



January 28, 2010

Dear Customer:

It has come to our attention that the Centers for Medicare and Medicaid Services (CMS) has issued conflicting guidance regarding the use of germicidal products specifically to disinfect glucometers between and after each patient use to prevent cross-transmission. As a valued customer of Professional Disposables International, Inc. (PDI), this letter provides clarification about the appropriate use of the Sani-Cloth[®] products in accordance with established regulatory and clinical guideline requirements.

Reducing and/or preventing infections through indirect contact requires the decontamination (i.e., cleaning, sanitizing, or disinfecting of 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 devices. The choice of decontamination method depends on the risk of infection to the resident coming into contact with equipment or medical device.

The Centers for Disease Control and Prevention (CDC) has adopted the Spaulding classification system that identifies three risk levels associated with medical and surgical instruments: critical, semi-critical and noncritical. 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.
- **Semi-critical items** (e.g., thermometers, podiatry equipment, and 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.
- **Non-critical items** (e.g., stethoscopes, over-bed tables, and glucometers) are defined as those objects 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 registered disinfectant detergent or germicide that is labeled for use in a health care setting.

As cited in the CMS TAG F441, an example regarding an immediate jeopardy citation specific to the disinfection of glucometers was identified: "The facility failed to follow standard precautions during the performance of routine testing of blood sugars. The facility did not clean and disinfect the glucometers before or after use and did not use new glucometer lancets on residents who required blood sugar monitoring. This practice of not cleaning and disinfecting glucometers between every use and re-using glucometer lancet created an Immediate Jeopardy to resident health by potentially exposing residents to the spread of blood borne infections for multiple residents in the facility who required blood sugar testing."

OUR PASSION IS PREVENTION™



In accordance with the Association for Professionals in Infection Control and Epidemiology (APIC) Position Paper: *Safe Injection, Infusion, and Medication Vial Practices in Healthcare*, glucometers should be disinfected after each use according to the manufacturer's directions using an EPA-registered disinfectant effective against Hepatitis B, Hepatitis C, and HIV, or a 1:10 bleach solution (one part bleach to 9 parts water).

In addition, according to the Occupational Safety and Health Administration (OSHA) 29 CFR 1910.1030 standard, EPA-registered disinfectants or a sodium hypochlorite solution should be used for surface disinfection and disinfection on noncritical patient-care equipment such as glucometers as long as the disinfectant is effective against Bloodborne Pathogens HIV, Hepatitis B, and Hepatitis C.

Special Note Regarding Ongoing Nosocomial Transmission of *C. difficile* in Healthcare Settings:

According to the Centers for Disease Control and Prevention, *Clostridium difficile* (*C. difficile*) can survive in the environment (e.g., on floors, bed rails or around toilet seats) in its spore form for up to six months. Rigorously cleaning the environment removes *C. difficile* spores, and can help prevent transmission of the organism.

The PDI Super Sani-Cloth[®] Germicidal Disposable Wipe and Sani-Cloth[®] Plus Germicidal Disposable Cloth products are efficacious alternatives to bleach and are both appropriate for use on non-critical items, such as glucometers, and meet the standards set forth by the CDC, CMS, and APIC and successfully inactivate the Bloodborne Pathogens HIV, Hepatitis B, and Hepatitis C.

As with all medical equipment, clinicians should follow the advice of the equipment's manufacturer for proper disinfection and cleaning. As additional information is made available by CMS, the PDI Clinical Affairs Team will provide this information to our customers as necessary. If you have any additional questions regarding this matter, please contact the PDI Customer Service Center at 1-800-999-6423 to speak with one of our Customer Service Experts or speak directly with your local Territory Sales Manager.

Sincerely,

PDI Clinical Affairs Team

Attachment (s):

- CMS Nursing Homes - Issuance of Revisions to Interpretive Guidance at F Tag 441, as Part of Appendix PP, State Operations Manual (SOM), and Training Materials
- Association in Infection Control and Epidemiology Position Paper: Safe Injection, Infusion, and Medication Vial Practices in Healthcare
- CDC Recommended Infection Control and Safe Injection Practices to Patient Transmission of Bloodborne Pathogens



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APIC Position Paper: Safe Injection, Infusion and Medication Vial Practices in Healthcare

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The transmission of bloodborne viruses and other microbial pathogens to patients during routine healthcare procedures continues to occur due to unsafe and improper injection, infusion and medication vial practices being used by healthcare professionals within various clinical settings throughout the United States.¹⁻¹³

Breaches in safe injection, infusion and medication vial practices continue to result in unacceptable and devastating events for patients. More than 35 outbreaks of hepatitis have occurred in the United States in the past 10 years due to these unsafe practices and other breaches of infection prevention procedures. These outbreaks have resulted in the transmission of either hepatitis B or C to more than 500 patients.¹³ The unsafe practices that were used by physicians and/or nurses in these outbreaks can be categorized by:

- a) syringe reuse between patients during medication administration to multiple patients;
- b) contamination of medication vials or intravenous (IV) bags;
- c) failure to follow basic injection safety practices when preparing and administering parenteral medications to multiple patients;
- d) inappropriate use of glucometer equipment between patients.

In 2001, an anesthesiologist at a New York endoscopy clinic infected 19 patients with hepatitis C virus (HCV) by improperly reusing syringes and contaminating a multi-dose anesthesia medication vial subsequently used for multiple patients.³ A similar HCV outbreak due to unsafe injection practices occurred in New York in 2002 and 2007, affecting 102 patients in total.¹³ In 2002, nearly 100 Nebraska Hematology Oncology clinic patients contracted hepatitis C after a nurse used the same syringe and needle from a hepatitis C-positive patient's blood draw to obtain saline flush solution from an IV bag. As a result, the patient's blood that was on the needle of the syringe was inoculated into the IV bag which was then used as flushing solution for several other patients.² One of the most recent hepatitis C outbreaks occurred in Nevada in 2008 and was again due to unsafe injection practices involving the reuse of syringes and sharing single-use medication vials between patients. This outbreak occurred at an endoscopy center and received significant public media attention, in part due to the 63,000 persons identified as being at potential risk for acquisition of hepatitis. More than 12,000 patients have

been tested to date with at least 115 patients infected with one of the viruses. The investigation is ongoing.¹²

APIC recognizes these outbreaks as unacceptable. Each of them was preventable by the use of proper aseptic technique in conjunction with basic infection prevention practices for handling parenteral medications, administration of injections and procurement and sampling of blood. Responsibility for the oversight and monitoring of patient safety must be clearly designated in healthcare settings to assure that staff education is available for all healthcare professionals providing such services to patients. Furthermore, periodic monitoring for absolute adherence to safe injection practices in healthcare settings is vital in order to ensure effective engineering of and adherence to safe practices in everyday patient care.

APIC strongly supports adherence to the following safe injection, infusion and medication vial practices.¹⁴⁻²⁵

Aseptic Technique

- Perform hand hygiene prior to accessing supplies, handling vials and IV solutions, and preparing or administering medications.
- Use aseptic technique in all aspects of parenteral medication administration, medication vial use, injections and glucose monitoring procedures.
- Store and prepare medications and supplies in a clean area on a clean surface.
- Never store needles and syringes unwrapped as sterility cannot be assured.
- Discard all opened vials, IV solutions and prepared or opened syringes that were involved in an emergency situation.

IV Solutions

- Never use intravenous solution containers (e.g., bags or bottles) to obtain flush solutions, etc. for more than one patient.
- Never use infusion supplies such as needles, syringes, flush solutions, administration sets or intravenous fluids on more than one patient.
- Initiate administration of IV solutions within one hour of preparation, otherwise discard prepared IV solution/tubing.²²
- Disinfect IV ports using friction and 70% alcohol¹⁵, an iodophor¹⁵ or an approved antiseptic agent. Allow to dry prior to accessing.

Flushing

- Use single-dose containers for flush solutions.
- If a multidose vial must be used, it should be used for only one patient and then discarded. Each entry into the multidose vial (dedicated to the one patient) must be with a new unused sterile needle and syringe.

Syringes

- Remove sterile needle/cannula and/or syringe from package just prior to use.
- Never use medication in a syringe for more than one patient even if the needle is changed between patients. Changing the needle but not the syringe is unacceptable.

- Utilize sharps safety devices whenever possible.
- Discard syringes, needles and cannulas after used directly on an individual patient or in their IV administration system.
- Dispose of used needles at the point of use in an approved sharps container.

Vials

- Always follow the manufacturer's instructions for use.
- Use single-use or single-dose vials whenever possible.
- Always use a sterile syringe and needle/cannula when entering a vial. Never enter a vial with a syringe or needle/cannula that has been used on a patient.
- Cleanse the access diaphragm of vials using friction and 70% alcohol. Allow to dry before inserting a device into the vial.
- Discard single-dose vials after use. Never use them again for another patient.
- Use multidose medication vials for a single patient whenever possible and access all vials using a new sterile syringe, needle/cannula and adherence to aseptic technique. The risk of transmission posed by multi-dose vials has been clearly demonstrated and mandates a practice of one vial per one patient whenever possible. Infection transmission risk is reduced when multi-dose vials are dedicated to a single patient.
- Keep multidose vials away from the immediate patient environment.
- Never store vials in clothing or pockets.
- Never pool or combine leftover contents of vials for later use.
- Never leave a needle or cannula inserted into a medication vial rubber stopper because it leaves the vial vulnerable to contamination.
- Dispose of opened multidose medication vials 28 days after opening.²² Date vial to reflect date opened and/or date of expiration. CDC Immunization Program states vaccines are to be discarded per manufacturer's expiration date.²⁵
- Inspect vials and discard if sterility has been, or is thought to be compromised. Examine the vial for any particulate matter, discoloration or turbidity. If present, do not use and discard immediately. All vials used during an emergency should be discarded as sterility cannot be guaranteed.

