committee's *responsibilities to identify and correct quality deficiencies* effectively. *The QAA committee determines what performance data will be monitored and the schedule or frequency for monitoring this data. There is no expectation that all performance data will be monitored at each committee meeting, however, the data must be reviewed with enough frequency to enable the committee to know if improvement is needed or if improvement is occurring (for current corrective actions).*

KEY ELEMENTS OF NONCOMPLIANCE

To cite deficient practice at F868, the surveyor's investigation must generally show that the facility failed to meet any one of the following:

- *Establish and maintain a QAA committee;*
- *Ensure the QAA committee is composed of the required committee members;*
- *Meet at least quarterly, and with enough frequency to conduct required QAPI/QAA activities.*

INVESTIGATIVE SUMMARY

Use the Facility Task Pathway for Quality Assurance and Performance Improvement (QAPI) Plan and Quality Assessment and Assurance (QAA) Review, as appropriate, along with the above interpretive guidelines when determining if the facility meets the requirements for, or investigating concerns related to the QAA Committee and QAPI program.

Summary of Investigative Procedure

Prior to conducting the QAPI Plan/QAA review, the survey team should identify and validate systemic problems in the facility. This includes concerns identified from offsite preparation that represent repeat deficient practice, and concerns or issues identified throughout the survey that will potentially be cited at a S/S of E or above.

F880

§483.*80* Infection Control

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

§483.*80(a)* Infection *prevention and* control program.

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

§483.*80(a)(1) A system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases for all residents, staff, volunteers, visitors, and other individuals providing services under a contractual arrangement based upon the facility assessment conducted according to §483.70(e) and following accepted national standards;*

§483.*80(a)(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;

(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.

§483.*80(a)(4) A system for recording incidents identified under the facility's IPCP and the corrective actions taken by the facility.*

§483.*80(e)* Linens.
Personnel must handle, store, process, and transport linens so as to prevent the spread of infection.

§483.*80(f) Annual review.*
The facility will conduct an annual review of its IPCP and update their program, as necessary.

INTENT 483.80(a),(e),(f)
The intent of this regulation is to ensure that the facility:

- *Develops and implements an ongoing infection prevention and control program (IPCP) to prevent, recognize, and control the onset and spread of infection to the extent possible and reviews and updates the IPCP annually and as necessary. This would include revision of the IPCP as national standards change;*
- *Establishes facility-wide systems for the prevention, identification, investigation and control of infections of residents, staff, and visitors. It must include an ongoing system of surveillance designed to identify possible communicable diseases or infections before they can spread to other persons in the facility and procedures for reporting possible incidents of communicable disease or infections;* ***NOTE****: For purposes of this guidance, "staff" includes employees, consultants, contractors, volunteers, caregivers who provide care and services to residents on behalf of the facility, and students in the facility's nurse aide training programs or from affiliated academic institutions.*
- *Develops and implements written policies and procedures for infection control that, at a minimum:*
  - *Explain how standard precautions and when transmission-based precautions should be utilized, including but not limited to the type and duration of precautions for particular infections or organisms involved and that the precautions should be the least restrictive possible for the resident given the circumstances and the resident's ability to follow the precautions;*

- *Prohibit staff with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit the disease; and*
- *Require staff follow hand hygiene practices consistent with accepted standards of practice.*

- *Requires staff handle, store, process, and transport all linens and laundry in accordance with accepted national standards in order to produce hygienically clean laundry and prevent the spread of infection to the extent possible.*

DEFINITIONS

"Airborne precautions": actions taken to prevent or minimize the transmission of infectious agents/organisms that remain infectious over long distances when suspended in the air. These infectious 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.[40]

"Alcohol-based handrub (ABHR)": a 60-95 percent ethanol or isopropyl alcohol- containing preparation base designed for application to the hands to reduce the number of viable microorganisms.

"Cleaning"*: removal of visible soil (e.g., organic and inorganic material) from objects and surfaces and is normally accomplished manually or mechanically using water with detergents or enzymatic products.*

"Cohorting": 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).[40] During outbreaks, healthcare *staff* may be assigned to a *specific* cohort of residents to further limit opportunities for transmission (cohorting staff). *The terms "cohort or cohorting" is standardized language used in the practice of infection prevention and control; the use of this terminology is not intended to offend residents or staff.*

"Colonization": the presence of microorganisms on or within body sites without detectable host immune response, cellular damage, or clinical expression. [40]

"Communicable disease" (also known as [a.k.a.] "contagious disease"): an infection transmissible (*e.g.,* from person-to-person) by direct contact with an affected individual or the individual's body fluids or by indirect means (e.g., contaminated object).

"Community-*acquired* infections" *(a.k.a. "present on admission")***:** infections that are present or incubating at the time of admission and *which* generally develop within 72 hours of admission.

