

§483.80 Infection Control (F441)

**Surveyor Training
Interpretive Guidance
Investigative Protocol
Cindy Deporter
Updated 1/17**

Federal Regulatory Language

§483.80 Infection Control

The facility must establish and maintain an infection ***prevention and*** control program designed to provide a safe, sanitary and comfortable environment and to help prevent the development and transmission of ***communicable*** disease and infection.

§483.80(a) Infection Control Program

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

Program Elements:

- ***1) A system for preventing, identifying, reporting, investigation and controlling infections and communicable diseases for all residents, staff, volunteers, visitors and other individuals providing services under a contractual arrangement base upon the facility assessment conducted according to 483.70 (e) and following accepted national standards:***
- ***(As linked to Facility Assessment 483.70(e) will be implemented beginning November 28, 2017 (Phase 2)***

Programs Elements...

- (2) Written standards, policies, and procedures for the program, which must include, but are not limited to:***
- (i) A system of surveillance designed to identify possible communicable diseases or infections before they can spread to other persons in the facility;***
 - (ii) When and to whom possible incidents of communicable disease or infections should be reported;***
 - (iii) Standard and transmission-based precautions to be followed to prevent spread of infections;***

Program elements....

- *(iv) When and how isolation should be used for a resident; including but not limited to:*
 - *(A) The type and duration of the isolation, depending upon the infectious agent or organism involved, and*
 - *(B) A requirement that the isolation should be the least restrictive possible for the resident under the circumstances.*
 - *(v) The circumstances under which* 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; *and*
 - *(vi) The hand hygiene procedures to be followed by staff involved in direct resident contact.*

Program Elements....

- ***(3) An antibiotic stewardship program that includes antibiotic use protocols and a system to monitor antibiotic use.***
- ***[\$483.80(a)(3) will be implemented beginning November 28, 2017 (Phase 2)]***
- ***(4) A system for recording incidents identified under the facility's IPCP and the corrective actions taken by the facility.***



***§483.80 (b) Infection preventionist
[§483.80(b) and all subparts will be implemented beginning
November 28, 2019 (Phase 3)]***

- Remember in NC we have a State Law that requires that you have a designated staff to be the Infection Preventionist
- We already require in NC most of this under state law.



483.80(b) Infection Preventionist: all subparts implemented beginning 11/28/19

The facility must designate one or more individual(s) as the infection Preventionist(s) (IP)(s) who is responsible for the facility's IPCP. The IP must:

- (1) Have primary professional training in nursing, medical technology, microbiology, epidemiology, or other related field;***
- (2) Is qualified by education, training, experience or certification;***
- (3) Works at least part-time at the facility; and***
- (4) Has completed specialized training in infection prevention and control. NC SPICE Program***

§483.80 (c) IP participation on QA and A Committee (beginning November 28, 2019 (Phase 3))

- ***The individual designated as the IP, or at least one of the individuals if there is more than one IP, must be a member of the facility's quality assessment and assurance committee and report to the committee on the IPCP on a regular basis.***
- ***[§483.95(c) will be implemented beginning November 28, 2019 (Phase 3)]***

483.80 (c) continued...

- ***(e) Linens. Personnel must handle, store, process, and transport linens so as to prevent the spread of infection.***
- ***(f) Annual review. The facility will conduct an annual review of its IPCP and update their program, as necessary.***

§483.80(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.

§483.80(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.

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.

- Surveyors are looking for the following:

Infection Prevention and Control Program Infrastructure

- Does the facility have written infection prevention and control policies and procedures which are based on current evidenced based guidelines, regulations or standards?
CDC/HICPAC
- Does the facility have evidence of mandatory personnel training which includes the policy and procedures?

Surveyor Questions

- Does the facility have documentation of a facility infection control risk assessment conducted according to infection control standards of practices?
- Does the facility have a documentation of an annual review of Infection Control Procedures of both the facility and community and update these as necessary?

Infection Control Preventionist

- Has the facility designated one individual to be the Infection Prevention and Control staff?
- Has this person attended the required state training course?
- Is the Infection Control designated staff a member of the QA committee?
- NC State Statutes require the facility to designate a staff and the staff take this course.