Blood Glucose Monitoring Devices

- Assign glucometers to individual patients. Clean and disinfect glucometers if they must be reused between patients.
- Restrict use of fingerstick capillary blood sampling devices to individual patients.
- Maintain supplies and equipment such as fingerstick devices and glucometers within individual inpatient rooms, if possible.
- Use single-use lancets that permanently retract upon puncture.
- Never reuse fingerstick devices and lancets. Dispose of them at the point of use in an approved sharps container. Lancets in a pen are to be removed by mechanical means (hemostat) to avoid finger contact.
- Thoroughly clean all visible soil or organic material (e.g., blood) from glucometer prior to disinfection.

- Disinfect the exterior surfaces of the glucometer after each use following the manufacturer's directions. Use an EPA-registered disinfectant effective against HBV, HCV and HIV, or a 1:10 bleach solution (one part bleach to 9 parts water).

Healthcare Workers

- Provide the hepatitis B vaccination series to all previously-unvaccinated healthcare personnel whose activities involve contact with blood or body fluids.¹⁸
- Check and document post-vaccination titers one to two months after completion of the vaccination series.¹⁸
- Report body fluid and needlestick/sharps injuries immediately.
- Ensure staff preparing or administering injections or other parenteral medications are competent to aseptically perform these tasks.
- Periodically assess compliance with safe injection practices by observing and evaluating personnel performing these procedures.

Conclusion:

Use of safe injection practices is critical to prevent microbial contamination of products administered to patients. The ongoing United States reports of hepatitis B and C transmission to patients is an indication that much more is needed to assure that these preventive practices are being scrupulously followed in all healthcare settings. Healthcare workers and their managers must understand and practice these procedures safely. Administrators of medical facilities must be aware of safe injection practices and ensure that employees have the knowledge, training and equipment to safely implement these procedures. We must see to it that injectable medications, intravenous delivery systems and blood glucose monitoring are safely utilized in all healthcare settings. As Infection Preventionists we have an obligation to reiterate and ensure that safe injection, infusion and medication vial practices are the absolute standard of care throughout the variety of healthcare settings that exist today. We must take a lead role to assure adherence by healthcare workers to these safe practices in order to protect the health and safety of our patients.

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3. Centers for Disease Control. Transmission of hepatitis B and C viruses in outpatient settings – New York, Oklahoma, and Nebraska, 2000-2002. *MMWR* 2003;52(38):901-906.
4. Krause G, Trepka MJ, Whisenhunt RS, et al. Nosocomial transmission of hepatitis C virus associated with the use of multidose saline vials. *Infect Control Hosp Epidemiol* 2003;24:122-7.
5. Tallis GF, Ryan GM, Lambert SB, et al. Evidence of patient-to-patient transmission of hepatitis C virus through contaminated intravenous anaesthetic ampoules. *J Viral Hepat* 2003;10:234-9.

6. Comstock RD, Mallonee S, Fox J.L, et. al. [A large nosocomial outbreak of hepatitis C and hepatitis B among patients receiving pain remediation treatments.](#) *Infect Control Hosp Epidemiol* 2004;25(7):576-83.
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8. Centers for Disease Control. Transmission of hepatitis B Virus among persons undergoing blood glucose monitoring in long-term-care facilities: Mississippi, North Carolina and Los Angeles County, California, 2003-2004. *MMWR* 2005;54(09):220-223.
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10. Samandari T, Malakmadze N, Balter S, et al. A large outbreak of hepatitis B virus infections associated with frequent injections at a physician's office. *Infect Control Hosp Epidemiol* 2005;26:745-50.
11. Redd JT, Baumbach J, Kohn W, et.al. Patient-to-patient transmission of hepatitis B virus associated with oral surgery. *The Journal of Infectious Diseases* 2007;195:1311-1314.
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14. Infusion Nursing Standards of Practice. *Journal of Infusion Nursing*. 2006;29(1S).
15. O'Grady NP, Alexander M, Patchen E, et. al. Centers for Disease Control and Prevention. Guidelines for the Prevention of Intravascular Catheter-Related Infections. *MMWR* 2002;51(No.RR-10).
16. Centers for Disease Control. Guidelines for infection control in dental health-care settings—2003. *MMWR* 2003; 52(RR-17):10-1.
17. Guideline for environmental infection control in health-care facilities: recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee. *MMWR*, 2003;52(No. RR-10):1-44.
18. US Department of Labor, Occupational Safety and Health Administration. 29 C.F.R. pt. 1910.1030. Occupational exposure to bloodborne pathogens; needlesticks and other sharp injuries; final rule. *Fed. Reg.* 2001; 66:5317-25. As amended from and includes 29 C.F.R. pt. 1910.1030. Occupational exposure to bloodborne pathogens; final rule. *Fed. Reg.* 1991; 56:64174-82. Available at: <http://www.osha.gov/SLTC/dentistry/index.html>.
19. DeBaun B. Transmission of infection with multi-dose vials. *Infection Control Resource*. 2005;3(3):1,5-7. Available from: <http://www.infectioncontrolresource.org/past.html> (Accessed 4/20/2009)

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21. Hadaway L. Flushing vascular access catheters: Risks for infection transmission. *Infection Control Resource*. 4(2):1-8, 2007.
http://www.infectioncontrolresource.org/Past_Issues/IC14.pdf (Accessed 4/20/2009)
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24. Centers for Disease Control. Prevent patient-to-patient transmission of bloodborne pathogens in long term care settings. Available at: <http://wwwn.cdc.gov/pubs/hepa.aspx> (Accessed 4/20/2009)
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RECOMMENDED INFECTION-CONTROL AND SAFE INJECTION PRACTICES TO PREVENT PATIENT-TO-PATIENT TRANSMISSION OF BLOODBORNE PATHOGENS

Diabetes Care Procedures & Techniques

- Prepare medications such as insulin in a centralized medication area; multiple dose insulin vials should be assigned to individual patients and labeled appropriately.
- Never reuse needles, syringes, or lancets.
- Restrict use of fingerstick capillary blood sampling devices to individual patients. Consider selecting single-use lancets that permanently retract upon puncture.
- Dispose of used fingerstick devices and lancets at the point of use in an approved sharps container.
- Environmental surfaces such as glucometers should be decontaminated regularly and anytime contamination with blood or body fluids occurs or is suspected.
- Glucometers should be assigned to individual patients. If a glucometer that has been used for one patient must be reused for another patient, the device must be cleaned and disinfected.
- Maintain supplies and equipment such as fingerstick devices and glucometers within individual patient rooms if possible.
- Any trays or carts used to deliver medications or supplies to individual patients should remain outside patient rooms. Do not carry supplies and medications in pockets.
- Because of possible inadvertent contamination, unused supplies and medications taken to a patient's bedside during fingerstick monitoring or insulin administration should not be used for another patient.



CDC. Transmission of Hepatitis B Virus Among Persons Undergoing Blood Glucose Monitoring in Long-Term-Care Facilities --- Mississippi, North Carolina, and Los Angeles County, California, 2003—2004. MMWR 2005; 54(09):220-223.



RECOMMENDED INFECTION-CONTROL AND SAFE INJECTION PRACTICES TO PREVENT PATIENT-TO-PATIENT TRANSMISSION OF BLOODBORNE PATHOGENS

Hand hygiene and gloves

- Wear gloves during fingerstick glucose monitoring and during any other procedure that involves potential exposure to blood or body fluids.
- Change gloves between patient contacts. Change gloves that have touched potentially blood-contaminated objects or fingerstick wounds before touching clean surfaces.
- Remove and discard gloves in appropriate receptacles after every procedure that involves potential exposure to blood or body fluids, including fingerstick blood sampling.
- Perform hand hygiene (i.e., hand washing with soap and water or use of an alcohol-based hand rub) immediately after removal of gloves and before touching other medical supplies intended for use on other residents.

Medical management

- Review regularly the individual patients' schedules for fingerstick blood glucose sampling and insulin administration and reduce the number of percutaneous procedures to the minimum necessary for appropriate medical management of diabetes and its complications.
- Assure that adequate staffing levels are maintained to perform all scheduled diabetes care procedures, including fingerstick blood glucose monitoring.
- Consider the diagnosis of acute viral hepatitis infection in LTC residents who develop an illness that includes hepatic dysfunction or elevated aminotransaminase levels (AST or ALT).