"Contact precautions": measures that are intended to prevent transmission of infectious agents which are spread by direct or indirect contact with the resident or the resident's environment.[40]

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40 Siegel, J.D., Rhinehart, E., Jackson, M., Chiarello, L., & the Healthcare Infection Control Practices Advisory Committee. (2007). *2007 Guideline for isolation precautions: Preventing transmission of infectious agents in healthcare settings.* Accessed on June 9, 2017 from https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html

"Contaminated laundry": *laundry which has been soiled with blood/body fluids or other potentially infectious materials or may contain sharps.*

"Decontamination": *the use of physical or chemical means to remove, inactivate, or destroy pathogenic organisms on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.*

"Disinfectant"*: usually a chemical agent (but sometimes a physical agent) that destroys disease-causing pathogens or other harmful microorganisms but might not kill bacterial spores. It refers to substances applied to inanimate objects.* [41]

"Disinfection": *thermal or chemical destruction of pathogenic and other types of microorganisms. Disinfection is less lethal than sterilization because it destroys most recognized pathogenic microorganisms but not necessarily all microbial forms (e.g., bacterial spores).* [41]

"Droplet precautions": actions designed to reduce/prevent the transmission of pathogens spread through close respiratory or mucous membrane contact with respiratory secretions.

"Hand hygiene": a general term that applies to *hand washing,* antiseptic *hand wash, and alcohol-based hand rub.*[42]

"Hand washing": *the vigorous, brief rubbing together of all surfaces of hands with plain (i.e., nonantimicrobial) soap and water, followed by rinsing under a stream of water.*[43]

"Healthcare-associated infection (HAI)": an infection that *residents acquire, that is associated with a medical or surgical intervention (e.g., podiatry, wound care debridement) within a nursing home and was not present or incubating at the time of admission.*

"Hygienically clean": being free of pathogens in sufficient numbers to cause human illness.[44]

"Infection": 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.).

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41 Centers for Disease Control and Prevention. (2008). *Guideline for disinfection and sterilization in healthcare facilities, 2008.* Accessed on June 9, 2017 from https://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf

42 Centers for Disease Control and Prevention. (2002, October 25). Guideline for hand hygiene in health-care settings: Recommendations of The Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. *MMWR;51*(No.RR-16). Accessed on June 9, 2017 from http://www.cdc.gov/mmwr/PDF/rr/rr5116.pdf

43 Centers for Disease Control and Prevention (2009, July 20). *OPRP – General information on hand hygiene.* Accessed on June 9, 2017 from https://www.cdc.gov/nceh/vsp/cruiselines/hand_hygiene_general.htm.

44 Association for the Advancement of Medical Instrumentation (AAMI). (2009). *ANSI/AAMI ST65:2008/(R)2013. Processing of reusable surgical textiles for use in health care facilities, 2008.* Arlington, VA.

"Infection preventionist"*: term used for the person(s) designated by the facility to be responsible for the infection prevention and control program.* ***NOTE:*** *Designation of a specific individual, detailed training, qualifications, and hourly requirements for an infection preventionist are not required until implementation of Phase 3.*

"Personal protective equipment (PPE)": protective items or garments worn to protect the body or clothing from hazards that can cause injury *and to protect residents from cross-transmission.*

"(Regulated) Medical waste": *liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling (e.g., blood-soaked bandages); contaminated sharps.*[45]

NOTE*: Authorities having jurisdiction may have more stringent regulations than OSHA.*

"Standard Precautions": infection prevention practices that apply to all residents, regardless of suspected or confirmed diagnosis or presumed infection status. *Standard precautions is based on the principle that all blood, body fluids, secretions, excretions except sweat, regardless of whether they contain visible blood, non-intact skin, and mucous membranes may contain transmissible infectious agents. Furthermore, equipment or items in the patient environment likely to have been contaminated with infectious body fluids must be handled in a manner to prevent transmission of infectious agents. Standard precautions include but are not limited to hand hygiene; use of gloves, gown, mask, eye protection, or face shield, depending on the anticipated exposure; safe injection practices, and respiratory hygiene/cough etiquette. Also, equipment or items in the patient environment likely to have been contaminated with infectious body fluids must be handled in a manner to prevent transmission of infectious agents (e.g., wear gloves for direct contact, properly clean and disinfect or sterilize reusable equipment before use on another patient).*[40]

"Transmission-based precautions" (a.k.a. "Isolation Precautions"): 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. ***NOTE****: Although the regulatory language refers to "isolation," the nomenclature widely accepted and used in this guidance will refer to "transmission-based precautions" instead of "isolation".*

NOTE: *References to non-U. S. Department of Health and Human Services (HHS) sources or sites on the internet are provided as a service and do not constitute or imply endorsement of these organizations or their programs by CMS. CMS is not responsible for the content of pages found at these sites. URL addresses were current as of the date of this publication.*

GUIDANCE §483.80(a),(e),(f)

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45 Occupational Safety and Health Administration. *Title 29 Part 1910.1030. Bloodborne pathogens.* Accessed on June 9, 2017 from http://www.ecfr.gov/cgi-bin/text-idx?SID=4e5245f66094d270bc2bd93105f6a92d&mc=true&node=se29.6.1910_11030&rgn=div8

Effective November 28, 2017

INFECTION PREVENTION AND CONTROL PROGRAM

Healthcare-associated infections (HAIs) can cause significant pain and discomfort for residents in nursing homes and can have significant adverse consequences. The facility must establish and maintain an IPCP designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of communicable diseases and infections. This program must include, at a minimum, a system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases for all residents, staff, and visitors. The IPCP must follow national standards and guidelines.

