

§483.65 Infection Control (F441)

Surveyor Training of Trainers: Interpretive Guidance Investigative Protocol

Tags Collapsed

- With regard to the revised guidance F441 Infection Control, there have been significant changes. Namely, F Tags 441, 442, 443, 444, and 445 have been collapsed into this single guidance at F441. However, the regulatory language has remained the same.

Federal Regulatory Language

§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;

§483.65(a) Infection Control Program

- 2) Decides what procedures, such as isolation, should be applied to an individual resident; and

§483.65(a) Infection Control Program

- 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.

§483.65(b) Preventing Spread of Infection

- 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.

§483.65(b) Preventing Spread of Infection

- 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

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.

§483.65 Infection Control Interpretive Guidelines Background

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 occur an average of 2 to 4 times per year for each nursing home resident.

Endemic Infections in Nursing Home Residents

Most Frequently Occurring:

- Urinary tract
- Respiratory
- Skin and Soft Tissue

Other Commonly Occurring:

- Conjunctivitis
- Gastroenteritis
- Influenza

Critical Aspects of Infection Prevention and Control Programs

- Recognizing and managing infections at the time of a resident's admission to the facility and throughout their stay
- Following recognized infection control practices while providing care

Considerations

It can be difficult to promote the individual resident's rights and well-being while trying to prevent and control the spread of infections.

Components of an Infection Prevention and Control Program

- Program Development and Oversight
- Policies and Procedures
- Infection Preventionist
- Surveillance
- Documentation
- Monitoring
- Data Analysis
- Communicable Disease Reporting
- Education
- Antibiotic Review

Program Development & Oversight: Core Focus

- Establishing goals and priorities
- Monitoring implementation of the program
- Responding to errors, problems, or other identified issues

Program Development and Oversight: Additional Activities

- Identifying roles and responsibilities during routine implementation as well as unusual occurrences or threats of infection
- Defining and managing resident health initiatives
- Managing food safety
- Providing a nursing home liaison to work with local and state health agencies

Program Development and Oversight: Personnel

Personnel are identified as being responsible for overall program oversight.

May include the collaboration of the:

- Administrator
- Medical Director (or a designee)
- Director of Nursing
- Other staff as appropriate

Policies and Procedures

- Written policies establish the program's expectations and parameters
- Procedures guide the implementation of the policies and performance of specific tasks

These serve as the foundation to the program and should undergo periodic review and revision to conform to current standards of practice or to address specific facility concerns

Infection Preventionist (IP)

Serves as the coordinator of the program and responsibilities may include:

- education and training
- collecting, analyzing, and providing infection data and trends to nursing staff and healthcare practitioners;
- consulting on infection risk assessment, prevention, and control strategies

Surveillance

- Essential Elements
- Two Types
 - Process
 - Outcome

Process Surveillance

Process surveillance reviews practices directly related to resident care in order to identify whether the practices are compliant with established prevention, control and policies based on recognized guidelines.

Outcome Surveillance

Outcome surveillance is designed to identify and report evidence of an infectious disease. The outcome surveillance process consists of collecting/documenting data on individual cases and comparing the collected data to standard written definitions (criteria) of infections.

Documentation

- Various approaches to gathering, documenting and listing surveillance data
 - Infection control reports describe the types of infections and are used to identify trends and patterns

It is up to the program to define how often and by what means surveillance data will be collected.

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.

Data Analysis

- Comparing past and present surveillance data enables detection of unusual or unexpected outcomes, trends, effective practices, and performance issues.
- Processes and/or practices can be changed to enhance infection prevention and minimize the potential for transmission of infections.

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 understand and comply with infection control practices.
- In addition to general infection control principles, some infection control training is discipline and task-specific.

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.

Preventing the Spread of Infection

- Individual and institutional factors contribute to the increased frequency and severity of infections in nursing homes
- Modes of transmission include:
 - Contact
 - Droplet
 - Airborne

Individual Factors

- Medications
- Limited physiologic reserve
- Compromised host defenses
- Impaired responses
- Coexisting chronic diseases
- Complications from invasive procedures
- Increased frequency of therapeutic toxicity

Institutional Factors

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

Direct Transmission (Person to Person)

- Direct transmission occurs when microorganisms are transferred from one infected/colonized person to another with a contaminated intermediate object or person.
- Contaminated hands of healthcare personnel are often implicated in direct contact transmission.

Indirect Transmission

- Indirect transmission involves the transfer of an infectious agent through a contaminated intermediate object or person. Examples include:
 - Resident care devices
 - Clothing, including Proper Protective Equipment (PPE)
 - Toilets and bedpans

Indirect Transmission (cont'd)

To reduce or prevent infections transmitted via indirect contact, resident equipment, medical devices, and the environment must be decontaminated.

- Single-use disposable devices may also be used.