Training and oversight

- Provide a full hepatitis B vaccination series to all previously unvaccinated LTC staff persons whose activities involve contact with blood or body fluids. Check and document post-vaccination titers one to two months after completion of the vaccination series.
- Establish responsibility for oversight of infection control activities. Investigate and report any suspected case that may represent a newly acquired bloodborne infection.
- Have staff demonstrate knowledge of standard precautions guidelines and proficiency in application of these guidelines during procedures that involve possible blood or body fluid exposures.
- Provide staff members who assume responsibilities involving percutaneous procedures with infection control training that includes practical demonstration of aseptic techniques and instruction regarding reporting exposures or breaches. Direct annual retraining to all staff members who perform procedures that involve exposure to blood or body fluids.
- Assess compliance with infection control recommendations for fingerstick glucose monitoring (such as hand hygiene and glove changes between patients) by periodically observing personnel and tracking use of supplies.

CDC. Transmission of Hepatitis B Virus Among Persons Undergoing Blood Glucose Monitoring in Long-Term-Care Facilities --- Mississippi, North Carolina, and Los Angeles County, California, 2003—2004. MMWR 2005; 54(09):220-223.



CMS Manual System

Pub. 100-07 State Operations Provider Certification

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

Transmittal 55

Date: December 2, 2009

Transmittal 54, dated November 30, 2009, is being rescinded and replaced by Transmittal 55 dated December 2, 2009. The C. difficile can survive in the environment (e.g., on floors, bed rails or around toilet seats) in its spore form for up to 6 months. Rigorously cleaning the environment removes C. difficile spores, and can help prevent transmission of the organism.ⁱ Cleaning equipment used for residents with C. difficile with a 1:10 dilution of sodium hypochlorite (nine parts water to one part bleach) will also reduce the spread of the organism. Once mixed, the solution is effective for 24 hours. Previously, a portion of this information was incorrectly stated and is now corrected. All other information in this instruction remains the same.

SUBJECT: Revisions to Appendix PP – “Interpretive Guidelines for Long-Term Care Facilities,” Tag F441”

I. SUMMARY OF CHANGES: This instruction combines F Tags 441, 442, 443, 444 and 445, and incorporates the guidance into Tag F441. This was done to bring everything that relates to infection control into one location to best utilize the surveyors time and resources.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: September 30, 2009
IMPLEMENTATION DATE: September 30, 2009

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/§483.65(a)/Infection Control/Tag F441
R	Appendix PP/§483.65(b)/Preventing Spread of Infection/Tag F441
R	Appendix PP/§483.65(c)/Linens/Tag F441
D	Appendix PP/§483.65(b)/Preventing Spread of Infection/Tag F442
D	Appendix PP/§483.65(b)(2)/Tag F443
D	Appendix PP/§493.65(b)(3)/Tag F444
D	Appendix PP/§493.65(c)/Linens/Tag F445

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.**

ⁱ Mayfield, J.L., Leet, T., Miller, J., and Mundy, L.M. (2000, Oct. 25). Environmental control to reduce transmission of Clostridium Difficile. Clinical Infectious Disease. 2000;31. Pp.998

F441

(Rev.55, Issued: 12-02-09 Effective: 09-30-09, Implementation: 09-30-09)

§483.65 Infection Control

The facility must establish and maintain an Infection Control Program designed to provide a safe, sanitary and comfortable environment and to help prevent the development and transmission of disease and infection.

§483.65(a) Infection Control Program

The facility must establish an Infection Control Program under which it –

- (1) Investigates, controls, and prevents infections in the facility;**
- (2) Decides what procedures, such as isolation, should be applied to an individual resident; and**
- (3) Maintains a record of incidents and corrective actions related to infections.**

§483.65(b) Preventing Spread of Infection

- (1) When the Infection Control Program determines that a resident needs isolation to prevent the spread of infection, the facility must isolate the resident.**
- (2) The facility must prohibit employees with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit the disease.**
- (3) The facility must require staff to wash their hands after each direct resident contact for which hand washing is indicated by accepted professional practice.**

§483.65(c) Linens

Personnel must handle, store, process and transport linens so as to prevent the spread of infection.

INTENT: (F441) 42CFR 483.65 Infection Control

The intent of this regulation is to assure that the facility develops, implements, and maintains an Infection Prevention and Control Program in order to prevent, recognize, and control, to the extent possible, the onset and spread of infection within the facility. The program will:

- Perform surveillance and investigation to prevent, to the extent possible, the onset and the spread of infection;*

- *Prevent and control outbreaks and cross-contamination using transmission-based precautions in addition to standard precautions;*
- *Use records of infection incidents to improve its infection control processes and outcomes by taking corrective actions, as indicated;*
- *Implement hand hygiene (hand washing) practices consistent with accepted standards of practice, to reduce the spread of infections and prevent cross-contamination; and*
- *Properly store, handle, process, and transport linens to minimize contamination.*

DEFINITIONS

Definitions are provided to clarify terminology or terms related to infection control practices in nursing homes.

- *“**Airborne precautions**” refers to actions taken to prevent or minimize the transmission of infectious agents/organisms that remain infectious over long distances when suspended in the air. These particles can remain suspended in the air for prolonged periods of time and can be carried on normal air currents in a room or beyond, to adjacent spaces or areas receiving exhaust air.¹*
- *“**Alcohol-based hand rub**” (ABHR) refers to a 60-95 percent ethanol or isopropyl-containing preparation base designed for application to the hands to reduce the number of viable microorganisms.*
- *“**Antifungal**” refers to a medication used to treat a fungal infection such as athlete’s foot, ringworm or candidiasis.*
- *“**Anti-infective**” refers to a group of medications used to treat infections.*
- *“**Antiseptic hand wash**” is “washing hands with water and soap or other detergents containing an antiseptic agent.”²*
- *“**Cohorting**” refers to the practice of grouping residents infected or colonized with the same infectious agent together to confine their care to one area and prevent contact with susceptible residents (cohorting residents). During outbreaks, healthcare personnel may be assigned to a cohort of residents to further limit opportunities for transmission (cohorting staff).*
- *“**Colonization**” refers to the presence of microorganisms on or within body sites without detectable host immune response, cellular damage, or clinical expression.*

- **“Communicable disease”** (also known as [a.k.a.] “Contagious disease”) refers to an infection transmissible (as from person-to-person) by direct contact with an affected individual or the individual's body fluids or by indirect means (as by a vector).
- **“Community associated infections”** (formerly “Community Acquired Infections”) refers to infections that are present or incubating at the time of admission, or generally develop within 72 hours of admission.
- **“Contact precautions”** are measures that are “intended to prevent transmission of infectious agents, including epidemiologically important microorganisms, which are spread by direct or indirect contact with the resident or the resident’s environment.”³
- **“Droplet precautions”** refers to actions designed to reduce/prevent the transmission of pathogens spread through close respiratory or mucous membrane contact with respiratory secretions.⁴
- **“Hand hygiene”** is a general term that applies to washing hands with water and either plain soap or soap/detergent containing an antiseptic agent; or thoroughly applying an alcohol-based hand rub (ABHR).
- **“Hand washing”** refers to washing hands with plain (i.e., nonantimicrobial) soap and water.
- **“Health care associated infection [HAI]”** (a.k.a. “nosocomial” and “facility-acquired” infection) refers to an infection that generally occurs after 72 hours from the time of admission to a health care facility.
- **“Infection”** refers the establishment of an infective agent in or on a suitable host, producing clinical signs and symptoms (e.g., fever, redness, heat, purulent exudates, etc).
- **“Infection prevention and control program”** refers to a program (including surveillance, investigation, prevention, control, and reporting) that provides a safe, sanitary and comfortable environment to help prevent the development and transmission of infection.
- **“Infection preventionist (IP)”** (a.k.a. infection control professional) refers to a person whose primary training is in either nursing, medical technology, microbiology, or epidemiology and who has acquired additional training in infection control.
- **“Isolation”** refers to the practices employed to reduce the spread of an infectious agent and/or minimize the transmission of infection.
- **“Isolation precautions”** see “Transmission-Based Precautions”

- **“Medical waste”** refers to any solid waste that is generated in the diagnosis, treatment, or immunization of human beings or animals, in research pertaining to, or in the production or testing of biologicals (e.g., blood-soaked bandages, sharps).
- **“Methicillin resistant staphylococcus aureus (MRSA)”** refers to *Staphylococcus aureus* bacteria that are resistant to treatment with semi-synthetic penicillins (e.g., Oxacillin/Nafcillin/Methicillin).
- **“Multi-Drug resistant organisms (MDROs)”** refers to microorganisms, predominantly bacteria, that are resistant to one or more classes of antimicrobial agents. Although the names of certain MDROs describe resistance to only one agent, these pathogens are frequently resistant to most available antimicrobial agents.⁵
- **“Outbreak”** is the occurrence of more cases of a particular infection than is normally expected, the occurrence of an unusual organism, or the occurrence of unusual antibiotic resistance patterns.⁶
- **“Personal protective equipment” (PPE)** refers to protective items or garments worn to protect the body or clothing from hazards that can cause injury.
- **“Standard precautions”** (formerly “Universal Precautions”) refers to infection prevention practices that apply to all residents, regardless of suspected or confirmed diagnosis or presumed infection status. Standard Precautions is a combination and expansion of Universal Precautions and Body Substance Isolation (a practice of isolating all body substances such as blood, urine, and feces).⁷
- **“Surveillance”** refers to the ongoing, systematic collection, analysis, interpretation, and dissemination of data to identify infections and infection risks, to try to reduce morbidity and mortality and to improve resident health status.
- **“Transmission-based precautions”** (a.k.a. “Isolation Precautions”) refers to the actions (precautions) implemented, in addition to standard precautions, that are based upon the means of transmission (airborne, contact, and droplet) in order to prevent or control infections.
- **“Vancomycin resistant enterococcus (VRE)”** refers to enterococcus that has developed resistance to vancomycin.