483.70e: Facility Assessment

- ***The facility must conduct and document a facility-wide assessment to determine what resources are necessary to care for its residents competently during both day-to-day operations and emergencies. The facility must review and update that assessment, as necessary, and at least annually. The facility must also review and update this assessment whenever there is, or the facility plans for, any change that would require a substantial modification to any part of this assessment. The facility assessment must address or include:***

§483.95(e) *Infection control.*

- A facility must include as part of its infection prevention and control program mandatory training that includes the written standards, policies, and procedures for the program as described at §483.80(a)(2).
- *[§483.95(e) will be implemented beginning November 28, 2019 (Phase 3)]*

§483.95(d) *Quality assurance and performance improvement.*

- A facility must include as part of its QAPI program mandatory training that outlines and informs staff of the elements and goals of the facility's QAPI program as set forth at § 483.75.
- *[\$483.95(d) will be implemented beginning November 28, 2019 (Phase 3)]*

The logo for the Centers for Medicare & Medicaid Services (CMS). It features the letters "CMS" in a bold, blue, italicized sans-serif font. A thick yellow diagonal line crosses the letters from the top right to the bottom left. Below the letters, a thin yellow horizontal line spans the width of the text.

CENTERS for MEDICARE & MEDICAID SERVICES

Survey expectations

QUALITY ASSURANCE

QAA Committee

- The committee has a system for identifying incidents of communicable disease and infections?
- The QA committees plan includes monitoring and evaluation of the infection control program in the facility
- There is evidences that the QAA committee develops plans of action to address resident safety incidents and staff adherence to infection prevention practices and antibiotic stewardship that is provided by the Infection Control Program

§483.75(g) Quality assessment and assurance.

[\$483.75(g)(1)(i)-(iii) will be implemented beginning November 28, 2016 (Phase 1)]

- (iii) At least **three** other members of the facility's staff, **at least one of who must be the administrator, owner, a board member or other individual in a leadership role; and**
- (iv) **The infection control and prevention officer.**

QAA committee

- Evidence that adverse events related to breaches in infection prevention practices are analyzed using root cause analysis in order to promote sustainable practice improvement throughout the facility?
- The facility has a written surveillance plan based on the risk assessment, outlining the activities for monitoring/tracking infections occurring in residents of the facility

QAA Committee

- The facility has a system in place for early detection and management of potentially infectious symptomatic residents at the time of admission including implementation of precautions as appropriate. (c-diff, or antibiotic resistant organisms)

QAA

- Does the facility has a system in place (e.g., notification of IPCO by clinical laboratory) for early detection and management of potentially infectious symptomatic residents identified **during their stay** in the facility including implementation of precautions as appropriate.



What surveyors look for!

Surveillance Practices

- Use of published surveillance criteria (e.g., 2012 CDC National Healthcare Safety Network (NHSN) Long Term Care Criteria) to define infections.
- Use of a data collection tool.
- Periodic (e.g. minimally quarterly) based on the risk analysis of the ongoing review, an analysis and summary of the surveillance data presented to the QAA Committee.
- Follow-up activity in response to surveillance data (e.g. outbreaks).
- Report summarizing surveillance data annually.

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.

- Contacting the health department if there is need.

Communication with the hospital

- Does the facility have a process for obtaining results and diagnosis of infection when residents are transferred **back** from acute care hospitals.
- Does the facility have a process to provide diagnosis, antibiotic use, and test results when transferring a resident **to** an acute care hospital or other healthcare provider.

Communication

- The facility can demonstrate knowledge of when and to whom to report communicable diseases, healthcare associated infections (as appropriate), and potential outbreaks.

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.

- Long term antibiotics should have clear physician documentation as to the rationale.

Antibiotic Stewardship Programs

- Does the facility have an antibiotic stewardship program to improve antibiotic use?
- Does the facility have written protocols on antibiotic prescribing.
- Does the facility track through a reporting mechanism antibiotic resistance



Hand Hygiene

Hand Hygiene

- The facility hand hygiene (HH) policies promote preferential use of alcohol-based hand rub (ABHR) over soap and water in all clinical situations except when hands are visibly soiled (e.g., blood, body fluids) or after caring for a resident with known or suspected *C. difficile* or norovirus during an outbreak or if endemic rates of *C. difficile* infection (CDI) are high.