For purposes of this guidance, we would expect facilities to tailor the emphasis of their IPCP for visitors. We expect facilities to work to prevent transmission of infection to the resident from the visitor using reasonable precautions and national standards.[40] For example, passive screening through the use of signs at the entrances to alert visitors with signs and symptoms of communicable diseases not to enter the facility.[40] If a facility has a visitor exception protocol (e.g., end-of-life care), this would need to be determined by the facility. In this case, if a symptomatic visitor/family member must enter the facility, the visitor must still follow the facility's policies for prevention of transmission (e.g., following respiratory hygiene/cough etiquette procedures).

The Infection Prevention and Control Program must include the following parts:

- *A system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases that:*
  - *Covers all residents, staff, volunteers, visitors, and other individuals providing services under a contractual arrangement;*
  - *Is based on the individual facility assessment;*
  - *Follows accepted national standards;*
- *Written standards, policies and procedures in accordance with §483.80(a)(2);*
- *A system for recording incidents identified under the IPCP and corrective actions taken by the facility; and*
- *An antibiotic stewardship program (ASP) (F881).*

FACILITY ASSESSMENT

Pursuant to §483.70(e) (F838), 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 a facility-based and community-based risk assessment, utilizing an all-hazards approach. See §483.70(e) (F838) for guidance on the facility assessment. The results of the facility assessment must be used, in part, to establish and update the IPCP, its policies and/or protocols to include a system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases for residents, staff, and visitors.

***NOTE:** A community-based risk assessment should include review for risk of infections (e.g., multidrug-resistant organisms- MDROs) and communicable diseases such as tuberculosis and*

influenza. Appropriate resident tuberculosis screening should be performed based on state requirements.

***NOTE**: While not required for compliance, a sample tool of an infection control risk assessment is available for adaptation.*[46]

INFECTION CONTROL POLICIES AND PROCEDURES

The facility must develop and implement written policies and procedures for the provision of infection prevention and control. The facility administration and medical director should ensure that current standards of practice based on recognized guidelines are incorporated in the resident care policies and procedures. These IPCP policies and procedures must include, at a minimum:

- *As necessary, and at least annually, review and revision of the IPCP based upon the facility assessment (according to 483.70(e)) which includes any facility and community risk;*
- *An ongoing system of surveillance designed to identify possible communicable diseases or infections before they can spread to other persons in the facility;*
- *When and to whom possible incidents of communicable disease or infections should be reported within the facility;*
- *Which communicable diseases are reportable to local/state public health authorities;*
- *How to use standard precautions and how and when to use transmission-based precautions (i.e., contact precautions, droplet precautions, airborne isolation precautions). The areas described below are part of standard and transmission-based precautions*[40] *which are further described under their respective sections. For example:*
  - *Hand hygiene (HH) (e.g., hand washing and/or ABHR): consistent with accepted standards of practice such as the use of ABHR instead of 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 Clostridium (C.) difficile or norovirus infection during an outbreak, or if infection rates of C. difficile infection (CDI) are high; in these circumstances, soap and water should be used;*[47] ***NOTE:** According to the CDC, strict adherence to glove use is the most effective means of preventing hand contamination with C. difficile spores as spores are not killed by ABHR and may be difficult to remove even with thorough hand washing. For further information on appropriate hand hygiene practices see the following CDC website: http://www.cdc.gov/handhygiene/providers/index.html*
  - *The selection and use of PPE (e.g., indications, donning/doffing procedures) and the clinical conditions for which specific PPE should be used (e.g., CDI, influenza);*
  - *Addressing the provision of facemasks for residents with new respiratory symptoms;*

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46 Association for Professionals in Infection Control and Epidemiology. *IC risk assessment tool form and IC risk assessment analysis.* Accessed on June 9, 2017 from

47 Dubberke, E.R., & Gerding, D.N. (2011). Rationale for hand hygiene recommendations after caring for a patient with *Clostridium difficile* infection. *In A compendium of strategies to prevent healthcare-associated infections in acute care hospitals: A fall 2011 update.* Accessed on June 9, 2017 from https://www.shea-online.org/images/patients/CDI-hand-hygiene-Update.pdf

- *Addressing resident room assignment (e.g. single/private room/cohorted) as appropriate and/or available, based on a case by case analysis of the presence of risk factors for increased likelihood of transmission (e.g., uncontained drainage, stool incontinence);*[40]
- *The process to manage a resident on transmission-based precautions when a single/private room is not available;*
- *Limiting the movement of a resident with a highly infectious disease (e.g., norovirus, CDI) who is on transmission-based precautions with active symptoms (e.g., resident has diarrhea, vomiting, draining wounds, or other uncontained excretions or secretions) while outside of his/her room for medically necessary purposes only;*[40] *and*
- *Respiratory Hygiene/Cough Etiquette*[40]*: Implementing policies and procedures would include providing resources and instructions for performing HH in or near lobby areas or entrances; provide conveniently-located dispensers of ABHR and supplies for hand washing where sinks are available. During times of increased prevalence of respiratory infections in the community, facilities must have facemasks available and should offer facemasks to coughing or sneezing visitors and other symptomatic persons (e.g., family who accompany ill residents upon entry to the facility). Symptomatic (e.g., coughing) visitors should wear a facemask or maintain at least a three foot separation from others in common areas (e.g., admitting office). In addition, the facility should consider posting signs in the facility with instructions to family/visitors with symptoms of respiratory infection to cover their mouth/nose when coughing or sneezing; use and dispose of tissues; perform hand hygiene after contact with respiratory secretions; and to take appropriate precautions if they are having symptoms of respiratory infection or other communicable diseases.*