Indirect Transmission (cont'd)

- 3 Risk levels associated with instruments commonly used in Nursing Homes
 1. Critical
 2. Semi-Critical
 3. Non-Critical

Prevention and Control of Transmission of Infection: Standard Precautions

- based upon the principle that all blood, body fluids, secretions, excretions (except sweat), non-intact skin, and mucous membranes may contain transmissible infectious agents
- 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

Standard Precautions (cont'd)

Examples of standard precautions include:

- hand hygiene
- safe injection practices
- the proper use of personal protective equipment
- care of the environment, textiles and laundry
- resident placement
- appropriate waste disposal and management

Personal Protective Equipment (PPE)

- PPE includes items such as gloves, gowns, eye protection, and masks
- These items are used as barrier to any body fluids or other potentially infected materials

Hand Hygiene

- Primary means of preventing the transmission of infection
- Requires proper hand washing facilities with available soap (regular or anti-microbial), warm water, and disposable towels and/or heat/air drying methods
- ABHR may be utilized in situations where hand washing with soap and water is not specifically required

Hand Hygiene (cont'd): Technique

1. Wet hands with clean, running warm water
2. Apply the amount of product recommended by the manufacturer to the hands
3. Rub hands together vigorously for at least 15 seconds, covering all surfaces of the hands and fingers
4. Rinse hands with water and dry thoroughly with a disposable towel or heat/air dryer
5. Turn off the faucet on the sink with a disposable paper towel, if available

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.
- Personal hygiene must be maintained in a manner so as to minimize the potential for harboring and/or transmitting infectious organisms.

Transmission-Based Precautions (formerly Isolation Precautions)

- 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.
- It is appropriate to individualize decisions regarding resident placement based on a number of factors.

Transmission-Based Precautions (cont'd)

- Transmission-Based Precautions shall be maintained for only 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.

Airborne Precautions

- Intended to prevent the transmission of organisms that remain infectious when suspended in the air.
 - E.g. varicella zoster [shingles] and M. tuberculosis
- Personnel caring for residents on Airborne Precautions wear a mask or respirator that is donned prior to room entry, depending on the disease-specific recommendations.

Contact Precautions

Contact transmission risk requires the use of contact precautions to prevent infections that are spread by person-to-person contact.

Droplet Precautions

Respiratory droplets transmit infections directly from the respiratory tract of an infected individual to susceptible mucosal surfaces of the recipient.

Interpretive Guidance

Type of Precaution	Type(s) of PPE Required	Resident Placement	Other Considerations
Airborne	Mask or Respirator, Gloves	Private room, Cohorting, Room sharing with limited risk factors	Private AIR room (active TB)
Contact	Gown, Gloves	Private room, Cohorting, Room sharing with limited risk factors	
Droplet	Mask/Facial Protection, Gloves	Private room, Cohorting, Room sharing with limited risk factors	3-10 ft. distance* for transmission

All Transmission-based Precautions require appropriate hand hygiene practices

Implementation of Transmission-Based Precautions

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.

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.

Handling Linens to Prevent and Control Infection 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
- If Standard Precautions for contaminated linens are not used, then some identification with labels, color coding or other alternatives means of communication is needed.

Handling Linens (cont'd)

If linen is sent off to a professional laundry facility, the nursing home facility obtains 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.

Handling Linens (cont'd)

An effective way to destroy microorganisms in laundry items is through hot water washing at temperatures above 160°F (71°C) for 25 minutes. Alternatively, low temperature washing at 71 to 77 degrees F (22-25 degrees C) plus a 125-part-per-million (ppm) chlorine bleach rinse has been found to be effective and comparable to high temperature wash cycles

Handling Linens (cont'd)

- Standard mattresses and pillows can become contaminated with body substances during patient care
 - Clean and disinfect moisture-resistant mattress covers between patients with an EPA approved germicidal detergent. All fabric mattress covers are to be laundered between patients.
 - Launder pillow covers and washable pillows in hot water cycle between residents or when they become contaminated with body substances.

Recognizing and Containing Outbreaks

- An outbreak is typically one of the following:
 - 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.
 - Occurrence of three or more cases of the same infection over a specified length of time on the same unit or other defined areas.

Recognizing and Containing Outbreaks (cont'd)

- 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.
 - Plans for containing outbreaks usually include efforts to prevent further transmission of the infection

Prevention of the Spread of Illness Related to Multidrug Resistant Organisms (MDROs)

- Common MDROs include MRSA, VRE, and Clostridium Difficile
- Transmission-based precautions are employed for all MDROs
- Aggressive infection control measures and strict compliance can help minimize transmission of MDROs

MRSA

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

VRE

- Enterococcus is an organism that normally occurs in the colorectal tract.
- VRE is an infection with enterococcus organisms that have developed resistance to the antibiotic Vancomycin
- Preventing infection with MRSA and the limited use of antibiotics for individuals who are only colonized can also help prevent the development of VRE

Clostridium Difficile (C. difficile)

- C. difficile is a bacterial species of the genus Clostridium, which are gram-positive, anaerobic, spore-forming rods (bacillus).
- 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.

Clostridium Difficile (cont'd)

- More severe cases can lead to additional complications such as intestinal damage and severe fluid loss.
- 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.