OVERVIEW

Infections are a significant source of morbidity and mortality for nursing home residents and account for up to half of all nursing home resident transfers to hospitals. Infections result in an estimated 150,000 to 200,000 hospital admissions per year at an estimated cost of \$673 million to \$2 billion annually. When a nursing home resident is hospitalized with a primary diagnosis of infection, the death rate can reach as high as 40 percent.

It is estimated that an average of 1.6 to 3.8 infections per resident occur annually in nursing homes. Urinary tract, respiratory (e.g., pneumonia and bronchitis), and skin and soft tissue infections (e.g., pressure ulcers) represent the most common endemic infections in residents of nursing homes.⁸ Other common infections include conjunctivitis, gastroenteritis, and influenza.⁹

Confirming and managing an infectious outbreak can be costly and time consuming. An effective facility-wide infection prevention and control program can help to contain costs and reduce adverse consequences. An effective program relies upon the involvement, support, and knowledge of the facility's administration, the entire interdisciplinary team, residents, and visitors.

Critical aspects of the infection prevention and control program include recognizing and managing infections at the time of a resident's admission to the facility and throughout their stay, as well as following recognized infection control practices while providing care (e.g., hand hygiene, handling and processing of linens, use of standard precautions, and appropriate use of transmission-based precautions and cohorting or separating residents). It is important that residents' conditions be reassessed because older adults may have coexisting diseases that complicate the diagnosis of an infection (e.g., joint degeneration vs. infectious arthritis, COPD versus pneumonia), and they may also have atypical or non-specific signs and symptoms related to infections, such as altered mental status, function or behavior, and impaired fever response.

Because of the potential negative impact that a resident may experience as a result of the implementation of special precautions, the facility is challenged to promote the individual resident's rights and well-being while trying to prevent and control the spread of infections.

NOTE: *It is important that all infection prevention and control practices reflect current Centers for Disease Control (CDC) guidelines.*

INFECTION PREVENTION AND CONTROL PROGRAM

An effective infection prevention and control program is necessary to control the spread of infections and/or outbreaks.

Program Development and Oversight

Program development and oversight emphasize the prevention and management of infections. Program oversight involves establishing goals and priorities for the program, planning, and implementing strategies to achieve the goals, monitoring the implementation of the program

(including the interdisciplinary team's infection control practices), and responding to errors, problems, or other identified issues. Additional activities involved in program development and oversight may include but are not limited to:

- *Identifying the staff's roles and responsibilities for the routine implementation of the program as well as in case of an outbreak of a communicable disease, an episode of infection, or the threat of a bio-hazard attack;*
- *Developing and implementing appropriate infection control policies and procedures, and training staff on them;*
- *Monitoring and documenting infections, including tracking and analyzing outbreaks of infection as well as implementing and documenting actions to resolve related problems;*
- *Defining and managing appropriate resident health initiatives, such as:*
 - *The immunization program (influenza, pneumonia, etc); and*
 - *Tuberculosis screening on admission and following the discovery of a new case, and managing active cases consistent with State requirements;*
- *Providing a nursing home liaison to work with local and State health agencies; and*
- *Managing food safety, including employee health and hygiene, pest control, investigating potential food-borne illnesses, and waste disposal.*

The facility identifies personnel responsible for overall program oversight, which may involve collaboration of the administrator, the medical director or his/her designee, the director of nursing, and other appropriate facility staff as needed. This group may define how and when the program is to be routinely monitored and situations that may trigger a focused review of the program. The group communicates the findings from collecting and analyzing data to the facility's staff and management, and directs changes in practice based on identified trends, government infection control advisories, and other factors.

Components of an Infection Prevention and Control Program

An effective infection prevention and control program incorporates, but is not limited to, the following components:

- *Policies, procedures, and practices which promote consistent adherence to evidence-based infection control practices;*
- *Program oversight including planning, organizing, implementing, operating, monitoring, and maintaining all of the elements of the program and ensuring that the facility's interdisciplinary team is involved in infection prevention and control;*

- *Infection preventionist, a person designated to serve as coordinator of the infection prevention and control program;*
- *Surveillance, including process and outcome surveillance, monitoring, data analysis, documentation and communicable diseases reporting (as required by State and Federal law and regulation);*
- *Education, including training in infection prevention and control practices, to ensure compliance with facility requirements as well as State and Federal regulation; and*
- *Antibiotic review including reviewing data to monitor the appropriate use of antibiotics in the resident population.*

Examples of activities related to the Infection Prevention and Control Program may include but are not limited to:

- *Undertaking process and/or outcome surveillance activities to identify infections that are causing, or have the potential to cause an outbreak;*
- *Conducting data analysis to help detect unusual or unexpected outcomes and to determine the effectiveness of infection prevention and control practices;*
- *Documenting observations related to the causes of infection and/or infection trends; and*
- *Implementing measures to prevent the transmission of infectious agents and to reduce risks for device and procedure-related infections.*

Policies and Procedures

Policies and procedures are the foundation of the facility's infection prevention and control program. Policies and procedures are reviewed periodically and revised as needed to conform to current standards of practice or to address specific facility concerns.

Written policies establish the program's expectations and parameters. For example, policies may specify the use of standard precautions facility-wide and use of transmission-based precautions when indicated, define the frequency and nature of surveillance activities, require that staff use accepted hand hygiene after each direct resident contact for which hand hygiene is indicated, or prohibit direct resident contact by an employee who has an infected skin lesion or communicable disease.

Procedures guide the implementation of the policies and performance of specific tasks. Procedures may include, for example, how to identify and communicate information about residents with potentially transmissible infectious agents, how to obtain vital signs for a resident on contact precautions and what to do with the equipment after its use, and essential steps and considerations (including choosing agents) for performing hand hygiene.

Infection Preventionist (IP)

A facility may designate an IP to serve as the coordinator of an Infection Prevention and Control Program. Responsibilities may include collecting, analyzing, and providing infection data and trends to nursing staff and health care practitioners; consulting on infection risk assessment, prevention, and control strategies; providing education and training; and implementing evidence-based infection control practices, including those mandated by regulatory and licensing agencies, and guidelines from the Centers for Disease Control and Prevention..

Surveillance

Essential elements of a surveillance system include use of standardized definitions and listings of the symptoms of infections, use of surveillance tools such as infection surveys and data collection templates, walking rounds throughout the facility,¹⁰ identification of segments of the resident populations at risk for infection, identification of the processes or outcomes selected for surveillance, statistical analysis of data that can uncover an outbreak, and feedback of results to the primary caregivers so that they can assess the residents for signs of infection.

Two types of surveillance (process and outcome) can be implemented in facilities.

Process Surveillance

Process surveillance reviews practices directly related to resident care¹⁰ in order to identify whether the practices comply with established prevention and control procedures and policies based on recognized guidelines. Examples of this type of surveillance include monitoring of compliance with transmission based precautions, proper hand hygiene,¹¹ and the use and disposal of gloves. Process surveillance determines, for example, whether the facility:

- Minimizes exposure to a potential source of infection;*
- Uses appropriate hand hygiene prior to and after all procedures;¹²*
- Ensures that appropriate sterile techniques are followed; for example, that staff:*
 - Use sterile gloves, fluids, and materials, when indicated,¹³ depending on the site and the procedure;¹⁴*
 - Avoid contaminating sterile procedures;¹⁵ and*
 - Ensure that contaminated/non-sterile items are not placed in a sterile field.*
- Uses Personal Protective Equipment (PPE) when indicated;¹⁶*
- Ensures that reusable equipment is appropriately cleaned, disinfected, or reprocessed; and*
- Uses single-use medication vials and other single use items appropriately (proper disposal after every single use).¹⁷*

Outcome Surveillance

In contrast to process surveillance, outcome surveillance is designed to identify and report evidence of an infection. The outcome surveillance process consists of collecting/documenting data on individual cases and comparing the collected data to standard written definitions (criteria) of infections. The IP or other designated staff reviews data (including residents with fever or purulent drainage, and cultures or other diagnostic test results consistent with potential infections) to detect clusters and trends. Other sources of relevant data may include antibiotic orders, laboratory antibiograms (antibiotic susceptibility profiles), medication regimen review reports, and medical record documentation such as physician progress notes and transfer summaries accompanying newly admitted residents.¹⁸ The facility's program should choose to either track the prevalence of infections (existing/current cases both old and new) at a specific point, or focus on regularly identifying new cases during defined time periods. When conducting outcome surveillance, the facility may choose to use one or more of the automated systems and authoritative resources that are available, and include definitions.

