DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

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

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C 17-30-Hospitals/CAHs/NHs REVISED 06.09.2017
EXPIRED EFFECTIVE: July 16, 2018

DATE: September 2, 2025

ORIGINAL POSTING DATE: June 02, 2017

TO: State Survey Agency Directors

FROM: Director, Survey and Certification Group

SUBJECT: ***EXPIRED:*** Requirement to Reduce *Legionella* Risk in Healthcare Facility Water Systems to Prevent Cases and Outbreaks of Legionnaires' Disease (LD)

Memo Expiration Information:

Expiration Date: ***07/16/2018***
Expiration Information: ***This memo was superseded by Revised QSO-17-30-Hospitals/CAHs/NHs on 07/16/2018, refer to the revised memo for updated requirements regarding Legionnaires' Disease.***

Memorandum Summary

- ***Legionella* Infections**: The bacterium *Legionella* can cause a serious type of pneumonia called LD in persons at risk. Those at risk include persons who are at least 50 years old, smokers, or those with underlying medical conditions such as chronic lung disease or immunosuppression. Outbreaks have been linked to poorly maintained water systems in buildings with large or complex water systems including hospitals and long-term care facilities. Transmission can occur via aerosols from devices such as showerheads, cooling towers, hot tubs, and decorative fountains.
- **Facility Requirements to Prevent Legionella Infections:** Facilities must develop and adhere to policies and procedures that inhibit microbial growth in building water systems that reduce the risk of growth and spread of *legionella* and other opportunistic pathogens in water.
- This policy memorandum applies to Hospitals, Critical Access Hospitals (CAHs) and Long-Term Care (LTC). However, this policy memorandum is also intended to provide general awareness for all healthcare organizations.

Background

LD, a severe sometimes fatal pneumonia, can occur in persons who inhale aerosolized droplets of water contaminated with the bacterium *Legionella*. In a recent review of LD outbreaks in the United States occurring in 2000–2014, 19% of outbreaks were associated with long-term care facilities and 15% with hospitals. The rate of reported cases of legionellosis, which comprises both LD and Pontiac fever (a milder, self-limited, influenza-like illness) has increased 286% in the US during 2000–2014, with approximately 5,000 cases reported to the Centers for Disease Control and Prevention (CDC) in 2014. Approximately 9% of reported legionellosis cases are fatal.

The Centers for Medicare & Medicaid Service (CMS) is aware of multiple recent LD outbreaks in hospitals and long-term care facilities as reported by the CDC, state and local health departments, or investigated by State Survey Agencies (SA).

Outbreaks generally are linked to environmental reservoirs in large or complex water systems, including those found in healthcare facilities such as hospitals and long-term care facilities. Transmission from these water systems to humans requires aerosol generation, as can occur from

showerheads, cooling towers, hot tubs, and decorative fountains. *Legionella* is less commonly spread by aspiration of drinking water or ice. Only one case of possible person-to-person transmission has been reported.

In manmade water systems, *Legionella* can grow and spread to susceptible hosts, such as persons who are at least 50 years old, smokers, and those with underlying medical conditions such as chronic lung disease or immunosuppression. *Legionella* can grow in parts of building water systems that are continually wet, and certain devices can spread contaminated water droplets via aerosolization. Examples of these system components and devices include:

- Hot and cold water storage tanks
- Water heaters
- Water-hammer arrestors
- Pipes, valves, and fittings
- Expansion tanks
- Water filters
- Electronic and manual faucets
- Aerators
- Faucet flow restrictors
- Showerheads and hoses
- Centrally-installed misters, atomizers, air washers, and humidifiers
- Nonsteam aerosol-generating humidifiers
- Eyewash stations
- Ice machines
- Hot tubs/saunas
- Decorative fountains
- Cooling towers

- Medical devices (such as CPAP machines, hydrotherapy equipment, bronchoscopes, heater-cooler units)

CMS Regulatory Authorities

Pertinent regulations include, but are not limited to, the following:

42 CFR §482.42 for hospitals:
"The hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases."

42 CFR §483.80 for skilled nursing facilities and nursing facilities:
"The facility must establish and maintain an infection prevention and control program designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of communicable diseases and infections."

42 CFR §485.635(a)(3)(vi) for critical access hospitals (CAHs):
CAH policies must include: "A system for identifying, reporting, investigating and controlling infections and communicable diseases of patients and personnel."

Expectations for Healthcare Facilities and Surveyors

CMS expects Medicare certified healthcare facilities to have water management policies and procedures to reduce the risk of growth and spread of *Legionella* and other opportunistic pathogens in building water systems. An industry standard[1] calling for the development and implementation of water management programs in large or complex building water systems to reduce the risk of legionellosis was published in 2015 by American Society of Heating, Refrigerating, and Air Conditioning Engineers (ASHRAE). In 2016, the CDC and its partners developed a toolkit to facilitate implementation of this ASHRAE Standard (https://www.cdc.gov/legionella/maintenance/wmp-toolkit.html). Environmental, clinical, and epidemiologic considerations for healthcare facilities are described in this toolkit.

Surveyors will review policies, procedures, and reports documenting water management implementation results to verify that facilities:

- Conduct a facility risk assessment to identify where *Legionella* and other opportunistic waterborne pathogens (e.g. *Pseudomonas*, *Acinetobacter*, *Burkholderia*, *Stenotrophomonas*, nontuberculous mycobacteria, and fungi) could grow and spread in the facility water system.

- Implement a water management program that considers the ASHRAE industry standard and the CDC toolkit, and includes control measures such as physical controls, temperature management, disinfectant level control, visual inspections, and environmental testing for pathogens.

