Revised Guidance for F Tag 441: The Centers for Medicare & Medicaid Services (CMS) is clarifying and revising guidance to surveyors in Appendix PP of the SOM regarding citations under F Tag 441 related to 42 CFR §483.65(c). The memo addresses laundry detergents with and without antimicrobial claims, use of chlorine bleach rinses, water temperatures during the process of washing laundry, maintenance of laundry equipment and laundry items, and ozone laundry cleaning systems.

A. Background

Currently, the requirements for Skilled Nursing Facilities (SNFs) and Nursing Facilities (NFs) at 42 CFR §483.65(c) Infection Control, Linens, state that “personnel must handle, store, process, and transport linens so as to prevent the spread of infection.”

Current interpretive guidance does not address recent changes in manufacturer’s technology for laundry equipment and cleaning agents. There have been many questions related to infection control and laundry processing. In the process of responding to some of these questions, the CMS has identified a need to update the related interpretive guidance.

B. Interpretive Guidance, 42 CFR §483.65(c)

In consultation with the Centers for Disease Control and Prevention (CDC), the CMS is updating surveyor guidance to address improvements in technology utilized in laundry processing. Specifically, the CMS is updating the existing interpretive guidance:
“Detergent and water physically remove many microorganisms from linen through dilution during the wash cycle. An effective way to destroy microorganisms in laundry items is through hot water washing at temperatures above 160 degrees F (71 degrees C) for 25 minutes. Alternatively, low temperature washing at 71 to 77 degrees F (22-25 degrees C) plus a 125-part-per-million (ppm) chlorine bleach rinse has been found to be effective and comparable to high temperature wash cycles.”

The CMS is also adding guidance on maintenance of laundry equipment and laundry items and ozone laundry cleaning systems. These updates in interpretive guidance complement other guidance within the SOM under “Handling Linens to Prevent and Control Infection Transmission.”

C. Procedures 42 CFR §483.65(c)

**Laundry detergents.** Advances in technology allow modern-day detergents to be much more effective in removing soil and reducing the presence of microbes than those used in the past when much of the research on laundry processing was first conducted. The CMS in collaboration with the CDC has determined that facilities may use any detergent designated for laundry in laundry processing. Further, laundry detergents used within nursing facilities are not required to have stated anti-microbial claims. Facilities should closely follow manufacturer’s instructions for laundry detergents used. The CMS does not endorse any specific laundry detergent or product.

**Water temperatures and chlorine bleach rinses.** Laundry processing conducted within facilities typically occurs in a low water temperature environment. Many laundry items are composed of materials that cannot withstand a chlorine bleach rinse and remain intact. The chlorine bleach rinse is not required for all laundry items processed in low temperature washing environments due to the availability of modern laundry detergents that are able to produce hygienically clean laundry without the presence of chlorine bleach (The Association for the Advancement of Medical Instrumentation defines the term "hygienically clean" as "free of pathogens in sufficient numbers to cause human illness."). However, the chlorine bleach rinse may still be used for laundry items composed of materials such as cottons. Hot water washing at temperatures greater than 160 degrees F for 25 minutes and low temperature washing at 71 to 77 degrees F (22-25 degrees C) with a 125-part-per-million (ppm) chlorine bleach rinse remain effective ways to process laundry. If a facility chooses to process laundry using a hot water temperature environment, the temperature maintained for 25 minutes should be 160 degrees Fahrenheit.

**Maintenance of equipment and laundry items.** Facilities are not required to maintain a record of water temperatures during laundry processing cycles. The CDC recommends leaving washing machines open to air when not in use to allow the machine to dry completely and to prevent growth of microorganisms in wet, potentially warm environments. Facilities are required to follow manufacturer’s instructions for all materials involved in laundry processing (e.g., washing machines; dryers; any laundry detergents, rinse aids, or other additives employed during the
Facilities should also follow manufacturer’s instructions for clothing, linens, and other laundry items to determine the appropriate methods to use to produce a hygienically clean product. Facilities should also consider a resident’s individual needs (e.g., allergies) when selecting methods for processing laundry. Facilities should have written policies & procedures which should include training for staff who will handle linens and laundry.

**Ozone cleaning systems.** Ozone laundry cleaning systems are relatively new. The CMS in collaboration with the CDC has determined that ozone cleaning systems are acceptable methods of processing laundry. This method also requires closely following manufacturer’s instructions. Facilities opting to utilize an ozone laundry cleaning system will need to obtain an initial agreement between the laundry service and facility that stipulates the laundry will be hygienically clean and handled to prevent recontamination from dust and dirt during loading and transport. This is not an endorsement of ozone cleaning systems.

Please direct any additional questions or concerns regarding F Tag 441 related to handling linens to prevent and control infection transmission to Jemima Drake via phone at 410-786-1526 or email at jemima.drake@cms.hhs.gov.

**Effective Date:** Immediately. This information 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 SOM Guidance

cc: Survey and Certification Regional Office Management
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, Handling Linens to Prevent and Control Infection 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.)