- *Resident Care Activities:*
  - *The use and care of urinary catheters, which must include a written rationale for the use, consistent with evidence-based guidelines (e.g., acute urinary retention, bladder outlet obstruction, neurogenic bladder or terminally ill for comfort measures) (Refer to §483.25(e)(2)(i)(ii)&(iii) Incontinence, F690, for further information.);*
  - *Wound care, fecal/urinary incontinence care, and skin care. Since the IPCP must be based on the facility assessment, the presence of certain resident conditions would require that the facility have policies and procedures related to other specific services such as mechanical ventilation, infusion therapy, and/or dialysis either onsite or at an offsite dialysis facility;*
  - *Performing fingersticks and point-of-care testing (e.g., assisted blood glucose monitoring) to the extent identified as a resident need based on the facility assessment;*
  - *Preparation, administration, and care for medications administered by injection or peripheral and central venous catheters, if performed by the facility; and*
  - *Use and care of peripheral and central venous catheters, if performed by the facility.*
- *Environmental cleaning/disinfection:*
  - *Routine cleaning and disinfection of high-touch surfaces in common areas, resident rooms, and at the time of discharge; and*

***NOTE**: Privacy curtains in the resident's room should be changed when visibly dirty by laundering or cleaning with an Environmental Protection Agency (EPA)-registered disinfectant per manufacturer's instructions.*

- *Cleaning/disinfection of resident care equipment including equipment shared among residents (e.g., blood pressure cuffs, rehabilitation therapy equipment, blood glucose meters, etc.).*

- *Written occupational health policies that address:*
  - *Reporting of staff illnesses and following work restrictions per nationally recognized standards and guidelines;*[48]
  - *Prohibiting contact with residents or their food when staff have potentially communicable diseases or infected skin lesions;*
  - *Assessing risks for tuberculosis (TB) based on regional/community data and screening staff to the extent permitted under applicable federal guidelines* [49] *and state law;*
  - *Monitoring and evaluating for clusters or outbreaks of illness among staff;*
  - *Implementing an exposure control plan in order to address potential hazards posed by blood and body fluids, from dialysis, glucose monitoring or any other point of care testing; and*
  - *Education and competency assessment: facilities must ensure staff follow the IPCP's standards, policies and procedures. Therefore, staff must be informed and competent. Knowledge and skills pertaining to the IPCP's standards, policies and procedures are needed by all staff in order to follow proper infection control practices (e.g., hand hygiene and appropriate use of personal protective equipment) while other needs are specific to particular roles, responsibilities, and situations (e.g., injection safety and point of care testing). Furthermore, residents and their representatives should receive education on the facility's IPCP as it relates to them (e.g., hand hygiene, cough etiquette) and to the degree possible/consistent with the resident's capacity. For example, residents should be advised of the IPCP's standards, policies and procedures regarding hand hygiene before eating and after using the restroom.*

SURVEILLANCE

The facility must establish a system for surveillance based upon national standards of practice and the facility assessment, including the resident population and the services and care provided. The facility must establish routine, ongoing, and systematic collection, analysis, interpretation, and dissemination of surveillance data to identify infections (i.e., HAI and community-acquired), infection risks, communicable disease outbreaks, and to maintain or improve resident health status. As part of the system of surveillance, identification and

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48 Bolyard, E.A., Tablan, O.C., Williams, W.W., Pearson, M.L., Shapiro, C.N., Deitchman, S.D., & The Healthcare Infection Control Practices Advisory Committee. (1998). Guideline for infection control in health care personnel, 1998. *American Journal of Infection Control 26*, 289-354. Accessed on June 9, 2017 from https://www.cdc.gov/hicpac/pdf/InfectControl98.pdf

49 Jensen, P.A., Lambert, L.A., Iademarco, M.F., & Ridzon, R. (CDC's Division of Tuberculosis Elimination, National Center for HIV, STD, and TB Prevention). (2005, December 30). Guidelines for preventing the transmission of *Mycobacterium tuberculosis* in health-care settings, 2005. *MMWR; 54* (No.RR-17). Accessed on June 9, 2017 from https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5417a1.htm

prevention, the facility should determine how it will track the extent to which staff are following the facility's IPCP policies and procedures, and facilities would want to particularly address any areas that are related to a corrective action.

The facility's surveillance system must include a data collection tool and the use of nationally-recognized surveillance criteria such as but not limited to CDC's National Healthcare Safety Network (NHSN) Long Term Care Criteria to define infections or updated McGeer criteria[50]. Furthermore, the facility must know when and to whom to report communicable diseases, healthcare-associated infections (as appropriate), and potential outbreaks (e.g., list of communicable diseases which are reportable to local/state public health authorities). The facility must document follow-up activity in response to important surveillance findings (e.g., outbreaks).

In addition, the facility must establish and implement a system, including who to notify (e.g. infection preventionist), for early detection and management of a potentially infectious, symptomatic resident at the time of admission. This includes the identification and use of appropriate transmission-based precautions.[40] This is important to incorporate into the resident's baseline care plan that must be developed within 48 hours of admission and include the minimum healthcare information necessary to properly care for a resident, including physician orders (e.g., medication orders). See §483.21, Comprehensive Person-Centered Care Planning for further information.