[1] ASHRAE 188: *Legionellosis: Risk Management for Building Water Systems* June 26, 2015. ASHRAE: Atlanta. www.ashrae.org

- Specify testing protocols and acceptable ranges for control measures, and document the results of testing and corrective actions taken when control limits are not maintained.

Healthcare facilities are expected to comply with CMS requirements to protect the health and safety of its patients. Those facilities unable to demonstrate measures to minimize the risk of LD are at risk of citation for non-compliance with the CMS Conditions of Participation. Accrediting organizations will be surveying healthcare facilities deemed to participate in Medicare for compliance with the requirements listed in this memorandum, as well, and will cite non-compliance accordingly.

Contact: For questions or concerns regarding this policy memorandum, please contact Dr. Daniel Schwartz at Daniel.schwartz2@cms.hhs.gov.

Effective Date: Immediately. This guidance 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/
David R. Wright

cc: Survey and Certification Regional Office Management

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-21-19-NH
EXPIRED EFFECTIVE: April 28,2025

DATE:	September 2, 2025
ORIGINAL POSTING DATE:	May 11, 2021
TO:	State Survey Agency Directors
FROM:	Director, Quality, Safety & Oversight Group
SUBJECT:	***EXPIRED:*** Interim Final Rule - COVID-19 Vaccine Immunization Requirements for Residents and Staff

Memo Expiration Information:

Expiration Date:	***04/28/2025***
Expiration Information:	***Refer to QSO-25-11-NH Long-Term Care (LTC) Facility Acute Respiratory Illness Reporting Requirements for current requirements regarding respiratory illness reporting, and F887 in Appendix PP of CMS' State Operations Manual for current requirements and guidance regarding COVID-19 immunization requirements.***

Memorandum Summary

- CMS is committed to continually taking critical steps to ensure America's healthcare facilities continue to respond effectively to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE).
- On May 11, 2021, CMS published an interim final rule with comment period (IFC). This rule establishes **Long-Term Care (LTC) Facility Vaccine Immunization Requirements for Residents and Staff.** This includes new requirements for educating residents or resident representatives and staff regarding the benefits and potential side effects associated with the COVID-19 vaccine, and offering the vaccine. Furthermore, LTC facilities must report COVID-19 vaccine and therapeutics treatment information to the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN).
- Transparency: CMS will post the new information reported to the NHSN for viewing by facilities, stakeholders, or the general public on CMS's COVID-19 Nursing Home Data website.
- **Updated Survey Tools:** CMS has updated tools used by surveyors to assess compliance with these new requirements.

Background

On December 1, 2020, the Advisory Committee in Immunization Practices (ACIP) recommended that health care personnel (HCP) and long-term care (LTC) facility residents be offered COVID-19 vaccination first (Phase 1a).[1] Ensuring LTC residents receive COVID-19 vaccinations will help protect those who are most at risk of severe infection or death from COVID-19.

To support this, on May 11, 2021, CMS published an interim final rule with comment period (IFC), CMS-3414-IFC , entitled "Medicare and Medicaid Programs; COVID-19 Vaccine Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID) Residents, Clients, and Staff." CMS added new requirements at §483.80(d)(3)(i)-(vii) for LTC facilities to develop policies and procedures to educate residents or resident representatives and staff regarding the benefits and potential side effects associated with the COVID-19 vaccine and offer the vaccine unless it is medically contraindicated or the resident or staff member has already been immunized. Additionally, the facility must maintain appropriate documentation to reflect that the facility provided the required COVID-19 vaccine education, and whether the resident and staff member received the vaccine.

Furthermore, CMS added a new requirement at §483.80(g)(1)(viii)-(ix) for LTC facilities to report COVID-19 vaccine status of residents and staff, each dose of vaccine received, COVID-19 vaccination adverse events, and therapeutics administered to residents for treatment of COVID-19. As already required at §483.80(g)(2), this data also must be reported to CDC's NHSN system and CMS intends to post the new information collected on the CMS COVID-19 Nursing Home Data website. This reporting will help public health agencies and stakeholders monitor the level of vaccinated residents and staff and target resources accordingly to improve vaccination rates. Additionally, reporting the use of therapeutics will help agencies and stakeholders monitor the prevalence of these treatments, their impact on reducing the effect of COVID-19 on nursing home residents, and support allocation efforts to ensure that nursing homes have access to supplies to meet their needs.

Noncompliance related to the new requirements for educating and offering COVID-19 vaccination to residents and staff will be cited at F-tag 887, and noncompliance related to COVID-19 vaccination reporting will be cited at F-tag 884.

§483.80 Infection control

(d) Influenza, pneumococcal, and COVID-19 immunizations. . .

(3) *COVID-19 immunizations*. The LTC facility must develop and implement policies and procedures to ensure all the following:

(i) When COVID-19 vaccine is available to the facility, each resident and staff member is offered the COVID-19 vaccine unless the immunization is medically contraindicated or the resident or staff member has already been immunized;

[1] https://www.cdc.gov/mmwr/volumes/69/wr/mm6949e1.htm

(ii) Before offering COVID-19 vaccine, all staff members are provided with education regarding the benefits and risks and potential side effects associated with the vaccine;

(iii) Before offering COVID-19 vaccine, each resident or the resident representative receives education regarding the benefits and risks and potential side effects associated with the COVID-19 vaccine;

(iv) In situations where COVID-19 vaccination requires multiple doses, the resident, resident representative, or staff member is provided with current information regarding those additional doses, including any changes in the benefits or risks and potential side effects, associated with the COVID-19 vaccine, before requesting consent for administration of any additional doses.