Documentation

Facilities may use various approaches to gathering, documenting, and listing surveillance data. The facility's infection control reports describe the types of infections and are used to identify trends and patterns. Descriptive documentation provides the facility with summaries of the observations of staff practices and/or the investigation of the causes of an infection and/or identification of underlying cause(s) of infection trends.

It is important that the infection prevention and control program define how often and by what means surveillance data will be collected, regardless of whether the facility creates its own forms, purchases preprinted forms, or uses automated systems.

Monitoring

Monitoring of the implementation of the program, its effectiveness, the condition of any resident with an infection, and the resolution of the infection and/or an outbreak is considered an integral part of nursing home infection surveillance. The facility monitors practices (e.g., dressing changes and transmission-based precaution procedures) to ensure consistent implementation of established infection prevention and control policies and procedures based on current standards of practice. All residents are monitored for current infections and infection risks.

Data Analysis

Determining the origin of infections helps the facility identify the number of residents who developed infections within the nursing home. Comparing current infection control surveillance data (including the incidence or prevalence of infections and staff practices) to past data enables detection of unusual or unexpected outcomes, trends, effective practices, and performance issues. The facility can then evaluate whether it needs to change processes or practices to enhance infection prevention and minimize the potential for transmission of infections.

It is important that surveillance reports be shared with appropriate individuals including, but not limited to, the director of nursing and medical director. In addition, it is important that the staff and practitioners receive reports that are relevant to their practices to help them recognize the impact of their care on infection rates and outcome.

Communicable Disease Reporting

It is important for each facility to have processes that enable them to consistently comply with State and local health department requirements for reporting communicable diseases.

Education

Both initial and ongoing infection control education help staff comply with infection control practices. Updated education and training are appropriate when policies and procedures are revised or when there is a special circumstance, such as an outbreak, that requires modification or replacement of current practices.¹⁹ In addition to education regarding general infection control principles, some infection control training is discipline and task specific (e.g., insertion of urinary catheters, suctioning, intravenous care or blood glucose monitoring). Follow-up competency evaluations identify staff compliance.

Essential topics of infection control training include, but are not limited to routes of disease transmission, hand hygiene, sanitation procedures, MDROs, transmission-based precaution techniques, and the federally required OSHA education.

Antibiotic Review

Because of increases in MDROs, review of the use of antibiotics (including comparing prescribed antibiotics with available susceptibility reports) is a vital aspect of the infection prevention and control program. It is the physician's (or other appropriate authorized practitioner's) responsibility to prescribe appropriate antibiotics and to establish the indication for use of specific medications. As part of the medication regimen review, the consultant pharmacist can assist with the oversight by identifying antibiotics prescribed for resistant organisms or for situations with questionable indications, and reporting such findings to the director of nursing and the attending physician. See the Guidance at §483.65, Tag F329 regarding use of a medication without adequate indication for use and at §483.65, Tag F428 regarding medication regimen review.

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.²⁰ 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;²⁰*
- *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. Devices labeled by the manufacturer for single use are never to be reused, even if they are reprocessed.

Prevention and Control of Transmission of Infection

Infectious organisms (e.g., bacteria, viruses, or parasites) may be transmitted by direct contact (e.g., skin to skin) or indirect contact (e.g., via air, water, inanimate objects). Healthcare personnel and resident care equipment often move from resident to resident and therefore may serve as a vehicle for transferring infectious organisms. Another potential challenge is that the transmission of infectious organisms within the facility may be facilitated by inadequate hand hygiene facilities, rinsing bed pans in inappropriate places (e.g., resident's sink), or inappropriate placement of colonized or infected residents (e.g., sharing a bathroom with a non-infected resident).

*Airborne transmission can occur by inhaling pathogenic droplet nuclei (e.g., *M Tuberculosis*). Contaminated environmental surfaces are also potential reservoirs for infections. Infections caused by bacteria and viruses are especially common. *Clostridium difficile* can live on inanimate surfaces for up to 5 months²¹ while the hepatitis B virus can last up to a week²² and the influenza virus can survive on fomites (e.g., any inanimate object or substance capable of carrying infectious organisms and transferring them from one individual to another) for up to 8 hours.²³*

The appropriate disposal of waste helps minimize the potential transmission of infections. It is important for the facility to monitor safe handling of blood and body fluids and the disposal of contaminated waste.

General Approaches to Prevention and Control

A facility's infection control practices are important to preventing the transmission of infections. Infection control precautions used by the facility include two primary tiers: "Standard Precautions" and "Transmission-Based Precautions."

Standard Precautions

Standard precautions are based upon the principle that all blood, body fluids, secretions, excretions (except sweat), non-intact skin, and mucous membranes may contain transmissible infectious agents. Standard precautions are intended to be applied to the care of all persons in all healthcare settings, regardless of the suspected or confirmed presence of an infectious agent. Implementation of standard precautions constitutes the primary strategy for preventing healthcare-associated transmission of infectious agents among residents and healthcare personnel. Appropriate infection control measures should be used in each resident interaction.

Standard precautions include but are not limited to hand hygiene, safe injection practices, the proper use of PPE (e.g., gloves, gowns, and masks), resident placement, and care of the environment, textiles, and laundry. Also, equipment or items in the resident environment likely to have been contaminated with infectious fluids or other potentially infectious matter must be handled in a manner so as to prevent transmission of infectious agents, (e.g., wear gloves for handling soiled equipment, and properly clean and disinfect or sterilize reusable equipment before use on another resident).²⁴ In addition to proper hand hygiene, it is important for staff to use appropriate protective equipment as a barrier to exposure to any body fluids (whether known to be infected or not). For example, in situations identified as appropriate, gloves and other equipment such as gowns and masks are to be used as necessary to control the spread of infections. Standard precautions are also intended to protect residents by ensuring that healthcare personnel do not carry infectious agents to residents on their hands or via equipment used during resident care.

Disposal of waste is also handled as though all body fluids are infectious. Potentially contaminated articles are stored and disposed of in appropriate containers (e.g., sharps containers, biohazard bags, etc.), and the environment is cleaned using germicidal agents to reduce the risk of transmission of infection.

Hand Hygiene

Hand hygiene continues to be the primary means of preventing the transmission of infection. The following is a list of some situations that require hand hygiene:

- *When coming on duty;*
- *When hands are visibly soiled (hand washing with soap and water); Before and after direct resident contact (for which hand hygiene is indicated by acceptable professional practice);*
- *Before and after performing any invasive procedure (e.g., fingerstick blood sampling);*
- *Before and after entering isolation precaution settings;*
- *Before and after eating or handling food (hand washing with soap and water);*
- *Before and after assisting a resident with meals;*
- *Before and after assisting a resident with personal care (e.g., oral care, bathing);*
- *Before and after handling peripheral vascular catheters and other invasive devices;*
- *Before and after inserting indwelling catheters;*
- *Before and after changing a dressing;*

- *Upon and after coming in contact with a resident's intact skin, (e.g., when taking a pulse or blood pressure, and lifting a resident);*
- *After personal use of the toilet (hand washing with soap and water);*
- *Before and after assisting a resident with toileting (hand washing with soap and water);*
- *After contact with a resident with infectious diarrhea including, but not limited to infections caused by norovirus, salmonella, shigella, and C. difficile (hand washing with soap and water);*
- *After blowing or wiping nose;*
- *After contact with a resident's mucous membranes and body fluids or excretions;*
- *After handling soiled or used linens, dressings, bedpans, catheters and urinals;*
- *After handling soiled equipment or utensils;*
- *After performing your personal hygiene (hand washing with soap and water);*
- *After removing gloves or aprons; and*
- *After completing duty.*

Consistent use by staff of proper hygienic practices and techniques is critical to preventing the spread of infections. It is necessary for staff to have access to proper hand washing facilities with available soap (regular or anti-microbial), warm water, and disposable towels and/or heat/air drying methods. Alcohol based hand rubs (ABHR) cannot be used in place of proper hand washing techniques in a food service setting.²⁵

Recommended techniques for washing hands with soap and water include wetting hands first with clean, running warm water, applying the amount of product recommended by the manufacturer to hands, and rubbing hands together vigorously for at least 15 seconds covering all surfaces of the hands and fingers; then rinsing hands with water and drying thoroughly with a disposable towel; and turning off the faucet on the hand sink with the disposable paper towel.

Except for situations where hand washing is specifically required, antimicrobial agents such as ABHR are also appropriate for cleaning hands and can be used for direct resident care. Recommended techniques for performing hand hygiene with an ABHR include applying product to the palm of one hand and rubbing hands together, covering all surfaces of hands and fingers, until the hands are dry. In addition, gloves or the use of baby wipes are not a substitute for hand hygiene.

Other Staff-Related Preventive Measures

Facility staff who have direct contact with residents or who handle food must be free of communicable diseases and open skin lesions, if direct contact will transmit the disease. It is important that the facility maintain documentation of how they handle staff with communicable infections or open skin lesions.