Furthermore, the facility must have a process for communicating information at the time of transfer (e.g., CDC, state, or other standardized inter-facility infection transfer form) when a resident has an infection or is colonized.[51] When a resident is transferred, the information provided to the receiving provider must include special instructions or precautions for ongoing care and other necessary information including a discharge summary. When a resident is discharged, the discharge summary must include the resident's disease diagnoses and health conditions, course of illness/treatment or therapy, medications, and pertinent lab, radiology, consultation results, and instructions or precautions for ongoing care. See §483.21(c)(2), Discharge Summary (F661) and §483.15(c)(2)(iii), Transfer and Discharge (F622) for further information on these requirements.

Additionally, as part of the overall IPCP for surveillance, the facility shall establish process and outcome surveillance.

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50 Stone, N.D., Ashraf, M.S., Calder, J., Crnich, C. J., Crossley, K., Drinka, P.J., …Bradley, S.F. (2012). Surveillance definitions of infections in long-term care facilities: Revisiting the McGeer criteria. *Infect Control Hosp Epidemiology*. 33(10), 965-977.

51 Siegel, J.D., Rhinehart, E., Jackson, M., and Chiarello, L. (2006). *Management of multidrug-resistant organisms in healthcare settings, 2006.* Accessed on June 9, 2017 from https://www.cdc.gov/hicpac/pdf/mdro/mdroguideline2006.pdf

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Process Surveillance

Process surveillance is the review of practices by staff directly related to resident care.[52] *The purpose is to identify whether staff implement and comply with the facility's IPCP policies and procedures. Some areas that facilities may want to consider for process surveillance are the following:*

- *Hand hygiene;*
- *Appropriate use of personal protective equipment (e.g., gowns, gloves, facemask);*
- *Injection safety;*
- *Point-of-care testing (e.g., during assisted blood glucose monitoring);*
- *Implementation of infection control practices for resident care such as but not limited to urinary catheter care, wound care, injection/IV care, fecal/urinary incontinence care, skin care, respiratory care, dialysis care, and other invasive treatments;*
- *Managing a bloodborne pathogen exposure.*

  ***NOTE**: This may not lend itself to monitoring and feedback;*

- *Cleaning and disinfection products and procedures for environmental surfaces and equipment;*
- *Appropriate use of transmission-based precautions; and*
- *Handling, storing, processing, and transporting linens so as to prevent the spread of infection.*

Outcome Surveillance

Another component of a system of identification is outcome surveillance. For example, this addresses the criteria that staff would use to identify and report evidence of a suspected or confirmed HAI or communicable disease. This process consists of collecting/documenting data on individual *resident* cases and *comparing* the collected data to standard written definitions (criteria) of infections.

***NOTE**: Refer to the CDC/SHEA Position Statement: Surveillance Definitions of Infections in Long-Term Care Facilities: Revisiting the McGeer Criteria*[50] *or NHSN at https://www.cdc.gov/nhsn/ for examples of nationally accepted surveillance definitions.*

The following are some sources of data that can be utilized in outcome surveillance for infections, antibiotic use and susceptibility: Monitoring a resident(s) with fever or *other signs or symptoms suspicious for infection*;

- Laboratory cultures or other diagnostic test results consistent with potential infections to detect clusters, trends, *or susceptibility patterns*;
- Antibiotic orders;
- Medication regimen review reports;
- *Documentation from the clinical record of residents with suspicion of an infection such as physician orders/progress notes; and/or*

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52 Smith, P.W., Bennett, G., Bradley, S., Drinka, P., Lautenbach, E., Marx, J.... Stevenson, K. (2008). SHEA/APIC Guideline: infection prevention and control in the long-term care facility. *Infect Control Hosp Epidemiology*. *29*(9), 785-814.

- *Transfer/discharge summaries for new or readmitted residents for infections.*[52]

SYSTEM OF SURVEILLANCE: DATA ANALYSIS, DOCUMENTATION AND REPORTING

The facility's policies and procedures for a system of surveillance must include data to properly identify communicable diseases or infections before they spread. Therefore, the policies and procedures would include identifying:

- *Data to be collected, including how often and the type of data to be documented, including:*
  - *The infection site (i.e., type of infection), pathogen (if available), signs and symptoms, and resident location, including summary and analysis of the number of residents (and staff, if applicable) who developed infections;*
  - *Observations of staff including the identification of ineffective practices (e.g., not practicing hand hygiene and/or using PPE when indicated as well as practices that do not follow the facility's IPCP policies and procedures), if any; and*
  - *The identification of unusual or unexpected outcomes (e.g. foodborne outbreak), infection trends and patterns.*
- *How the data will be used and shared with appropriate individuals (e.g., staff, medical director, director of nursing, quality assessment and assurance committee- QAA), when applicable, to ensure that staff minimize spread of the infection or disease (e.g., require revision of staff education and competency assessment).*

The facility must identify how reports will be provided to staff and/or prescribing practitioners in order to revise interventions/approaches and/or re-evaluate medical interventions related to the infection rates and outcomes.