(v) The resident, resident representative, or staff member has the opportunity to accept or refuse a COVID-19 vaccine, and change their decision; and

(vi) The resident's medical record includes documentation that indicates, at a minimum, the following:

(A) That the resident or resident representative was provided education regarding the benefits and potential risks associated with COVID-19 vaccine; and

(B) Each dose of COVID-19 vaccine administered to the resident, or

(C) If the resident did not receive the COVID-19 vaccine due to medical contraindications or refusal.

(vii) The facility maintains documentation related to staff COVID-19 vaccination that includes at a minimum, the following:

(A) That staff were provided education regarding the benefits and potential risks associated with COVID-19 vaccine;

(B) Staff were offered the COVID-19 vaccine or information on obtaining COVID-19 vaccine; and

(C) The COVID-19 vaccine status of staff and related information as indicated by NHSN.

(g)(1)(viii) The COVID-19 vaccine status of residents and staff, including total numbers of residents and staff, numbers of residents and staff vaccinated, numbers of each dose of COVID-19 vaccine received, and COVID-19 vaccination adverse events; and

(ix) Therapeutics administered to residents for treatment of COVID-19.

F887: COVID-19 Immunization

DEFINITIONS

"Staff" means those individuals who work in the facility on a regular (that is, at least once a week) basis, including individuals who may not be physically in the LTC facility for a period of time due to illness, disability, or scheduled time off, but who are expected to return to work. This also includes individuals under contract or arrangement, including hospice and dialysis staff, physical therapists, occupational therapists, mental health professionals, or volunteers, who are in the facility on a regular basis, as the vaccine is available.

"Emergency Use Authorization (EUA)" is a mechanism to facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies, such as the current COVID-19 pandemic. The EUA process is a way to ensure safety while still expediting approval in emergent situations.

GUIDANCE
In order to protect LTC residents from COVID-19, each facility must develop and implement policies and procedures that meet each resident's, resident representative's, and staff member's information needs and provides vaccines to all residents and staff that elect them.

Education
All residents and/or resident representatives and staff must be educated on the COVID-19 vaccine they are offered, in a manner they can understand, and receive the FDA COVID-19 EUA Fact Sheet before being offered the vaccine. The Food and Drug Administration (FDA) requires that vaccine recipients or their representative are provided with certain vaccine-specific EUA information to help make an informed decision about vaccination. Fact Sheets can be found at the Center for Disease Control and Prevention's (CDC) COVID-19 Vaccine Emergency Use Authorization (EUA) Fact Sheets for Recipients and Caregivers website.

Education must cover the benefits and potential side effects of the vaccine. This should include common reactions, such as aches or fever, and rare reactions such as anaphylaxis.

If the vaccination requires multiple doses of vaccine, the resident or resident representative and staff are again provided with education regarding the benefits and potential side effects of the vaccine and current information regarding those additional doses, including any changes in the benefits or potential side effects, before requesting consent for administration of any additional doses. The resident, resident representative, or staff member must be provided the opportunity to refuse the vaccine and to change their decision about vaccination at any time.

The CDC, FDA, Immunization Action Coalition (IAC), and vaccine manufacturers have developed a variety of educational and training resources for healthcare professionals related to COVID-19 vaccines. CMS recommends that staff work with their LTC facility's Medical Director and Infection Preventionist and use the CDC and FDA resources as the source of information for their vaccination education initiatives. The CDC's LTC Facility Toolkit: Preparing for COVID-19 Vaccination at Your Facility has information and resources to build confidence among staff and residents.

Offering Vaccinations
LTC facilities must offer residents and staff vaccination against COVID-19 when vaccine supplies are available to the facility. Screening individuals prior to offering the vaccination for prior immunization, medical precautions and contraindications is necessary for determining whether they are appropriate candidates for vaccination at any given time. The vaccine may be offered and provided directly by the LTC facility or indirectly, such as through an arrangement with a pharmacy partner, local health department, or other appropriate health entity.

The facility is not required to educate and offer COVID-19 vaccinations to individuals who enter the facility for specific purposes and for a limited amount of time, such as delivery and repair personnel or volunteers who may enter the LTC facility infrequently (meaning less than once weekly). However, if the facility has the availability, they may offer education and vaccination to these individuals.

If a resident or staff member requests vaccination against COVID-19, but missed earlier opportunities for any reason (including recent residency or employment, changing health status, overcoming vaccine hesitancy, or any other reason), we expect the facility to offer the vaccine to

that individual as soon as possible. If the vaccine is unavailable in the facility, the facility should provide information on obtaining vaccination opportunities (e.g. health department or local pharmacy) to the individual, however it is expected that the facility will provide evidence, upon request, of efforts made to make the vaccine available to its staff and residents. Similar to influenza vaccines, if there is a manufacturing delay, the facility should provide evidence of the delay, including efforts to acquire subsequent doses as necessary.

Indications and contraindications for COVID-19 vaccination are evolving and facilities should be alert to any new or revised guidelines issued by the CDC, FDA, vaccine manufacturers, or other expert stakeholders.

Vaccination Administration
For residents and staff who opt to receive the vaccine, vaccination must be conducted in accordance with CDC, ACIP, FDA, and manufacturer guidelines. All facilities must adhere to current infection prevention and control recommendations when preparing and administering vaccines.

Administration of any vaccine includes appropriate monitoring of recipients for adverse reactions, and long-term care facilities must have strategies in place to appropriately evaluate and manage post-vaccination adverse reactions among their residents and staff, per 483.45(d), F757. Particularly for COVID-19 vaccines, safety monitoring is required under the associated EUAs.

Vaccination Adverse Event Reporting
In accordance with FDA requirements, select adverse events for COVID-19 vaccines must be reported to the Vaccine Adverse Event Reporting System (VAERS), (that is, vaccine administration errors, serious adverse events, multisystem inflammatory syndrome (MIS) in children or adults, and cases of COVID-19 that result in hospitalization or death). Any revised safety reporting requirements must also be followed. For additional information see VAERS – Vaccine Adverse Event Reporting System at https://vaers.hhs.gov.