It is important that all staff involved in direct resident contact maintain fingernails that are clean, neat, and trimmed. Wearing intact disposable gloves in good condition and that are changed after each use helps reduce the spread of microorganisms. It is important for dietary staff to wear hair restraints (e.g., hairnet, hat, and/or beard restraint) while in the kitchen areas to prevent their hair from contacting exposed food. Since jewelry can harbor microorganisms, it is recommended by the FDA that dietary staff keep jewelry to a minimum and remove or cover hand jewelry when handling food.²⁶

Transmission-based Precautions

Transmission-based precautions are used for residents who are known to be, or suspected of being infected or colonized with infectious agents, including pathogens that require additional control measures to prevent transmission. In nursing homes, it is appropriate to individualize decisions regarding resident placement (shared or private), balancing infection risks with the need for more than one occupant in a room, the presence of risk factors that increase the likelihood of transmission, and the potential for adverse psychological impact on the infected or colonized resident.²⁷

It is essential both to communicate transmission-based precautions to all health care personnel, and for personnel to comply with requirements. Pertinent signage (i.e., isolation precautions) and verbal reporting between staff can enhance compliance with transmission-based precautions to help minimize the transmission of infections within the facility.

It is important to use the standard approaches, as defined by the CDC for transmission-based precautions: airborne, contact, and droplet precautions.²⁸ The category of transmission-based precaution determines the type of PPE to be used. Communication (e.g., verbal reports, signage) regarding the particular type of precaution to be utilized is important. When transmission-based precautions are in place, PPE should be readily available. Proper hand washing remains a key preventive measure, regardless of the type of transmission-based precaution employed.

Transmission-based precautions are maintained for as long as necessary to prevent the transmission of infection. It is appropriate to use the least restrictive approach possible that adequately protects the resident and others. Maintaining isolation longer than necessary may adversely affect psychosocial well-being. The facility should document in the medical record the rationale for the selected transmission-based precautions.

Airborne Precautions

*Airborne precautions prevent the transmission of organisms that remain infectious when suspended in the air (e.g., varicella zoster (shingles) and *M. tuberculosis*). Resident health*

activities related to infection control include tuberculosis (TB) screening and management of active cases, consistent with State requirements. Management of some airborne infections such as active TB requires a single-resident airborne infection isolation room (AIIR) that is equipped with special air handling and ventilation capacity. Although not all residents with airborne infections will require an AIIR, residents with infections requiring an AIIR may need to be transported to an acute care setting unless the facility can place the resident in a private AIIR room with the door closed. In cases when AIIR is required it is important for the facility to have a plan in place to effectively manage a situation involving a resident with suspected or active TB while awaiting the resident's transfer to an acute care setting.

Personnel caring for residents on airborne precautions should wear a mask or respirator that is donned prior to room entry, depending on the disease-specific recommendations.²⁹ Depending on the condition, staff can use N95 or higher level respirators or wear masks if respirators are not available.

Contact Precautions

Contact transmission risk requires the use of contact precautions to prevent infections that are spread by person-to-person contact. Contact precautions require the use of appropriate PPE, including a gown and gloves upon entering the contact precaution room. Prior to leaving the contact precaution room the PPE is removed and hand hygiene is performed.

Depending on the situation, options for residents on contact precautions may include the following: a private room, cohorting, or sharing a room with a roommate with limited risk factors (e.g., without indwelling devices, without pressure ulcers and not immunocompromised).

Droplet Precautions

In contrast to contact transmission, respiratory droplets transmit infections directly from the respiratory tract of an infected individual to susceptible mucosal surfaces of the recipient. Since this generally occurs at close proximity, facial protection is necessary. Respiratory droplets are generated when an infected person coughs, sneezes, or talks; or during procedures such as suctioning, endotracheal intubation, cough induction by chest physiotherapy, and cardiopulmonary resuscitation. Studies have shown that respiratory viruses can enter the body via the nasal mucosa, conjunctivae and less frequently the mouth.³⁰ Examples of droplet-borne organisms that may cause infections include, but are not limited to influenza and mycoplasma.

The maximum distance for droplet transmission is currently unresolved, but the area of defined risk based on epidemiological findings is approximately 3-10 feet.³¹ In contrast to airborne pathogens, droplet-borne pathogens are generally not transmitted through the air over long distances. Masks are to be used within approximately 6 to 10 feet of a resident or upon entry into a resident's room with respiratory droplet precautions. Residents with droplet precautions are placed in either a private room, cohorted, or share a room with a roommate with limited risk factors.

Implementation of Transmission-Based Precautions

It is important that facility staff clearly identify the type of precautions and the appropriate PPE to be used in the care of the resident. The PPE should be readily available near the entrance to the resident's room. Signage can be posted on the resident's door instructing visitors to see the nurse before entering.

It is not always possible to identify prospectively residents needing transmission-based precautions. The diagnosis of many infections is based on clinical signs and symptoms, but often requires laboratory confirmation. However, since laboratory tests (especially those that depend on culture techniques) may require two or more days to complete, transmission-based precautions may need to be implemented while test results are pending, based on the clinical presentation and the likely category of pathogens.³² The use of appropriate transmission-based precautions when a resident develops symptoms or signs of a transmissible infection or arrives at a nursing home with symptoms of an infection (pending laboratory confirmation) reduces transmission opportunities. However, once it is confirmed that the resident is no longer a risk for transmitting the infection, removing transmission-based precautions avoids unnecessary social isolation.

Safe Water Precautions

Safe drinking water is also critical to controlling the spread of infections. The facility is responsible for maintaining a safe and sanitary water supply, by meeting nationally recognized standards set by the FDA for drinking water (<500 CFU/mL per heterotrophic plate count).

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 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.

Detergent and water physically remove many microorganisms from the 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°F (71°C) for 25 minutes.³³ 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.³⁴

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.

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.³⁵

RECOGNIZING AND CONTAINING OUTBREAKS

It is important that facilities know how to recognize and contain infectious outbreaks. An outbreak is typically one or more of the following:³⁶

- *One case of an infection that is highly communicable;*
- *Trends that are 10 percent higher than the historical rate of infection for the facility that may reflect an outbreak or seasonal variation and therefore warrant further investigation; or*

- Occurrence of three or more cases of the same infection over a specified length of time on the same unit or other defined areas.

Once an outbreak has been identified, it is important that the facility take the appropriate steps to contain it. State health departments offer guidance and regulations regarding responding to and reporting outbreaks. This information is often received in advance of an outbreak and included in the infection prevention and control program. Plans for containing outbreaks usually include efforts to prevent further transmission of the infection while considering the needs of all residents and staff.³⁶

PREVENTING SPREAD OF ILLNESS RELATED TO MDROs

The MDROs found in facilities include, but are not limited to MRSA, VRE, and clostridium difficile (*C. difficile*). Transmission-based precautions are employed for residents who are actively infected with multi-drug resistant organisms. Aggressive infection control measures and strict compliance by healthcare personnel can help minimize the spread of MDROs to other susceptible individuals.³⁷

Staphylococcus is a common cause of infections in hospitals and nursing homes, and increasingly in the community. Common sites of MRSA colonization include the rectum, perineum, skin and nares.³⁸ Colonization may precede or endure beyond an acute infection. MRSA is transmitted person-to-person (most common), and on inanimate objects.

The MRSA infection is commonly treated with vancomycin, which in turn can lead to increased enterococcus antibiotic resistance. Therefore, preventing infection with MRSA and the limited use of antibiotics for individuals who are only colonized can also help prevent the development of VRE. Enterococcus is an organism that normally occurs in the colorectal tract. VRE infections have been associated with prior antibiotic use.

C. difficile is a bacterial species of the genus clostridium, which are gram-positive, anaerobic, spore-forming rods (bacilli). The organism normally lives benignly in the colon in spore form. When antibiotic use eradicates normal intestinal flora, the organism may become active and produce a toxin that causes symptoms such as diarrhea, abdominal pain, and fever. More severe cases can lead to additional complications such as intestinal damage and severe fluid loss. Treatment options include stopping antibiotics and starting specific anticlostridial antibiotics, e.g., metronidazole or oral vancomycin. If a resident has diarrhea due to *C. difficile*, large numbers of *C. difficile* organisms will be released from the intestine into the environment and may be transferred to other individuals, causing additional infections.

Contact precautions are instituted for residents with symptomatic *C. difficile* infection. Thorough hand washing with soap and water after caring for the resident reduces the risk of cross-transmission. Another control measure is to give the resident his or her own toilet facilities that will not be shared by other residents.

The *C. difficile* can survive in the environment (e.g., on floors, bed rails or around toilet seats) in its spore form for up to 6 months. Rigorously cleaning the environment removes *C. difficile* spores, and can help prevent transmission of the organism.³⁹ Cleaning equipment used for

residents with *C. difficile* with a 1:10 dilution of sodium hypochlorite (nine parts water to one part bleach) will also reduce the spread of the organism. Once mixed, the solution is effective for 24 hours.

PREVENTING INFECTIONS RELATED TO THE USE OF SPECIFIC DEVICES

Intravascular catheters are used widely to provide vascular access, and are increasingly seen in nursing homes. While providing such access, they may increase the risk for local and systemic infections and additional complications such as septic thrombophlebitis.