RECOGNIZING, CONTAINING AND REPORTING COMMUNICABLE DISEASE OUTBREAKS

The facility must know how to recognize and contain infectious disease outbreaks. An outbreak is the occurrence of more cases than expected in a given area or among a specific group of people over a particular period of time.[53] *If a condition is rare or has serious health implications, an outbreak may involve only one case. While a single case of a rare infectious condition or one that has serious health implications may or may not constitute an outbreak, facilities should not wait for the definition of an outbreak to act. For example, one case of laboratory confirmed influenza in a resident should alert the facility to begin an outbreak investigation.*[54] *If an outbreak is identified, the facility must:*

- *Take the appropriate steps to diagnose and manage cases, implement appropriate precautions, and prevent further transmission of the disease as well as documentation of follow-up activity in response; and*
- *Comply with state and local public health authority requirements for identification, reporting, and containing communicable diseases and outbreaks.*

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53 Centers for Disease Control and Prevention. (2015, January 21). *Epidemiology glossary.* Accessed on June 9, 2017 from http://www.cdc.gov/reproductivehealth/data_stats/glossary.html#O

54 Schweon, S., Burdsall D., Hanchett, M., Hilley, S., Greene, D., Kenneley, I., Marx, J., Rosenbaum, P. (2013). *Infection preventionist's guide to long-term care.* Washington DC: APIC.

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NOTE: *Some states have specific regulations regarding responding to and reporting outbreaks that must be included in the IPCP.*

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., inanimate objects). Healthcare *staff* and resident care equipment often move from resident to resident and therefore may serve as a vehicle for transferring infectious organisms.

Direct *Contact* Transmission (Person-to-Person) occurs when microorganisms *such as methicillin-resistant Staphylococcus aureus (MRSA), vancomycin-resistant enterococci (VRE), carbapenem-resistant Enterobacteriaceae (CRE), influenza, or mites from a scabies-infected resident* are transferred from an infected or colonized person to another person. *In nursing homes, resident-to-resident direct contact transmission may occur in common areas of the facility such as the recreation room, rehabilitation area, and/or dining room.*

Indirect *Contact* Transmission: involves the transfer of an infectious agent through a contaminated *inanimate* object *or person.*

The following are examples of opportunities for indirect *contact transmission:*

- 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 *C. difficile*); and
- *Contamination of high touch environmental surfaces (e.g., bedside table, bed rails, toilets, sinks, and handrails), contributes to transmission of pathogens including C. difficile and norovirus.*

Certain pathogens may contaminate and survive on equipment and environmental surfaces for long periods of time. Examples include, but are not limited to:

- *C. difficile spores* can live on inanimate surfaces for up to 5 months;[55]
- The hepatitis B virus can last up to a week on inanimate surfaces;[56] 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.[57]

Mechanisms to prevent and control transmission of infectious organisms through direct and indirect contact include standard and transmission-based precautions and are described in their subsequent sections.

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55 Kim, K.H., Fekety, R., Batts, D.H.,Brown, D., Cudmore , M., Silva, J. Jr., & Waters, D. (1981, January 1). Isolation of *Clostridium difficile* from the environment and contacts of residents with antibiotic-associated colitis. *Journal of Infectious Disease. 143*(1), 42-50.

56 Centers for Disease Control and Prevention (CDC). *Hepatitis B FAQs for health professionals.* Accessed on June 9, 2017 from http://www.cdc.gov/hepatitis/HBV/HBVfaq.htm

57 Centers for Disease Control and Prevention (CDC). (2007, February 15). *Preventing seasonal flu.* Accessed on June 9, 2017 from https://www.cdc.gov/flu/protect/vaccine/index.htm

Effective November 28, 2017

STANDARD PRECAUTIONS

Standard precautions represent the infection prevention measures that apply to all resident care, regardless of suspected or confirmed infection status of the resident, in any setting where healthcare is being delivered. These evidence-based practices are designed to protect healthcare staff and residents by preventing the spread of infections among residents and ensuring staff do not carry infectious pathogens on their hands or via equipment during resident care. As mentioned in the definitions section, standard precautions include hand hygiene, use of PPE (e.g., gloves, gowns, facemasks), respiratory hygiene and cough etiquette, safe injection practices, and safe handling of equipment or items that are likely contaminated with infectious body fluids, as well as cleaning and disinfecting or sterilizing of potentially contaminated equipment.[40]

In order to perform hand hygiene appropriately, soap, water, ABHR, and a sink should be readily accessible in appropriate locations including but not limited to resident care areas, and food and medication preparation areas. Staff must perform hand hygiene (even if gloves are used):

- *Before and after contact with the resident;*
- *Before performing an aseptic task;*
- *After contact with blood, body fluids, visibly contaminated surfaces or after contact with objects in the resident's room;*
- *After removing personal protective equipment (e.g., gloves, gown, facemask);*
- *After using the restroom; and*
- *Before meals.*

If residents need assistance with hand hygiene, staff should assist with washing hands after toileting, before meals, and use of ABHR or soap and water at other times when indicated.