Vaccination Refusal
Residents and their representatives have the right to refuse the COVID-19 vaccine in accordance with Resident Rights requirements at 42 CFR 483.10(c)(6) and tag F578. Additionally, the regulation at §483.10(b)(2) states "The resident has the right to be free of interference, coercion, discrimination, and reprisal from the facility in exercising his or her rights and to be supported by the facility in the exercise of his or her rights as required under this subpart." Therefore, facilities cannot take any adverse action against a resident or representative who refuses the vaccine, including social isolation, denied visitation and involuntary discharge.

Facilities should follow state law and facility policies with respect to staff refusal of vaccination.

Documentation
The resident's medical record must include documentation that indicates, at a minimum, that the resident or resident representative was provided education regarding the benefits and potential side effects of the COVID-19 vaccine, and that the resident (or representative) either accepted and received the COVID-19 vaccine or did not receive the vaccine due to medical

contraindications, prior vaccination, or refusal. If there is a contraindication to the resident having the vaccination, the appropriate documentation must be made in the resident's medical record. Documentation should include the date the education and offering took place, and the name of the representative that received the education and accepted or refused the vaccine, if the resident has a representative that makes decisions for them. Facilities should also provide samples of the educational materials that were used to educate residents.

The facility must maintain documentation that each staff member was educated on the benefits and potential side effects of the COVID-19 vaccine and offered vaccination unless medically contraindicated or the staff member has already been immunized. Compliance can be demonstrated by providing a roster of staff that received education (e.g., a sign-in sheet), the date of the education, and samples of the educational materials that were used to educate staff. The facility must document the vaccination status of each staff member (i.e., immunized or not), including whether fully immunized (i.e., completed the series of multi-dose vaccines).

If a staff member is not eligible for COVID-19 vaccination because of previous immunization at another location or outside of the facility, the facility should request vaccination documentation from the staff member to confirm vaccination status.

LTC administrators and clinical leadership are encouraged to track vaccination coverage in their facilities and adjust communication with residents and staff accordingly to facilitate understanding and knowledge of the benefits of vaccination.

Resources for COVID-19 Vaccines

- COVID-19 Vaccination Training Programs and Reference Materials for Healthcare Professionals: https://www.cdc.gov/vaccines/covid-19/downloads/COVID-19-Clinical-Training-and-Resources-for-HCPs.pdf
- Immunization Action Coalition - for education and implementation materials: https://www.immunize.org/handouts/covid19-vaccines.asp
- CDC's Clinical Resources for COVID-19 Vaccine https://www.cdc.gov/vaccines/covid-19/index.html
- Long-Term Care Facilities COVID-19 Vaccination (landing page for LTC information, including the toolkit): https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-home-long-term-care/vaccination.html
- Understanding the Pharmacy Partnership for Long-Term Care Program: https://www.cdc.gov/vaccines/covid-19/long-term-care/pharmacy-partnerships.html
- COVID-19 Vaccine Emergency Use Authorization (EUA) Fact Sheets for Recipients and Caregivers https://www.cdc.gov/vaccines/covid-19/eua/index.html#:~:text=For%20each%20COVID%2D19%20vaccine,an%20informed%20decision%20about%20vaccination
- Post Vaccine Considerations for Residents and HCP: https://www.cdc.gov/coronavirus/2019-ncov/hcp/post-vaccine-considerations-residents.html,

https://www.cdc.gov/coronavirus/2019-ncov/hcp/post-vaccine-considerations-healthcare-personnel.html

- General Best Practice Guidelines for Immunization: Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP) www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html

INVESTIGATIVE PROCEDURES

Use the Infection Prevention, Control & Immunizations Facility Task, along with the above interpretive guidance, when determining if the facility meets the requirements for, or investigating concerns related to COVID-19 vaccination of residents and staff.

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

- F658: for concerns related to professional standards of practice for the provision of vaccines;
- F880: for concerns related to infection prevention and control;
- F660: for concerns related to provision of documentation of the resident's vaccination status to the next provider and follow-up vaccination instructions to the resident when the resident is transferred or discharged.

Updates to the Survey Process for F887

To determine compliance with §483.80(d)(3), surveyors will request a facility point of contact to provide information on how residents and staff are educated about and offered the COVID-19 vaccine, including samples of educational materials. Surveyors will also request a list of residents and staff and their COVID-19 vaccination status from which they will select a sample of residents and staff to review records and conduct interviews to confirm they were educated on and offered the COVID-19 vaccine in accordance with the new requirements. CMS will update the CMS-20054: "Infection Prevention, Control & Immunizations" Facility Task to include the new requirement at F887 for educating residents or resident representatives and staff and offering the COVID-19 vaccine. Additionally, CMS will update associated survey documents, which will be found under the "Survey Resources" link in the Downloads Section of the CMS Nursing Homes website. The updated documents will also be added to the Long-Term Care Survey Process software application.

F884: Reporting – National Healthcare Safety Network (NHSN)

42 CFR 483.80(g)(1)(viii)-(ix) requires LTC facilities report, on a weekly basis, the COVID-19 vaccination status of residents and staff, total numbers of residents and staff vaccinated, each dose of vaccine received, COVID-19 vaccination adverse events, and therapeutics administered to residents for treatment of COVID-19 through NHSN's LTCF COVID-19 Module.

LTC facility administrators and clinical leadership are encouraged to track vaccination coverage in their facility, which can help them target efforts to improve vaccination coverage. Facilities may use the COVID-19 Vaccination module in NHSN to track aggregate vaccination coverage.