Hand Hygiene

- Facility has written and implemented a resident HH policy. Surveyor Observations
- Hand hygiene is performed in a manner consistent with the nursing home infection control practices, policies, and procedures to maximize the prevention of infection and communicable disease

Hand Hygiene

- Soap, water, and a sink are readily accessible in appropriate locations including, but not limited to, resident care areas, food and medication preparation areas.

Hand Hygiene

- Alcohol-based hand rub is readily accessible and placed in appropriate locations. These may include:
- Entrances to resident rooms,
- At the bedside (as appropriate for resident population),
- In individual pocket-sized containers carriers by healthcare personnel,
- Staff work station, and/or
- Other convenient locations

Hand Hygiene

- Personnel perform hand hygiene (even if gloves are used):
- Before contact with the resident
- Before performing an aseptic task (e.g. insertion of an invasive device e.g. urinary catheter)

Hand Hygiene

- Personnel perform hand hygiene:
- After contact with the resident
- After contact with blood, body fluids, or visibly contaminated surfaces
- After contact with objects and surfaces in the resident's environment
- After removing personal protective equipment (e.g., gloves, gown, facemask)

Hand Hygiene

- When being assisted by healthcare personnel, resident hand hygiene is performed:
 - Prior to resident leaving room if on transmission-based precautions
 - After toileting
 - Before meals

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.



Survey Expectations

STANDARD PRECAUTIONS

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

Standard Precautions

- Supplies necessary for adherence to proper PPE use (e.g., gloves, gowns, masks) are readily accessible in resident care areas (i.e., nursing units, therapy rooms).
- Gloves worn if contact with blood or body fluid, mucous membranes, or non-intact skin.

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

Standard Precautions

- Gloves removed after contact with blood or body fluids, mucous membranes, or non-intact skin.
- Gloves changed and hand hygiene performed before moving from a contaminated-body site to a clean-body site during resident care.

Standard Precautions

- Gown worn for direct resident contact if the resident has uncontained secretions or excretions.
- Facemasks worn if contact with residents with new acute cough or respiratory symptoms (e.g. influenza-like illness).
- Appropriate mouth, nose and eye protection (e.g., facemasks, face shield) is worn for performing aerosol-generating and/or procedures that are likely to generate splashes or sprays of blood or body fluids.

Standard Precautions

- PPE appropriately discarded after resident care prior to leaving room followed by hand hygiene.

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.

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.
 - Facilities forget to take people off of precautions.

Transmission Based Precautions

- The facility has policies and procedures for transmission-based precautions (i.e. Contact Precautions, Droplet Precautions, Airborne Isolation Precautions) to be followed to prevent spread of infections; which includes selection and use of PPE (e.g., indications, donning/doffing procedures) and specifies the clinical conditions for which specific PPE should be used (e.g., C. difficile, Influenza).

Transmission Based Precautions

- Residents with known or suspected infections or with evidence of symptoms that represent an increased risk for transmission are placed on the appropriate transmission based precautions.
- Note: Resident placement (e.g. single/private room or co-horted) is made on an individual case basis based on presence of risk factors for increased likelihood of transmission (e.g. uncontained drainage, stool incontinence).
- Note: Facility has process to manage residents on transmission based precautions when no single/private room is available.

Transmission based...

- The facility limits the movement of residents (in accordance with policies) on Transmission-based Precaution with active symptoms (diarrhea, nausea and vomiting, draining wounds that cannot be contained for highly infectious diseases (e.g. norovirus, C difficile)) outside of their room to medically necessary purposes only. Resident Rights have to be respected.

Transmission Based.....

- Signs indicating resident is on transmission-based precautions are clear and visible.
- Hand hygiene is performed before entering resident care environment.
- Gloves and gowns are donned upon entry into the room or cubicle of resident on Contact Precautions.