The use of PPE during resident care is determined by the nature of staff interaction and the extent of anticipated blood, body fluid, or pathogen exposure to include contamination of environmental surfaces. Furthermore, appropriate use of PPE includes but is not limited to the following:

- *Gloves worn before and removed after contact with blood or body fluid, 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;*
- *Gown worn for direct resident contact if the resident has uncontained secretions or excretions or with contaminated or potentially contaminated items;*
- *Appropriate mouth, nose, and eye protection (e.g., facemasks, face shield) is worn for procedures that are likely to generate splashes or sprays of blood or body fluids;*
- *PPE appropriately discarded after resident care prior to leaving room followed by hand hygiene; and*
- *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) although, equipment supply carts should not be brought into the resident's room.*

Effective November 28, 2017

The facility must prevent infections through indirect contact transmission. This requires the decontamination (i.e., cleaning and/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 or designating reusable equipment for only an individual resident. ***NOTE****: Refer to the CDC website for information on environmental cleaning -* *https://www.cdc.gov/hicpac/pdf/guidelines/eic_in_HCF_03.pdf*

The facility must identify the decontamination method based upon the risk of infection to the resident coming into contact with equipment or medical devices. 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).[40]

The CDC has adopted the Spaulding classification system that identifies three risk levels associated with medical and surgical instruments: critical, semi-critical, and noncritical.[58] *This includes:*

- Critical items (e.g., needles, intravenous catheters, indwelling urinary catheters) enter sterile tissue or the vascular system. These items or equipment must be sterile when used, based on one of several accepted sterilization procedures. Most of the items in this category should be purchased as sterile or be sterilized;
- *Semi-critical items (e.g., dental, podiatry equipment, electric razors) contact mucous membranes or non-intact skin. Such items require meticulous cleaning followed by high-level disinfection treatment using a Food and Drug Administration (FDA)- approved high-level chemical disinfectant, or they may be sterilized. High-level disinfection is traditionally defined as complete elimination of all microorganisms in or on an instrument, except for small numbers of bacterial spores. Refer to the specific disinfectant label claim to determine effectiveness; and*
- *Non-critical items are those that come in contact with intact skin but not mucous membranes. Noncritical items are divided into noncritical resident care items (e.g., blood pressure cuffs, stethoscopes, wheelchairs, therapy equipment) and noncritical environmental surfaces (e.g., bed rails, bedside tables).* They require low level disinfection by cleaning periodically and after visible soiling, *following manufacturer's instructions* with an EPA-*registered* disinfectant, detergent or germicide that is approved for health care settings. *All applicable label instructions on EPA-registered disinfectant products must be followed (e.g., use-dilution, shelf life, storage, material compatibility, safe use and disposal).*

Single-use disposable equipment is an alternative to sterilizing reusable medical instruments. Single-use devices must be discarded after use and are never used for more than one resident. Nursing homes may purchase reprocessed single-use devices when these devices are reprocessed by an entity or a third party reprocessor that is registered with the FDA. The

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58 Sehulster, L.M., Chinn, R.Y., Arduino, M.J., Carpenter, J., Donlan, R., Ashford, D., … Cleveland, J. (2003, June 6). Guidelines for environmental infection control in health-care facilities. Recommendations from CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC). *MMWR; 52(*No. RR-10). Accessed on June 9, 2017 from https://www.cdc.gov/hicpac/pdf/guidelines/eic_in_HCF_03.pdf

nursing home must have documentation from the third party reprocessor that indicates that it has been cleared by the FDA to reprocess the specific device in question.

NOTE: *Refer to the CDC website for information on disinfection and sterilization – https://www.cdc.gov/infectioncontrol/guidelines/Disinfection/index.html*

TRANSMISSION-BASED PRECAUTIONS

Transmission-based precautions must be used when a resident develops signs and symptoms of a transmissible infection, arrives at a nursing home with symptoms of an infection (pending laboratory confirmation), or has a laboratory confirmed infection and is at risk of transmitting the infection to other residents. For example, a resident with influenza and signs of infection should wear a facemask (e.g., surgical or procedure facemask) when leaving his/her room for medically-necessary care (i.e., droplet precautions for the duration of the illness). 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.[40, 51]

Facility policies must identify the type (i.e., contact, droplet, airborne) and duration of the transmission-based precautions required, depending upon the infectious agent or organism involved. Furthermore, transmission-based precautions should be the least restrictive possible for the resident based on his/her clinical situation and used for the least amount of time. When used appropriately, transmission-based precautions is not to be considered involuntary seclusion. However, once the resident is no longer a risk for transmitting the infection (e.g., duration of the illness and/or can contain secretions), removing transmission-based precautions is required in order to avoid unnecessary involuntary seclusion. For example, a resident with vancomycin-resistant enterococci (VRE) who is colonized based on a urine culture, but is continent and cognizant, should be instructed regarding or as necessary, assisted with performing hand hygiene before leaving his/her room, but is not placed on transmission-based precautions.

Facility staff should take measures to reduce or minimize any potential psychosocial negative effects of isolation for whom transmission-based precautions are being used. Boredom, anger, withdrawal or depression are just some of the mood changes that could occur. The facility must pro-actively ensure that individualized needs (e.g., activities) are met.

Implementation of Transmission-Based Precautions

When implementing transmission-based precautions, consideration should be given to the following:[40]

- *The identification of resident risk factors that increase the likelihood of transmission, (such as uncontained secretions or excretions, non-compliance, cognition deficits, incontinence, etc.);*
- *The provision of a private room as available/appropriate;*
- *Cohorting residents with the same pathogen*; and
- *Sharing a room with a roommate with limited risk factors (e.g., without indwelling or*

invasive devices, without open wounds, and not immunocompromised) as appropriate.