Refer to CMS memorandum QSO-20-29-NH for additional NHSN reporting requirements under F884 as well as instructions on registering, enrolling, and reporting to NHSN. For NHSN questions, please email: NHSN@cdc.gov and add "Weekly COVID-19 Vaccination" in the subject header.

Facilities must continue submitting their COVID-19 data to NHSN at least weekly, but no later than Sunday at 11:59 p.m., each week. Facilities must begin including vaccination and therapeutic data reporting in facility NHSN submissions by 11:59 p.m. Sunday, June 13, 2021. To be compliant with the new reporting requirements, facilities must submit the data through the NHSN reporting system at least once every seven days. Facilities may choose to submit multiple times a week.

Enforcement for F884

Compliance with F884 requires facilities to continue to report COVID-19 data through NHSN's LTCF COVID-19 Module, and now, with finalization of the new reporting requirements at §483.80(g)(viii) and (ix), they must begin reporting vaccination data for residents and staff and the use of therapeutics for residents. **CMS will begin reviewing for compliance with the new vaccination reporting requirements Monday, June 14, 2021.**

As has been done since June 2020, CMS will continue to receive the CDC NHSN reported data and review for timely and complete reporting of **all** data elements. Facilities identified as not meeting the all reporting requirements under the provisions at §483.80(g)(1), including the new vaccination reporting requirements, will receive a deficiency citation at F884 on the CMS 2567, Statement of Deficiencies, at a scope and severity level of F (no actual harm with a potential for more than minimal harm that is not an Immediate Jeopardy [IJ] and that is widespread).

Failure to report the required elements to NHSN (including the new vaccination reporting requirements) will result in a single deficiency at F884 for that reporting week. In accordance with §488.447, a determination that a facility has failed to comply with the requirements to report weekly to the CDC pursuant to §483.80(g)(1)-(2) (tag F884) will result in a civil money penalty (CMP) imposition. Enforcement for F884 follows a progressive pattern, which leads to an increase of the CMP amount for each subsequent occurrence of noncompliance, not to exceed the maximum amount set forth in §488.408(d)(1)(iii), as specified in §488.447(a)(2).[2] The amount of the CMP imposed is incrementally increased based on the provider's history of noncompliance with F884 since June 2020 when providers were first required to start reporting COVID-19 related data to the CDC.

Per enforcement requirements at §488.447, failure to meet reporting requirements at §483.80(g)(1) will result in a CMP starting at $1,000 for the first occurrence of a failure to report. For each subsequent week that the facility fails to submit the required report, the noncompliance will result in an additional CMP imposed at an amount increased by $500 and added to the previously imposed CMP amount for each subsequent occurrence. Please refer to QSO 20-29-NH, which detailed how CMS will enforce the new reporting requirement.

CMS will continue to provide notification of noncompliance and imposition of a CMP, along with the CMS 2567 to facilities via their CASPER shared folders.

NHSN Resources for Providers

- LTCF COVID19 Module webpage (https://www.cdc.gov/nhsn/ltc/covid19/index.html): Visit this website before submitting questions to the NHSN help desk.

[2] See Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency, Interim Final Rule, 85 FR 54820, at 54823-54825 (Sept. 2, 2020).

- Enrollment help: https://www.cdc.gov/nhsn/pdfs/covid19/ltcf/covid19-enrollment-508.pdf or https://www.cdc.gov/nhsn/ltc/covid19/enroll.html. If you still need help with enrollment/data submission, contact NHSN@cdc.gov "LTCF" in the subject line.

- To correct facility type: https://www.cdc.gov/nhsn/pdfs/covid19/ltcf/change-ltcf-508.pdf.

- To change/update your NHSN facility administrator: https://www.cdc.gov/nhsn/facadmin/index.html

- For enforcement-related questions, please email: DNH_Enforcement@cms.hhs.gov

Contact: For questions or concerns regarding this memo, please contact DNH_TriageTeam@cms.hhs.gov.

Effective Date: This policy should be communicated with all survey and certification staff, their managers and the State/CMS Location training coordinators immediately. The effective dates of the specific actions are specified above.

/s/
David R. Wright

cc: Survey and Operations Group Management

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-24-08-NH
EXPIRED EFFECTIVE: 04/28/2025

DATE:	September 2, 2025
ORIGINAL POSTING DATE:	March 21, 2024
TO:	State Survey Agency Directors
FROM:	Director, Quality, Safety & Oversight Group (QSOG)
SUBJECT:	***EXPIRED:*** Enhanced Barrier Precautions in Nursing Homes to Prevent Spread of Multidrug-resistant Organisms (MDROs)

Memo Expiration Information:

Expiration Date:	***04/28/2025***
Expiration Information:	***Refer to F880 in Appendix PP of CMS' State Operations Manual for current guidance regarding enhanced barrier precautions in nursing homes to prevent the spread of multidrug-resistant organisms (MDROs).***

Memorandum Summary

- CMS is issuing new guidance for State Survey Agencies and long term care (LTC) facilities on the use of enhanced barrier precautions (EBP) to align with nationally accepted standards.
- EBP recommendations now include use of EBP for residents with chronic wounds or indwelling medical devices during high-contact resident care activities regardless of their multidrug-resistant organism status.
- The new guidance related to EBP is being incorporated into F880 Infection Prevention and Control.

Background:

Multidrug-resistant organism (MDRO) transmission is common in long term care (LTC) facilities (i.e., nursing homes), contributing to substantial resident morbidity and mortality and increased healthcare costs. Many residents in nursing homes are at increased risk of becoming colonized and developing infection with MDROs.

