the Spread of Infection, Indirect Transmission.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: Upon Issuance
IMPLEMENTATION DATE: Upon Issuance

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)
(R = REVISED, N = NEW, D = DELETED) – (Only One Per Row.)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Appendix PP/F tag 441

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	One-Time Notification -Confidential
	Recurring Update Notification

***Unless otherwise specified, the effective date is the date of service.**

ADVANCE COPY

PREVENTING THE SPREAD OF INFECTION

Factors Associated with the Spread of Infection in Nursing Homes

Many factors contribute to a substantial severity and frequency of infections and infectious diseases in nursing homes. These infections can arise from individual or institutional factors, or both. Modes of transmission of infection include, but are not limited to:

- Contact;
- Droplet; and
- Airborne.

Individual Factors

Examples of individual factors contributing to infections and the severity of the infection outcomes in facility residents include, but are not limited to the following:

- Medications affecting resistance to infection such as corticosteroids and chemotherapy;
- Limited physiologic reserve (e.g., decreased function of the heart, lungs, and kidneys);
- Compromised host defenses (e.g., decreased or absent cough reflex predisposing to aspiration pneumonia, thinning skin associated with pressure ulcers, decreased tear production predisposing to conjunctivitis, vascular insufficiency, and impaired immune function);
- Coexisting chronic diseases (e.g., diabetes, arthritis, cancer, COPD, anemia);
- Complications from invasive diagnostic procedures such as skin or bloodstream infections;
- Impaired responses to infection (e.g., cell mediated responses); and
- Increased frequency of therapeutic toxicity (e.g., declining kidney and liver function).

Institutional Factors

In addition to individual factors, institutional factors may also facilitate transmission of infections among residents, including but not limited to:

- Pathogen exposure in shared communal living space (e.g., handrails and equipment);
- Common air circulation;
- Direct/indirect contact with health care personnel/visitors/other residents;
- Direct/indirect contact with equipment used to provide care; and
- Transfer of residents to and from hospitals or other settings.

Residents can be exposed to potentially pathogenic organisms in several ways, including but not limited to the following:

- Improper hand hygiene;
- Improper glove use (e.g., utilizing a single pair of gloves for multiple tasks or multiple residents); and
- Improper food handling.

Direct Transmission (Person to Person)

Direct transmission occurs when microorganisms are transferred from an infected/colonized person to another person. Contaminated hands of healthcare personnel are often implicated in direct contact transmission. Agents that can be transmitted by direct contact include, but are not limited to MRSA, VRE, and Influenza.

Indirect Transmission

Indirect transmission involves the transfer of an infectious agent through a contaminated intermediate object. The following are examples of opportunities for indirect contact.

- Resident-care devices (e.g., electronic thermometers or glucose monitoring devices) may transmit pathogens if devices contaminated with blood or body fluids are shared without cleaning and disinfecting between uses for different residents; and
- Clothing, uniforms, laboratory coats, or isolation gowns used as PPE may become contaminated with potential pathogens after care of a resident colonized or infected with an infectious agent, (e.g., MRSA, VRE, and *Clostridium difficile*). Indirect contact may occur through toilets and bedpans. Examples of illnesses spread via a fecal-oral route

include salmonella, shigella, and pathogenic strains of E. coli, norovirus, and symptomatic Clostridium difficile.

Reducing and/or preventing infections through indirect contact requires the decontamination (i.e., cleaning, sanitizing, or disinfecting an object to render it safe for handling) of resident equipment, medical devices, and the environment. Alternatively, the facility may also consider using single-use disposable devices. The choice of decontamination method depends on the risk of infection to the resident coming into contact with equipment or medical devices.

The CDC has adopted the Spaulding classification system that identifies three risk levels associated with medical and surgical instruments: critical, semi-critical and noncritical.¹ This includes:

- Critical items (e.g., needles, intravenous catheters, indwelling urinary catheters) are defined as those items which normally enter sterile tissue, or the vascular system, or through which blood flows. The equipment must be sterile when used, based on one of several accepted sterilization procedures;¹
- Semi-critical items (e.g., thermometers, podiatry equipment, electric razors) are defined as those objects that touch mucous membranes or skin that is not intact. Such items require meticulous cleaning followed by high-level disinfection treatment using an FDA-approved chemo sterilizer agent, or they may be sterilized; and
- Non-critical items (e.g., stethoscopes, blood pressure cuffs, over-bed tables) are defined as those that come into contact with intact skin or do not contact the resident. They require low level disinfection by cleaning periodically and after visible soiling, with an EPA disinfectant detergent or germicide that is approved for health care settings.

Single-use disposable equipment is an alternative to sterilizing reusable medical instruments.

Single-use devices must be discarded after use and are never used for more than one resident. 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 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.

¹Sehulster, L.M., Chinn, R.Y.W., Arduino, M.J., Carpenter, J., Donlan, R., Ashford, D., Besser, R., Fields, B., McNeil, M.M., Whitney, C., Wong, S., Juranek, D., and Cleveland, J. (2003). *Guidelines for environmental infection control in health-care facilities. Recommendations from CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC)*. Accessed December 10, 2008 from http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Enviro_guide_03.pdf