Central venous catheters (CVCs) have also been associated with infectious complications. Other intravascular catheters such as dialysis catheters and implanted ports may be accessed multiple times per day, such as for hemodynamic measurements, or to obtain samples for laboratory analysis, thus increasing the risk of contamination and subsequent clinical infection. Limiting access to central venous catheters for only the primary purpose may help reduce the risk of infection.

Consistent use of appropriate infection control measures when caring for residents with vascular access catheters reduces the risk for catheter-related infections.⁴⁰ Surveillance consistently includes all residents with vascular access, including those with venous access and implanted ports such as peripherally inserted central catheter lines, and midline access catheters. Activities to reduce infection risk includes surveillance such as observation of insertion sites, routine dressing changes, use of appropriate PPE and hand hygiene during the care and treatment of residents with venous catheters, and review of the resident for clinical evidence of infection.⁴⁰ It is important that practices reflect the most current CDC guidelines.

ENDNOTES

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INVESTIGATIVE PROTOCOL FOR INFECTION CONTROL

Objectives

- *To determine if the facility has an infection prevention and control program that prevents, investigates, and controls infections in the facility, and determines appropriate procedures to be applied to a resident with an infection;*
- *To determine if the facility has a program that collects information regarding infections acquired in the facility, analyzes the information and develops a plan of action to prevent further infections;*
- *To determine if staff practices are consistent with current infection control principles and prevent cross-contamination (e.g., laundry and hand hygiene practices); and*
- *To determine whether staff with communicable disease or open lesions are prohibited, as appropriate, from direct contact with the resident.*

Use

Use this protocol to investigate compliance at F441 for every initial certification and recertification survey. In addition, use this protocol on revisit or abbreviated surveys (complaint investigations) when indicated.

Procedures

The surveyor(s), throughout the survey, should conduct the following observations, interviews and record reviews. In addition, the surveyor(s) should also review the facility's infection control policies, procedures, as well as documentation of staff training, and as necessary, interview facility staff with responsibility for oversight of the infection prevention and control program.

1. Observations

Observe various disciplines (nursing, dietary, and housekeeping) to determine if they follow appropriate infection control practices and transmission based precaution procedures. Observe, for example, whether:

- *Linens are handled, processed, transported, and stored to prevent contamination and the transmission of infection;*
- *Employees exhibit overt signs of illness or communicable disease that have the potential to transmit disease (e.g., cold symptoms, infected, open lesions on hands) and if present, whether they are prohibited from contact with the resident or the resident's food;*
- *Staff and visitors adhere to precautions and related processes, including the use of PPE;*

- *Precautions/accommodations are in place and followed (as recommended, e.g., gowns, singles rooms or adequate space between residents, exclusion from group activities, etc.) for residents with potentially transmissible infections;*
- *Staff utilize appropriate precautions when residents on special precautions are permitted out of their rooms,(e.g., mask on resident with TB in the halls, wound drainage contained); and*
- *Staff involved in the care and management of residents with special needs, e.g., urinary catheters (also note characteristics of urine, which may indicate potential infection), wound care, respiratory treatments, and residents on ventilators, receiving IVs, or with tracheotomies follow current accepted infection control standards of practice.*

Also, observe residents for signs and symptoms of potential infection, such as:

- *Elevated respiratory rate or labored breathing, coughing, congestion;*
- *Vomiting or loss of appetite, diarrhea;*
- *Skin rash, reddened or draining eyes, wound drainage; and*
- *Frequency/urgency of urination, malodorous urine.*

Observe for cleaning and disinfecting to determine whether:

- *Equipment in transmission based precaution rooms is either dedicated to that resident and appropriately cleaned or is thoroughly cleaned and disinfected between residents using appropriate agents and procedures;*
- *High touch surfaces in the environment are visibly soiled (i.e., contaminated) or have been cleaned and disinfected;*
- *Small non-disposable equipment such as glucose meters, scissors, and thermometers are cleaned and appropriately disinfected after each use for individual resident care;*
- *Single-use items (e.g., blood glucose lancet, other sharps) are properly disposed of after one use;*
- *Single resident use items (e.g., basins, bed pans) are maintained to be visibly clean for use, and are disposed of after use by a single resident;*
- *Resident dressings and supplies are properly stored to maintain their integrity, and soiled dressings and supplies are appropriately discarded; and*
- *Multiple use items (e.g., shower chairs, bedside scales, resident lifts, commodes, tubs) are properly cleaned/disinfected between each resident use.*

Observe whether hand hygiene and use of gloves (when indicated) is in accordance with current standards. Hand hygiene should occur before and after putting on sterile gloves and after taking off all gloves during all resident care that requires the use of gloves. This includes:

- *Medication administration (e.g., eye drops, sublinguals, and injections);*
- *Dressing changes that require the use of gloves (e.g., anticipated contact with body fluid, excretions, tissue and specimens);*
- *Insertion or removal of a catheter; and*
- *Any invasive procedure.*

Note the availability of gloves and the equipment and products to perform hand hygiene.

Interview

During the resident review, interview the resident, family or responsible party to the extent possible to identify, as appropriate, whether they have received education and information about infection control practices, such as appropriate hand hygiene and any special precautions applicable to the resident.

Interview direct care staff to determine:

- *Whether they are aware of and have reported any signs or symptoms exhibited by the resident that may be associated with an infection;*
- *Whether they are aware of and have been instructed on any special precautions that are applicable to any resident on transmission based precautions;*
- *Whether they are familiar with the indications for washing hands and/or using alcohol based products and understand the basis for the use of gloves and when they are to be removed;*
- *How staff know which residents are covered by transmission-based precautions; and*
- *Whether staff is aware of what specific actions are required for each type of transmission-based precautions.*

Record Review

Review the resident's record to determine, for example:

- *Whether the resident's record included an evaluation of the factors which may increase a resident's risk of infection (e.g., indwelling urinary catheters, intravenous catheters, and*

tracheostomy tubes), and if an infection is present, whether the resident's record reflects the identification of the infection, potential causes and contributing factors; and

- *Whether the resident's plan of care identifies interventions (device management and isolation precaution measures) to prevent the transmission of infection.*

Review the facility's record of incidents of infection and related corrective actions to help determine whether the facility is identifying, recording, and analyzing infections.

In order to investigate identified infection control concerns, review, as applicable, the facility's:

- *Infection control policies to determine if they are consistent with current professional standards of practice and if the infection control policies are defined by department (e.g., dietary, nursing, laundry);*
- *Documentation of whether and how the infection prevention and control program collects, analyzes, and uses data and implements a program to guide all disciplines to prevent the spread of infections and identify infections in a standardized and systematic way;*
- *Policies regarding handling and processing soiled linens as well as handling, transporting, and storing clean linens;*
- *Applied preventive components of the infection prevention and control program in the care of individual residents;*
- *Policies, procedures, and documentation regarding identifying and prohibiting contact with residents or food by employees with open lesions or communicable diseases and addressing occupational communicable disease exposure and post-exposure follow up;*
- *Employee records to determine if employees receive initial and ongoing employee infection control training regarding critical elements of the infection control plan; and*
- *Documentation related to their review of the appropriateness and effectiveness of antibiotics for residents that are identified as receiving antibiotics.*

Interview the Designated Infection Control Representative

If concerns are identified, (e.g., practices are not consistent with accepted principles of infection control or residents are exhibiting symptoms of infections, but have not been assessed or surveillance data are not available or being utilized) interview the facility staff members who are responsible for implementing and overseeing the infection prevention and control program. Investigate as appropriate, for example, whether:

- *The facility identifies where infections are acquired (e.g., nursing home, hospital, or community);*
- *The infection prevention and control program includes any review, in addition to the medication regimen review, of whether antibiotic use in the nursing home is appropriate and effective;*
- *Staff training includes critical areas of infection control such as hand hygiene, areas for improvement from surveillance data, and appropriate use of protective equipment and isolation precautions; how staff are apprised of changes in policies and procedures;*
- *The facility collects, analyzes, and uses data related to infections, to identify and prevent the spread of infections and to adjust its infection prevention and control program,(e.g., policies and procedures) as appropriate;*
- *The program implements processes to identify and address infection control issues and to monitor staff hand hygiene and sterile technique, and the implementation and discontinuation of transmission-based or other isolation precautions and cohorting or separating, as applicable;*
- *The facility appropriately implements and discontinues transmission based precaution procedures, and communicates initiation and discontinuation of these transmission-based precaution policies across departments;*
- *The facility has in place effective means to identify individuals (residents, staff, visitors, volunteers, practitioners) with infections;*
- *The facility has policies and procedures addressing linen handling and how it monitors how linens are stored, transported, and processed to prevent the spread of infection;*
- *The infection prevention and control program identifies and addresses infection control issues, for example whether the facility's infection control practices are consistent with CDC recommendations; and*
- *The facility effectively identifies and prevents employees with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit the disease.*

DETERMINATION OF COMPLIANCE CRITERIA FOR COMPLIANCE

Synopsis of Regulation (F441)

Criteria for Compliance

The facility is in compliance with 42 CFR 483.65 Infection Control if:

- *The infection prevention and control program demonstrates ongoing surveillance, recognition, investigation and control of infections to prevent the onset and the spread of infection, to the extent possible;*
- *The facility demonstrates practices to reduce the spread of infection and control outbreaks through transmission-based precautions (e.g., isolation precautions);*
- *The facility demonstrates practices and processes (e.g., intravenous catheter care, hand hygiene) consistent with infection prevention and prevention of cross-contamination;*
- *The facility demonstrates that it uses records of incidents to improve its infection control processes and outcomes by taking corrective action;*
- *The facility has processes and procedures to identify and prohibit employees with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit the disease;*
- *The facility consistently demonstrates appropriate hand hygiene (e.g., hand washing) practices, after each direct resident contact as indicated by professional practice; and*
- *The facility demonstrates handling, storage, processing and transporting of linens so as to prevent the spread of infection.*

If not, cite at Tag F441.