Transmission Based....

- Dedicated or disposable noncritical resident-care equipment (e.g., blood pressure cuffs) is used, or if not available, then equipment is cleaned and disinfected according to manufacturers' instructions prior to use on another resident.
- Gloves and gowns are removed and properly discarded, and hand hygiene is performed before leaving the resident care environment.

Transmission Based...

- In rooms with residents on Contact Precaution, objects and environmental surfaces that are touched frequently (e.g., bed rails, over-bed table, bedside commode, lavatory surfaces in resident bathrooms) are cleaned and disinfected with an EPA-registered disinfectant for healthcare use at least daily and when visibly soiled.



General Survey Information

SAFE INJECTION PRACTICES

Safe Injection Practices

- Appropriate personnel receive training and competency validation on injection safety procedures at time of employment.
- The facility audits (monitors and documents) and provides feedback to personnel regarding their adherence to injection safety practices
- Injections are prepared using clean (aseptic) technique in an area that has been cleaned and is free of contamination (e.g., visible blood, or body fluids).

Safe Injection Practices

- Needles are used for only one resident.
- Syringes are used for only one resident (this includes manufactured prefilled syringes).
- Insulin pens are used for only one resident.
- The rubber septum on all medications vials, whether unopened or previously accessed, is disinfected with alcohol prior to piercing

Safe Injection Practices

- Medication vials are entered with a new needle.
- Medication vials are entered with a new syringe.
- Medication vials labeled for single dose – single use is only used for one resident.

Safe Injection Practices

- Bags of IV solutions are used for only one resident (and not as a source of flush solution for multiple residents).
- Medication administration tubing and connectors are used for only one resident.
- Multi-dose medication vials are dated when they are first opened and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial.

Safe Injection Practices

- Multi-dose medication vials used for more than one resident are stored appropriately and do not enter the immediate resident care area (e.g. procedure rooms, resident room).
- All sharps are disposed of in puncture-resistant sharps containers.
- Sharps containers are replaced when the fill line is reached.
- Sharps containers are disposed of appropriately as medical waste. (NC has laws that govern this)



CMS

CENTERS for MEDICARE & MEDICAID SERVICES

General Expectations

CATHETER CARE

Indwelling Catheters

- The attending physician/practitioner provided a written rationale for the use of a urinary catheter consistent with evidence-based guidelines (e.g. acute urinary retention, bladder outlet obstruction, neurogenic bladder or terminally ill for comfort measures).
- Hand hygiene is performed before and after insertion of the urinary catheter.
- Catheter is placed using aseptic technique and sterile equipment.

Indwelling Catheters

- Catheter is secured properly after insertion.
- Catheter insertion date and indication are documented.

Catheter

- Hand hygiene is performed before and after manipulating the catheter and gloves are worn.
- Urine collection bag is kept below the level of the bladder and off the floor at all times.
- Catheter tubing is unobstructed and free of kinking.
- Urine bag is emptied using a separate, clean collection container for each resident; drainage spigot does not touch collecting container.

Catheters

- Urine samples are obtained via needleless port and not obtained from the collection bag.
- Residents with indwelling urinary catheters are assessed regularly, including for its removal, with documentation of continued need for the catheter.



CMS

CENTERS for MEDICARE & MEDICAID SERVICES

General Information

WOUND CARE

Wound Care

- Hand hygiene is performed before procedure.
- Gloves are worn during the dressing procedure.
- Reusable dressing care equipment (e.g., bandage scissors) must be cleaned and reprocessed (i.e., disinfected or sterilized according to manufacturer's instructions) if shared between residents. Refer to current CDC guidelines

Wound Care

- Clean wound dressing supplies are handled in a way to prevent cross contamination between residents (e.g. wound care supply cart which remains outside of resident care areas, unused supplies are discarded or remain dedicated to resident).

Wound Care

- The attending physician/practitioner orders should outline wound treatment, or refer to facilities policies on care of wounds.
- Multi-dose wound care medications (e.g., ointments, creams) should be dedicated to one resident whenever possible.