Clostridium Difficile (cont'd)

- Contact Precautions are instituted for residents with symptomatic *C. difficile* infection
 - Another control measure is to give the resident his or her own toilet facilities that will not be shared by other residents
- *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

Preventing Infections Related to the Use of Specific Devices

- Intravascular catheters
 - used widely to provide vascular access
 - increasingly seen in nursing homes
 - 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.

Preventing Infections Related to the Use of Specific Devices (cont'd)

- Limit access to central venous catheters for only the primary purpose
- Consistently use appropriate infection control measures
 - surveillance
 - observation of insertion sites

Preventing Infections Related to the Use of Specific Devices (cont'd)

- Consistently use appropriate infection control measures
 - routine dressing changes
 - use of appropriate PPE and hand hygiene
 - review of resident for clinical evidence of infection

Investigative Protocol Objectives determine if

- The facility has an Infection Prevention and Control Program that prevents, investigates and controls infections in the facility
- The facility has a program that collects and analyzes data regarding infections acquired in the facility
- Staff practices are consistent with current infection control principles
- staff with communicable diseases are prohibited from direct contact with resident

Procedures

- Observations
- Interviews
- Record Reviews
- Review of Facility Practices

Observe Staff

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

Observe Residents for

- Signs and symptoms of potential infections such as
 - Coughing and/or congestion
 - Vomiting or loss of appetite
 - Skin rash, reddened or draining eyes

Observe Cleaning and Disinfecting to determine:

- If equipment in Transmission Based Precaution rooms are appropriately cleaned
- If high touch surfaces in the environment are visibly soiled
- If small non-disposable equipment are cleaned

Observe Staff practice to determine:

- How single-use items are properly disposed of;
- How single resident use items are maintained
- How resident dressings and supplies are properly stored
- If multiple use items are properly cleaned/disinfected between each resident

Observe Hand Hygiene and use of gloves during:

- Resident care that requires use of gloves;
- Medication administration;
- Dressing changes and all resident care that requires use of gloves.
- Assisting Residents with Meals.

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.

Record Review

Review facility documents and interview staff to establish if the facility has processes and practices to promote infection control and prevention the spread of infectious diseases.

Determination of Compliance 483.65 Infection Control

Did the facility:

- Demonstrate practices to prevent the spread of infections ?
- Demonstrate practices to control outbreaks?

Criteria for Compliance with F441

The facility is in compliance if staff:

- Demonstrates ongoing surveillance, recognition, investigation and control of infections to prevent the onset and the spread of infection;
- Demonstrates practices and processes consistent with infection prevention and prevention of cross-contamination;

Criteria for Compliance with F441 (cont'd)

The facility is in compliance if staff:

- Demonstrates that it uses records of incidents to improve its infection control processes and outcomes by taking corrective action;
- Uses procedures to identify and prohibit employees with a communicable disease or infected skin lesions from direct contact with residents;

Criteria for Compliance with F441

The facility is in compliance if staff:

- Demonstrates appropriate hand hygiene practices, after each direct resident contact; and
- Demonstrates handling, storage, processing and transporting of linens so as to prevent the spread of infection.

Noncompliance with F441

May include, but is not limited to, one or more of the following, failure to:

- Develop an Infection Control and Prevention Program in accordance with the standards summarized in this guidance

Noncompliance with F441 (cont'd)

Failure to:

- 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;

Noncompliance with F441 (cont'd)

- **Failure to:**
- Demonstrate the use of surveillance; and
- Adjust facility processes as needed to address a known infection risk.

DEFICIENCY CATEGORIZATION (Part IV, Appendix P) Severity Determination Key Components

- Harm/negative outcome(s) or potential for negative outcomes due to a failure of care and services,
- Degree of harm (actual or potential) related to noncompliance, and
- Immediacy of correction required.

Determining Actual or Potential Harm

Actual or potential harm/negative outcomes for F441 may include:

- Onset of infections in the facility
- Spread of infection within the facility
- An infection outbreak in the facility

Determining Degree of Harm

How the facility practices caused, resulted in, allowed, or contributed to harm (actual/potential)

- 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.

Level 4 Immediate Jeopardy

- **Has allowed/caused/resulted in, or is likely to cause serious injury, harm, impairment, or death to a resident; and**

Level 4 Immediate Jeopardy (cont'd)

- Requires immediate correction, as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.

Level 4 Example

The facility failed to clean the spring-loaded lancet devices before or after use and reused lancet devices on residents who required blood sugar monitoring. This practice of re-using lancet devices 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.

Severity Level 3 Actual Harm that is *not* Immediate Jeopardy

The negative outcome may include but may not be limited to clinical compromise, decline, or the resident's inability to maintain and/or reach his/her highest practicable level of well-being.

Level 3 Example

The facility routinely sent urine cultures of asymptomatic residents with indwelling catheters, putting residents with positive cultures on antibiotics, resulting in two residents who get antibiotic-related colitis and significant weight loss.

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

- 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.

Level 2 Example

The facility failed to ensure that their staff demonstrate 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.

Level 1 No Actual Harm with Potential for Minimal Harm

The failure of the facility to develop, implement and maintain an infection prevention and control program to prevent, recognize, and control the onset and spread of infections places this highly susceptible population at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

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Questions?