Noncompliance for F441

After completing the Investigative Protocol, analyze the data in order to determine whether noncompliance with the regulation exists. Noncompliance for Tag F441 may include, but is not limited to, failure to do one or more of the following:

- *Develop an infection prevention and control program;*
- *Utilize infection precautions to minimize the transmission of infection;*
- *Identify and prohibit employees with a communicable disease from direct contact with a resident;*
- *Demonstrate proper hand hygiene;*
- *Properly dispose of soiled linens;*
- *Demonstrate the use of surveillance; or*
- *Adjust facility processes as needed to address a known infection risk.*

Potential Tags for Additional Investigation

During the investigation of F441, the surveyor may have identified concerns with additional outcome, process, and/or structure requirements. The surveyor is cautioned to investigate these related requirements before determining whether non-compliance may be present. Examples of some related requirements that may be considered when non-compliance at F441 has been identified include the following:

- *42 CFR §483.20(b), F272, Comprehensive Assessments*
 - *If the infection or risks were present at the time of the required comprehensive assessment, determine whether the facility comprehensively assessed the resident's physical, mental, and psychosocial needs to identify the risks and/or to determine underlying causes (to the extent possible) of the resident's condition and the impact upon the resident's function, mood, and cognition.*
- *42 CFR §483.20(b), F274, Significant Change Assessments*
 - *If there was a significant change in the infection or risk to the resident's condition, determine whether the facility did a significant change comprehensive assessment within 14 days.*
- *42 CFR §483.20(k)(1)(i), F279, Comprehensive Care Plan*
 - *Determine if the facility developed a care plan consistent with the resident's specific infection status, risks, needs, behaviors, and current standards of practice and included measurable objectives and timetables, and specific interventions/services to prevent the onset and/or transmission of infection.*
- *42 CFR §483.20(k)(2)(iii), F280, Comprehensive Care Plan Revision*
 - *Determine whether staff reassessed the effectiveness of the interventions and review and revised the plan of care (with input from the resident or representative, to the extent possible), if necessary, to meet the needs of the resident.*
- *42 CFR §483.25(l), F329, Unnecessary Drugs*
 - *Determine if the facility has reviewed with the prescriber the rationale for placing the resident on an antibiotic to which the organism seems to be resistant or when the resident remains on antibiotic therapy without adequate monitoring or appropriate indications, or for an excessive duration.*
- *42 CFR §483.25(l)(2)(n), F334, Influenza and Pneumococcal Immunizations*

- *Determine if the facility has systems in place to immunize residents against influenza and pneumococcal infections.*
- *42 CFR §483.35(i)(2), F371, Sanitary Conditions*
 - *Determine if the facility has implemented processes to prevent infection transmission via food handling, storing and delivery systems.*
- *42 CFR 483.75(f) (F498) Proficiency of Nurse Aides*
 - *Determine whether the nurse aides demonstrate the knowledge and skills regarding use of accepted infection control principles, e.g., hand hygiene, transmission barriers, signs and symptoms of infection to report to the nurse, etc.*

V. DEFICIENCY CATEGORIZATION (PART IV, APPENDIX P)

Once the team has completed its investigation, analyzed the data, reviewed the regulatory requirements, and determined that noncompliance exists, the team must determine the severity of each deficiency, based on the resultant effect or potential for harm to the resident.

The key elements for severity determination for Tag F441 are as follows:

- 1. Presence of harm/negative outcome(s) or potential for negative outcomes due to a failure of care and services.** *Actual or potential harm/negative outcomes for F441 may include but are not limited to facility failure to:*
 - *Properly implement transmission based precautions when indicated resulting in an increase (or potential) of infections or communicable diseases;*
 - *Develop and implement corrective actions despite recording an increase in infections in the facility;*
 - *Recognize and act on an increase or trend in infections within the facility;*
 - *Prohibit employees with symptoms of active communicable infections from continuing to provide resident care or have direct contact with food;*
 - *Properly perform hand hygiene when entering and exiting the room of a resident on special precautions; and*
 - *Recognize and investigate a resident's complaints of rash and pruritis resulting in additional resident's requiring treatment for scabies.*
- 2. Degree of harm (actual or potential) related to the noncompliance.** *Identify how the facility practices caused, resulted in, allowed, or contributed to the actual or potential for harm:*

- *If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise, or discomfort; and*
- *If harm has not yet occurred, determine how likely the potential is for serious injury, impairment, death, compromise or discomfort to occur to the resident.*

3. The immediacy of correction required. *Determine whether the noncompliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.*

The survey team must evaluate the harm or potential for harm based upon the following levels of severity for this tag. First, the team must rule out whether Severity Level 4, immediate jeopardy to a resident's health or safety exists by evaluating the deficient practice in relation to immediacy, culpability, and severity. (Follow the guidance in Appendix Q.)

Severity Level 4 Considerations: Immediate jeopardy to resident health or safety

Immediate jeopardy is a situation in which the facility's noncompliance:

- *With one or more requirements of participation has caused/resulted in, or is likely to cause, serious injury, harm, impairment, or death to a resident; and*
- *Requires immediate correction as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.*

NOTE: *The death or transfer of a resident who was harmed as a result of facility practices, does not remove a finding of immediate jeopardy. The facility is required to implement specific actions to correct the deficient practices which allowed or caused the immediate jeopardy.*

Examples of negative outcomes that occurred or have 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 sugars. The facility did not clean and disinfect the glucometers before or after use and/or did not use new glucometer lancets on residents who required blood sugar monitoring. This practice of not cleaning and disinfecting glucometers between every use and re-using glucometer lancets created an Immediate Jeopardy to resident health by potentially exposing residents to the spread of blood borne infections for multiple residents in the facility who required blood sugar testing.*
- *The facility failed to restrict a staff member with a documented open, draining and infected skin lesion that was colonized with MRSA from working without adequately covering the area, resulting in MSRA transmission and infection of one or more residents under that staff person's care.*

- *The facility failed to investigate, document surveillance of and try to contain an outbreak of gastrointestinal illness among residents; as a result, additional residents became ill with diarrheal illnesses.*

NOTE: *If immediate jeopardy has been ruled out based upon the evidence, then evaluate whether actual harm that is not immediate jeopardy exists at Severity Level 3 or the potential for more than minimal harm at Level 2 exists.*

Severity Level 3 Considerations: Actual Harm that is not Immediate Jeopardy

Level 3 indicates noncompliance that results in actual harm that is not immediate jeopardy. The negative outcome can include, but may not be limited to clinical compromise, decline, or the resident's inability to maintain and/or reach his/her highest practicable well-being.

Examples of avoidable actual resident outcomes that demonstrate severity at Level 3 may include, but are not limited to:

- *The facility routinely sent urine cultures of asymptomatic residents with indwelling catheters, putting residents with positive cultures on antibiotics, resulting in two residents acquiring antibiotic-related colitis and significant weight loss.*
- *The facility failed to institute internal surveillance for adherence to hand washing procedures or pertinent reminders to staff regarding appropriate respiratory precautions during an influenza outbreak, resulting in additional cases of influenza in residents on another, previously unaffected unit or section of the facility.*

NOTE: *If Severity Level 3 (actual harm that is not immediate jeopardy) has been ruled out based upon the evidence, then evaluate as to whether Severity Level 2 (no actual harm with the potential for more than minimal harm) exists.*

Severity Level 2 Considerations: No Actual Harm with potential for more than minimal harm that is not Immediate Jeopardy

Level 2 indicates noncompliance that results in a resident outcome of no more than minimal discomfort and/or has the potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well being. The potential exists for greater harm to occur if interventions are not provided.

For Level 2 severity, the resident was at risk for, or has experienced the presence of one or more outcome(s). Examples of avoidable outcomes include, but are not limited to:

- *The facility failed to ensure that their staff demonstrates proper hand hygiene between residents to prevent the spread of infections. The staff administered medications to a resident via a gastric tube and while wearing the same gloves proceeded to administer oral medications to another resident. The staff did not remove the used gloves and wash or sanitize their hands between residents.*

- *The facility failed to implement a surveillance program including the investigation of infections or attempt to distinguish facility-acquired infections from community-acquired infections.*
- *The facility identified issues related to staff infection control practices, as part of its infection prevention and control program, but did not follow up to identify the cause, and institute measures to correct the problems.*

Severity Level 1: No actual harm with potential for minimal harm

The failure of the facility to provide appropriate care and services for infection control practices places the resident at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.