In 2019, CDC introduced a new approach to the use of personal protective equipment (PPE) called Enhanced Barrier Precautions (EBP) as a strategy in nursing homes to decrease transmission of CDC-targeted and epidemiologically important MDROs when contact precautions do not apply. The approach recommended gown and glove use for certain residents

during specific high-contact resident care activities associated with MDRO transmission and did not involve resident room restriction.

As described in the Healthcare Infection Control Practices Advisory Committee (HICPAC) white paper, "Consideration for the Use of Enhanced Barrier Precautions in Skilled Nursing Facilities" dated June 2021, more than 50% of nursing home residents may be colonized with an MDRO. This report noted that the use of contact precautions to prevent MDRO transmission involves restricting residents to their room, which may negatively impact a resident's quality of life and pschyosocial well-being. As a result, many nursing homes only implemented contact precautions when residents are infected with an MDRO.

In July 2022, the CDC released updated EBP recommendations for "Implementation of PPE Use in nursing homes to prevent spread of MDROs," and therefore, CMS is updating its infection prevention and control guidance accordingly. The recommendations now include the use of EBP during high-contact care activities for residents with chronic wounds or indwelling medical devices, regardless of their MDRO status, in addition to residents who have an infection or colonization with a CDC-targeted or other epidemiologically important MDRO when contact precautions do not apply.

This new guidance related to EBP is being incorporated in F880 Infection Prevention and Control to assist LTC surveyors when evaluating the use of enhanced barrier precautions in nursing homes. We note that facilities have some discretion when implementing EBP and balancing the need to maintain a homelike environment for residents.

Regulations and Guidance:

F880
§483.80 Infection Control
The facility must establish and maintain an infection prevention and control program designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of communicable diseases and infections.

§483.80(a) Infection prevention and control program.
The facility must establish an infection prevention and control program (IPCP) that must include, at a minimum, the following elements:

§483.80(a)(1) A system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases for all residents, staff, volunteers, visitors, and other individuals providing services under a contractual arrangement based upon the facility assessment conducted according to §483.70(e) and following accepted national standards;
* * * * *

GUIDANCE
"Enhanced Barrier Precautions" (EBP) refer to an infection control intervention designed to reduce transmission of multidrug-resistant organisms that employs targeted gown and glove use during high contact resident care activities.

EBP are used in conjunction with standard precautions and expand the use of PPE to donning of gown and gloves during high-contact resident care activities that provide opportunities for

transfer of MDROs to staff hands and clothing.

EBP are indicated for residents with any of the following:

- Infection or colonization with a CDC-targeted MDRO when Contact Precautions do not otherwise apply; or
- Wounds and/or indwelling medical devices even if the resident is not known to be infected or colonized with a MDRO.

Wounds generally include chronic wounds, not shorter-lasting wounds, such as skin breaks or skin tears covered with an adhesive bandage (e.g., Band-Aid®) or similar dressing. Examples of chronic wounds include, but are not limited to, pressure ulcers, diabetic foot ulcers, unhealed surgical wounds, and venous stasis ulcers.

Indwelling medical device examples include central lines, urinary catheters, feeding tubes, and tracheostomies. A peripheral intravenous line (not a peripherally inserted central catheter) is not considered an indwelling medical device for the purpose of EBP.

EBP should be used for any residents who meet the above criteria, wherever they reside in the facility.

Facilities **have discretion** in using EBP for residents who do not have a chronic wound or indwelling medical device and are infected or colonized with an MDRO that is not currently targeted by CDC.

Table 1: Implementing Contact versus Enhanced Barrier Precautions

This table only applies to MDROs, not all pathogens that may require use of transmission-based precautions.

Resident Status	Contact Precautions	Use EBP
Infected or colonized with any MDRO and has secretions or excretions that are unable to be covered or contained.	Yes	No
Infected or colonized with a CDC-targeted MDRO **without** a wound, indwelling medical device or secretions or excretions that are unable to be covered or contained.	No	Yes
Infected or colonized with a non-CDC targeted MDRO **without** a wound, indwelling medical device, or secretions or excretions that are unable to be covered or contained.	No	At the discretion of the facility
Has a wound or indwelling medical device, **and** secretions or excretions that are unable to be covered or contained and are not known to be infected or colonized with any MDRO.	Yes, unless/until a specific organism is identified.	Yes, if they do not meet the criteria for contact precautions.

Resident Status	Contact Precautions	Use EBP
Has a wound or indwelling medical device, **without** secretions or excretions that are unable to be covered or contained and are not known to be infected or colonized with any MDRO.	No	Yes

Examples of secretions or excretions include wound drainage, fecal incontinence or diarrhea, or other discharges from the body that cannot be contained and pose an increased potential for extensive environmental contamination and risk of transmission of a pathogen.

For residents whom EBP are indicated, EBP is employed when performing the following high-contact resident care activities:

- Dressing
- Bathing/showering
- Transferring
- Providing hygiene
- Changing linens
- Changing briefs or assisting with toileting
- Device care or use: central line, urinary catheter, feeding tube, tracheostomy/ventilator
- Wound care: any skin opening requiring a dressing

Note: In general, gowns and gloves would not be recommended when performing transfers in common areas such as dining or activity rooms, where contact is anticipated to be shorter in duration. Outside the resident's room, EBP should be followed when performing transfers or assisting during bathing in a shared/common shower room and when working with residents in the therapy gym, specifically when anticipating close physical contact while assisting with transfers and mobility.

Residents are not restricted to their rooms or limited from participation in group activities. Because EBP do not impose the same activity and room placement restrictions as Contact Precautions, they are intended to be in place for the duration of a resident's stay in the facility or until resolution of the wound or discontinuation of the indwelling medical device that placed them at higher risk.