Wound Care

- Gloves are removed and hand hygiene is performed immediately after the procedure.
- Wound care documentation in resident's medical record includes the following:
 - Type of dressing
 - Frequency of dressing change
 - Wound description (e.g., measurement, characteristics)



Policy and Procedures, Standards of Practice

POINT OF CARE DEVICES

Point of Care Devices

- Appropriate personnel receive training and competency validation on point of care testing procedures at time of employment
- Hand hygiene is performed before and after the procedure for each resident.
- Gloves are worn by healthcare personnel when performing the finger stick procedure to obtain the sample of blood, and are removed after the procedure (followed by hand hygiene).

Point of Care Devices

- Finger stick devices are not used for more than one resident.
 - ***Note: This includes both the lancet and the lancet holding device.***

Glucometers

- If used for more than one resident, the point-of-care testing device (e.g., blood glucose meter, INR monitor) is **cleaned and disinfected** after every use according to manufacturer's instructions.

Point of Care Devices

- Does the facility have protocols for performing finger sticks and point of care testing (e.g., assisted blood glucose monitoring)
- Does the facility have audits (monitors and documents) and provides feedback to personnel regarding their adherence to point of care testing practices



CMS

CENTERS for MEDICARE & MEDICAID SERVICES

General Information

ENVIRONMENTAL CLEANING

Environmental Cleaning And Disinfection

- The facility has cleaning/disinfection policies which include routine and terminal cleaning and disinfection of resident rooms and high-touch surfaces in common areas.
 - *Note: Privacy curtains should be changed after discharged, or cleaned with an EPA approved disinfectant; in addition to as needed.*
- The facility cleaning/disinfection policies include handling of equipment shared among residents (e.g., blood pressure cuffs, rehab therapy equipment, etc.)

Environmental

- Facility has policies and procedures to ensure that reusable medical devices (e.g., wound care equipment, podiatry equipment, and dental equipment) are cleaned and reprocessed appropriately prior to use on another resident
- The facility audits (monitors and documents) and provides feedback to personnel regarding the quality of cleaning and disinfection procedures.



General Information

LINEN MANAGEMENT



Definitions

- Hygienically Clean: means being free of pathogens in sufficient numbers to cause human illness.

Linen Management

- Personnel handle soiled textiles/linens with minimum agitation to avoid contamination of air, surfaces, and persons.
- Soiled textiles/linens are bagged or otherwise contained at the point of collection in leak-proof containers or bags, and are not sorted or rinsed in the location of use.
- The receiving area for contaminated textiles is clearly separated from clean laundry areas.

Linens

- If facility laundry services are contracted out and performed offsite, the contract must show evidence that the contractor's laundry service meets healthcare industry laundry standards.
- The facility should be using the fabric manufacturer's recommended laundry cycles, water temperatures, and chemical/detergent products.

Handling Linens to Prevent and Control Infection Transmission

- 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 to Prevent and Control Infection Transmission

- The CDC recommends leaving washing machines open to air when not in use to allow the machine to dry completely and to prevent growth of microorganisms in wet potentially warm environments.
- Advances in technology allow modern-day detergents to be much more effective in removing soil and reducing the presence of microbes than those used in the past when much of the research on laundry processing was first conducted.

Handling Linens (cont'd)

- Facilities may use any detergent designated for laundry in laundry processing. Further laundry detergents used within facilities are not required to have stated anti-microbial claims. Facilities should closely follow manufacturer's instructions for laundry detergents used.
- CMS in collaboration with the CDC has determined that ozone cleaning systems are acceptable methods of processing laundry and should be used according to manufacturer's instructions.

Laundry

- If linen is sent off to a professional laundry the facility should have an initial agreement between the laundry service and the facility that stipulates the laundry will be hygienically clean and handled to prevent recontamination from duct and dirt during loading and transport.
- The facility should have written policies and procedures which should include training for staff who will handle linens and laundry. (There should be a contract)

Handling Linens

- Laundry washing within facilities typically occurs in a low water temperature environment. Many laundry items are composed of materials that cannot withstand a chlorine bleach rinse and remain intact.
 - A chlorine bleach rinse is not required for all laundry items processed in low temperature washing environments due to the availability of modern laundry detergents that are able to produce hygienically clean laundry without the presence of chlorine bleach.