<table>
<thead>
<tr>
<th>R/N/D</th>
<th>CHAPTER/SECTION/SUBSECTION/TITLE</th>
</tr>
</thead>
<tbody>
<tr>
<td>R</td>
<td>Appendix PP/F tag 441</td>
</tr>
</tbody>
</table>

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 |
HANDLING LINENS TO PREVENT AND CONTROL INFECTION TRANSMISSION

It is important that all potentially contaminated linen be handled with appropriate measures to prevent cross-transmission. If the facility handles all used linen as potentially contaminated (i.e., using standard precautions), no additional separating or special labeling of the linen is recommended. No special precautions (i.e., double bagging) or categorizing is recommended for linen originating in isolation rooms. Double bagging of linen is only recommended if the outside of the bag is visibly contaminated or is observed to be wet through to the outside of the bag. Alternatively, leak-resistant bags are recommended for linens contaminated with blood or body substances. If standard precautions for contaminated linens are not used, then some identification with labels, color coding or other alternatives means of communication is important.

For the routine handling of contaminated laundry, minimum agitation is recommended, to avoid the contamination of air, surfaces, and persons. The risk of environmental contamination may be reduced by having personnel bag or contain contaminated linen at the point of use, and not sorting or pre-rinsing in resident care areas.

It is important that laundry areas have hand washing facilities and products, as well as appropriate Personal Protective Equipment (PPE) (i.e., gloves and gowns) available for workers to wear while sorting linens. Laundry equipment should be used and maintained according to the manufacturer’s instructions to prevent microbial contamination of the system. It is recommended that damp linen is not left in machines overnight.

AAMI (Association for the Advancement of Medical Instrumentation) defines the term “hygienically clean” as “free of pathogens in sufficient numbers to cause human illness.” Detergent and water physically remove many microorganisms from the linen through dilution during the wash cycle. Advances in technology allow modern-day detergents to be much more effective in removing soil and reducing the presence of microbes than those used in the past when much of the research on laundry processing was first conducted. Facilities may use any detergent designated for laundry in laundry processing. Further, laundry detergents used within nursing facilities are not required to have stated anti-microbial claims. Facilities should closely follow manufacturer’s instructions for laundry detergents used.

Laundry processing conducted within facilities typically occurs in a low water temperature environment. Many laundry items are composed of materials that cannot withstand a chlorine bleach rinse and remain intact. A chlorine bleach rinse is not required for all laundry items.
processed in low temperature washing environments due to the availability of modern laundry detergents that are able to produce hygienically clean laundry without the presence of chlorine bleach. However, a chlorine bleach rinse may still be used for laundry items composed of materials such as cottons. Hot water washing at temperatures greater than 160 degrees F for 25 minutes and low temperature washing at 71 to 77 degrees F (22-25 degrees C) with a 125-part-per-million (ppm) chlorine bleach rinse remain effective ways to process laundry. If a facility chooses to process laundry using a hot water temperature environment, the temperature maintained for 25 minutes should be at or above 160 degrees Fahrenheit (71ºC).

Facilities are not required to maintain a record of water temperatures during laundry processing cycles. The CDC recommends leaving washing machines open to air when not in use to allow the machine to dry completely and to prevent growth of microorganisms in wet, potentially warm environments. Facilities are required to follow manufacturer’s instructions for all materials involved in laundry processing (e.g., washing machines; dryers; any laundry detergents, rinse aids, or other additives employed during the laundry process). Facilities should also follow manufacturer’s instructions for clothing, linens, and other laundry items to determine the appropriate methods to use to produce a hygienically clean product. Facilities should also consider a resident’s individual needs (e.g., allergies) when selecting methods for processing laundry. The CMS, in collaboration with the CDC, has also determined that ozone cleaning systems are acceptable methods of processing laundry. Ozone cleaning systems also should be used per manufacturer’s instructions.

If laundry chutes are used, it is recommended that they are properly designed and maintained so as to minimize dispersion of aerosols from contaminated laundry (e.g., no loose items in the chute and bags are closed before tossing into the chute).

If linen is sent off to a professional laundry, the facility should obtain an initial agreement between the laundry service and facility that stipulates the laundry will be hygienically clean and handled to prevent recontamination from dust and dirt during loading and transport. For example, an ozone laundry cleaning system is a method which may require a professional laundry service. The facility will need to obtain such an agreement in this instance. Whether laundry processing is completed within the facility or outside the facility, facilities should have written policies & procedures which should include training for staff who will handle linens and laundry.

Standard mattresses and pillows can become contaminated with body substances during resident care if the integrity of the covers of these items is compromised. A mattress cover is generally a fitted, protective material, the purpose of which is to prevent the mattress from becoming contaminated with body fluids and substances. A linen sheet placed on the mattress is not considered a mattress cover. Patches for tears and holes in mattress covers do not provide an impermeable surface over the mattress. Therefore it is recommended that mattress covers with tears or holes be replaced. It is recommended that moisture resistant mattress covers be cleansed and disinfected between residents with an EPA approved germicidal detergent to help prevent the spread of infections, and fabric mattress covers should be laundered between residents. Pillow covers and washable pillows should be laundered in a hot water laundry cycle between residents or when they become contaminated with body substances. Discarding mattresses if
fluids have penetrated into the mattress fabric and washing pillows and pillow covers in a hot-water laundry cycle will also reduce the risk of indirect contact with infectious agents.\textsuperscript{102}