Facilities have discretion on how to communicate to staff which residents require the use of EBP. CMS supports facilities in using creative (e.g., subtle) ways to alert staff when EBP use is necessary to help maintain a home-like environment, as long as staff are aware of which residents require the use of EBP prior to providing high-contact care activities.

Facilities should ensure PPE and alcohol-based hand rub are readily accessible to staff. Discretion may be used in the placement of supplies which may include placement near or outside the resident's room. PPE for enhanced barrier precautions is only necessary when performing high-contact care activities and may not need to be donned prior to entering the resident's room. For example, staff entering the resident's room to answer a call light, converse with a resident or provide medications who do **not** engage in a high-contact resident care activity would likely not need to employ EBP while interacting with the resident.

Information regarding CDC-targeted MDROs and current recommendations on EBP are available on the CDC's webpage, "Implementation of Personal Protective Equipment (PPE) Use in Nursing Homes to Prevent Spread of Multidrug-resistant Organisms (MDROs)," at https://www.cdc.gov/hai/containment/PPE-Nursing-Homes.html.

Survey Procedures

Surveyors will evaluate the use of EBP when reviewing sampled residents for whom EBP are indicated and focus their evaluation of EBP use as it relates to CDC-targeted MDROs.

CMS will update associated survey documents which will be found under the "Survey Resources" link in the Downloads Section of the CMS Nursing Homes webpage and will also be added to the Long-Term Care Survey Process software application.

Contact:

For questions or concerns relating to this memorandum, please contact DNH_TriageTeam@cms.hhs.gov.

Effective Date:

April 1, 2024. Please communicate to all appropriate staff within 30 days.

/s/
David R. Wright
Director, Quality, Safety & Oversight Group

Resources to Improve Quality of Care:

Check out CMS's new Quality in Focus interactive video series. The series of 10–15 minute videos are tailored to provider types and aim to reduce the deficiencies most commonly cited during the CMS survey process, like infection control and accident prevention. Reducing these common deficiencies increases the quality of care for people with Medicare and Medicaid. Learn to:

- *Understand surveyor evaluation criteria*
- *Recognize deficiencies*
- *Incorporate solutions into your facility's standards of care*

See the Quality, Safety, & Education Portal Training Catalog, and select Quality in Focus

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-12-25
Baltimore, Maryland 21244-1850

Center for Medicaid, CHIP, and Survey & Certification/Survey & Certification Group

Ref: S&C: 10-28-NH
EXPIRED EFFECTIVE: April 28, 2025

DATE:	September 2, 2025
ORIGINAL POSTING DATE:	August 27, 2010
TO:	State Survey Agency Directors
FROM:	Director, Survey and Certification Group
SUBJECT:	***EXPIRED:*** Point of Care Devices and Infection Control in Nursing Homes

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 regarding fingerstick devices and blood glucose meters.***

Memorandum Summary

Infection Control Standards for Nursing Homes at §483.65 - F441 –Determining Compliance: The following practices are deficiencies in infection control:

- Reusing fingerstick devices (e.g., pen-like devices) for more than one resident;
- Using a blood glucose meter (or other point-of-care device) for more than one resident without cleaning and disinfecting it after use.

If a surveyor observes a facility doing either of the above, the surveyor should follow the interpretive guidelines, investigative protocol, and severity determination information at F441 to determine the severity of the deficiency.

Scope & Severity: CMS is revising the example in Appendix PP to make a distinction between (a) reuse of fingerstick devices for more than one resident (immediate jeopardy) and (b) use of a blood glucose meter for more than one resident without proper cleaning and disinfection, so that scope and severity can be correctly assessed.

Background

Point-of-care testing is diagnostic testing that is performed at or near the site of resident care. This may be accomplished through use of portable, handheld instruments such as blood glucose meters or prothrombin time meters. This testing may involve obtaining a blood specimen from the resident using a fingerstick device. The guidance in this document regarding fingerstick devices and blood glucose meters is applicable to other point-of-care devices where a blood specimen is obtained (e.g., prothrombin time meters).

Deficiency Identification

- Fingerstick devices must never be used for more than one resident. Although the package instructions for some fingerstick devices may indicate or imply the potential for multiple patient use, surveyors and health care workers must adhere to this CMS guidance regarding the avoidance of multiple patient use of fingerstick devices, consistent with recent statements of the CDC and the FDA.
- Point-of-care devices, such as blood glucose meters, can become contaminated with blood and, if used for multiple residents, must be cleaned and disinfected after each use according to manufacturer's instructions.
- If the manufacturer does not specify steps for cleaning and disinfection between uses of a point-of-care device, then the device generally should not be used for more than one resident. In the case of point-of-care devices where there are no manufacturers' instructions for cleaning between uses, we strongly advise nursing homes not to share the devices among residents. In such cases involving sampled residents (or when triggered for further investigation) where there are no manufacturer's instructions, surveyors will inquire as to the methods used for cleaning and disinfection between shared uses and will cite a deficiency for such a practice unless the nursing home can clearly establish that commonly accepted safe infection control practices are being followed (through authoritative references to published research, CDC recommendations, recommendations of professional societies, or similar references to commonly accepted professional practices).

According to the interpretive guidance and investigative protocol F441, for sampled residents or when triggered for further investigation, nursing home surveyors should determine whether point-of-care equipment (such as blood glucose meters) used for more than one resident are appropriately cleaned and disinfected after each use following manufacturer's recommendations.

If the manufacturer's recommendations do not specify agents for cleaning and disinfection between uses, the device generally should not be used for more than one resident. In such a case of shared use of a point-of-care device for which there are no manufacturer's instructions for cleaning and the inquiry is triggered or sampled, inquire as to: (a) the methods used for cleaning and disinfection, (b) the basis for the methods used, as expressed in published research, CDC guidance, recommendations of professional societies, or similar authoritative references, and (c) cite a deficiency if the practice is not grounded in such research, communication from the

manufacturer that provides direction for cleaning/disinfection and product compatibility[1], professional recommendations, CDC guidance, guidance from the U.S. Food and Drug Administration (FDA), or other sources of commonly accepted professional infection control practice.