Handling Linens

- Chlorine bleach rinse may still be used for laundry items composed of materials such as cottons.
- Hot water washing at temperatures greater than 160 degrees F for 25 minutes and low temperature washing at 71 to 77 degrees with a 125 parts per million chlorine bleach rinse continues to be effective to wash laundry.
- If the facility chooses to use hot water temperature environment then it must be at or above 160 degrees for 25 minutes.

Laundry

- Facilities are not required to maintain a record of water temperatures during laundry processing cycles.
- Facilities are required to follow manufacturer's instructions for all materials involved in the laundry processing (washing machines, dryers, any laundry detergents, rinse aides, or other additives employed during the laundry process)

Laundry

- Facilities should follow manufacturer's instructions for clothing, linens and other laundry items to determine the appropriate methods to use to produce a hygienically clean product.
- Facilities should consider a resident's individual needs when selecting methods for processing laundry.

Ozone Systems

- Ozone cleaning systems are acceptable methods of processing laundry. They should be used per manufacture's instructions.

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.
 - items with holes should be replaced

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.



Health Department coordination

OUTBREAKS

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.
 - Contact the Health Department. 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

Resident Rights

- The Health Department will provide guidance toward the appropriate restrictions of visitation.
 - usually it is for children under a certain age
 - rarely is it total restrictions on visitation



General Information: Specific Devices

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

Single Dose/Single Use Medications

- Insulin Pens
 - Insulin pens are pen-shaped injector devices that contain a reservoir for insulin or an insulin cartridge. These devices are designed to permit self-injection and are intended for single-person use, using a new needle for each injection.
 - Insulin pens are designed to be used multiple times by a single resident only and must never be shared. Regurgitation of blood into the insulin cartridge after injection will create a risk of blood-borne pathogen transmission if the pen is used for more than one patient/resident, even when the needle is changed.

The FDA makes the following recommendations to prevent transmission of blood-borne infections in residents who require insulin pens.

- Insulin pens containing multiple doses of insulin are meant for single-resident use only and must never be used for more than one person, even when the needle is changed
- Insulin pens must be clearly labeled with the resident's name or other identifiers to verify that the correct pen is used on the correct resident
- Facilities should review their policies and procedures and educate their staff regarding safe use of insulin pens.

Single Dose/Single Use Medications

- Sharing insulin pens between residents is similar to reusing needles or syringes for more than one resident, and such a finding may warrant a further investigation of the overall infection control practices within the facility.
- If it is discovered that insulin pens are shared between residents, the facility's plan of correction should include notification of the local health department or state epidemiologist for determination of the need for post-exposure follow up of patients and residents. We have to notify CMS and the Health Department if we cite for this.

Investigative Protocol Objectives

- 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.

Investigative Protocol

- **Noncompliance:**
 - Use finger stick devices (e.g. pen like devices) for only one resident in accordance with appropriate infection control practices and process.
 - Appropriate use of or repackaging of SVDs (adherence to USP 797)
 - Using a blood glucose meter (or other point of care device) for more than one resident, cleaning and disinfecting it after each use



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.

New (not out yet)

- Infection and Control Program – IPCP for preventing, identifying, surveillance, investigating, and controlling infections and communicable diseases for residents, staff, volunteers, visitors, and other individuals providing services based upon facility and resident assessments as reviewed and updated annually; would also require incorporation of an antibiotic stewardship program.

- Designation of an Infection and Prevention Control Officer (IPCO) for whom the IPCP is their major responsibility and who would serve as a member of the facility's quality assessment and assurance (QAA) committee. (NC already requires this)

The logo for the Centers for Medicare & Medicaid Services (CMS). It features the letters "CMS" in a bold, blue, italicized sans-serif font. A thick yellow horizontal line runs beneath the letters, and a yellow diagonal line crosses the horizontal line from the bottom left to the top right.

CENTERS for MEDICARE & MEDICAID SERVICES

Questions?



YAY

We are done!