The example provided in the infection control examples of Appendix PP combined reuse of fingerstick devices (e.g., pen-like devices) and the cleaning and disinfection of blood glucose meters together in one sentence, which has led to some confusion about how to assess scope and severity for this requirement.

Deficiency Severity Determination

The reuse of fingerstick devices for more than one resident should be treated as immediate jeopardy.

Failure to clean and disinfect blood glucose meters used for more than one resident is a deficiency in infection control that warrants corrective action, but may not constitute immediate jeopardy. This deficiency should warrant further investigation following the interpretive guidelines, investigative protocol, and severity determination information at F441 to determine level of severity.

Next Steps

CMS will be revising the example related to the use of blood glucose meters in appendix PP to state the following:

> *An example of a negative outcome that occurred or has the potential to occur at Severity Level 4 as a result of the facility's deficient practices may include:*
>
> *The facility failed to follow Standard Precautions during the performance of routine testing of blood glucose. The facility reused fingerstick devices for more than one resident. This practice of re-using fingerstick devices for more than one resident created an Immediate Jeopardy to resident health by potentially exposing residents who required blood glucose testing to the spread of bloodborne infections in the facility.*

Effective Date: Immediately. Please ensure that all appropriate staff are fully informed within 30 days of the date of this memorandum.

Training: The information must be shared with all survey and certification staff, surveyors, managers, and the State and CMS regional office training coordinators.

[1] Manufacturers' instructions may derive from package inserts, published literature, communications between the manufacturer and the nursing home or other parties, or any other form of communication from the manufacturer that identifies cleaning agents, methods, and assurance of compatibility between agents used and the product itself.

Additional Resource Material

Both the CDC and FDA have updated their website reference material this week, accessible at:

http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html
http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html
http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm

Below are additional references which offer information about hepatitis, point-of-care devices, and/or blood glucose meter practices.

http://www.cdc.gov/hepatitis/Settings/GlucoseMonitoring.htm
http://www.cdc.gov/ncidod/dhqp/bp_hepatitisb_prevent.html
http://www.cdc.gov/ncidod/dhqp/bp_hepatitisc_prevent.html

http://www3.interscience.wiley.com/cgi-bin/fulltext/123236683/PDFSTART
http://journalofdst.org/March2009/Articles/VOL-3-2-ORG3-THOMPSON.pdf
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5409a2.htm
http://www.cdc.gov/mmwr/preview/mmwrhtml/00046679.htm

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management
U.S. Center for Disease Control and Prevention
U.S. Food and Drug Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid
Services 7500 Security Boulevard,
Mail Stop C2-21-16 Baltimore,
Maryland 21244-1850

Office of Clinical Standards and Quality/Survey & Certification Group

---

Ref: S&C-12-22-NH
EXPIRED EFFECTIVE: December 31, 2012

DATE: September 2, 2025

ORIGINAL POSTING DATE: March 16, 2012

TO: State Survey Agency Directors

FROM: Director, Survey and Certification Group

SUBJECT: ***EXPIRED:*** Healthcare Associated Infections (HAI) Prevention Program Environmental Scan of State Survey Agency Training Coordinators and State HAI Coordinators

Memo Expiration Information:

Expiration Date: ***12/31/2012***
Expiration Information: ***This environmental scan ended in 2012 and is no longer in effect.***

Memorandum Summary

- **Notification:** The Centers for Medicare & Medicaid Services (CMS) in collaboration with the Centers for Disease Control (CDC) will conduct a Healthcare Associated Infections Prevention Program Environmental Scan of State Survey Agency Training Coordinators and State HAI Coordinators.
- **State Selection:** The randomly selected States to participate in the pilot are Nebraska, Washington, Texas, Illinois, North Carolina, Colorado and Massachusetts.
- **Effective Date:** The pilot environmental scan will begin in late March 2012.

The CMS in collaboration with the CDC seeks to identify current State Health Department and State Survey Agency HAI prevention programs for nursing homes. Our goal is to determine how the current nursing home HAI prevention programs operate and learn from the States' experiences to identify promising practices that could be shared

with other State programs and help inform the development of a national infection prevention program for nursing homes.

The environmental scan will occur in two parts, one pilot interview of a few States and a second round of interviews with all States. We will begin the initial pilot scan of seven randomly selected States (Nebraska, Washington, Texas, Illinois, North Carolina, Colorado and Massachusetts) in late March 2012. Following the results of the pilot, we will make any necessary modifications to the interview questions.

We anticipate completing the full environmental scan of all States and U.S. Territories by late summer 2012.

Beginning in late March, each pilot State Survey Agency and State HAI Coordinator will receive a call from our contractor, Training Development Program Management (TDP), LLC, as they complete the environmental scan questionnaire. Please assist us with this very important project by sharing information about your programs for infection prevention in nursing homes when called.

Thank you for your cooperation, we appreciate your input.

Please direct any questions or comments regarding this memorandum to Debra Spears at debra.spears@cms.hhs.gov.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 13-09-NH
EXPIRED EFFECTIVE: April 28, 2025

DATE: September 2, 2025

ORIGINAL POSTING DATE: January 25, 2013

TO: State Survey Agency Directors

FROM: Director, Survey and Certification Group

SUBJECT: ***EXPIRED:*** Clarification of Interpretive Guidance at F Tag 441-Laundry and 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 regarding water management.***

Memorandum Summary

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 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. 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