When a resident is placed on transmission-based precautions, the staff should implement the following:

- *Clearly identify the type of precautions and the appropriate PPE to be used;*
- *Place signage in a conspicuous place outside the resident's room such as the door or on the wall next to the doorway identifying the CDC category of transmission-based precautions (e.g. contact, droplet, or airborne), instructions for use of PPE, and/or instructions to see the nurse before entering. Ensure that signage also complies with residents' rights to confidentiality and privacy;*
- *Make PPE readily available near the entrance to the resident's room;*
- *Don appropriate PPE upon entry into the environment (e.g., room or cubicle) of resident on transmission-based precautions (e.g., contact precautions);* [40]
- *Use disposable or dedicated noncritical resident-care equipment (e.g., blood pressure cuff, bedside commode). If noncritical equipment is shared between residents, it will be cleaned and disinfected following manufacturer's instructions with an EPA-registered disinfectant after use;* [40]
- *Clean and disinfect objects and environmental surfaces that are touched frequently (e.g., bed rails, over-bed table, bedside commode, lavatory surfaces in resident bathrooms) with an EPA-registered disinfectant for healthcare use at least daily and when visibly soiled;* [40] *and*
- *Provide education to residents (to the degree possible/consistent with the resident's capacity) and their representatives or visitors on the use of transmission-based precautions.*

NOTE: *Refer to CDC guidelines for current recommendations on standard and transmission-based precautions. http://www.cdc.gov/hicpac/2007IP/2007isolationPrecautions.html*

Contact Precautions

Contact precautions *are intended* to prevent *transmission of* infections that are spread by *direct (e.g.,* person-to-person*) or indirect* contact *with the resident or environment,* and require the use of appropriate PPE, including a gown and gloves upon entering *(i.e., before making contact with the resident or resident's environment)* the room *or cubicle.* Prior to leaving the resident's room *or cubicle*, the PPE is removed and hand hygiene is performed.

Droplet Precautions

The use of droplet precautions applies when respiratory droplets contain viruses or bacteria particles which may be spread to another susceptible individual. Respiratory viruses can enter the body via the nasal mucosa, conjunctivae and less frequently the mouth.[59] Examples of droplet-borne organisms that may cause infections include, but are not limited to Mycoplasma pneumoniae, influenza, and other respiratory viruses.

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59 Hall, C.B., Douglas, Jr., R.G., Schnabal, K.C., and Geiman, J.M. (1981, September). Infectivity of respiratory syncytial virus by various routes of inoculation. *Infection and Immunity*. *33*(3), 779-783.

Respiratory droplets are generated when an infected person coughs, sneezes, talks, or during procedures such as suctioning, endotracheal intubation, cough induction by chest physiotherapy, and cardiopulmonary resuscitation.[40] The maximum distance for droplet transmission is currently unresolved, but the area of defined risk based on epidemiological findings is approximately 3-10 feet.[40] In contrast to airborne pathogens, droplet-borne pathogens are generally not transmitted through the air over long distances.

Facemasks are to be used upon entry *(i.e., within three feet of a resident)* into a resident's room or cubicle with respiratory droplet precautions.[40] *If substantial spraying of respiratory secretions is anticipated, gloves and gown as well as goggles (or face shield in place of goggles) should be worn.*[40] *The preference for a resident on droplet precautions would be to place the resident in a private room.*[40] *If a private room is not available, the resident could be cohorted with a resident with the same infectious agent, or share a room with a roommate with limited risk factors.*[40] *Spatial separation of at least 3 feet and drawing the curtain between resident beds is especially important for residents in multi-bed rooms with infections transmitted by the droplet route.*[40]

Airborne Precautions

Airborne transmission occurs when pathogens are so small that they can be easily dispersed in the air, and because of this, there is a risk of transmitting the disease through inhalation. These small particles containing infectious agents may be dispersed over long distances by air currents and may be inhaled by individuals who have not had face-to-face contact with (or been in the same room with) the infectious individual. Staff caring for residents on airborne precautions should wear a fit-tested N95 or higher level respirator that is donned prior to room entry.[40]

NOTE: *According to the CDC, preventing the spread of pathogens that are transmitted by the airborne route requires the use of special air handling and ventilation systems such as an airborne infection isolation room (AIIR) to contain and then safely remove the infectious agent.*[40] *Residents with infections requiring an AIIR must 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, *such as for a resident with TB*, it is important for the facility to have a plan (e.g., public health notification and exposure workup) 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.[40]

MEDICAL DEVICE SAFETY

Medical devices may be used for administration of medications, point-of-care testing, or for other medical uses.

Point-of-Care Testing

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

Effective November 28, 2017

Fingerstick Devices

CDC recommends the use of single-use, auto-disabling fingerstick devices in settings where assisted blood glucose monitoring is performed. This practice prevents inadvertent reuse of fingerstick devices for more than one person. Additionally, the use of single-use, auto-disabling fingerstick devices protects healthcare staff from needlestick injuries. If reusable fingerstick devices are used for assisted monitoring of blood glucose, then they ***must never be used for more than one resident****. Although the package instructions for some fingerstick devices may indicate or imply the potential for multiple resident use, CMS guidance, based upon nationally recognized standards of practice from the CDC and FDA, prohibits the use of fingerstick devices for more than one resident.*

NOTE: If fingerstick devices are used on more than one resident, surveyors must cite at this tag and utilize the guidelines in Appendix Q for immediate jeopardy. *Furthermore, the state survey agency (SA) must notify the appropriate state public health authority of the deficient practice.*

NOTE: *For information on fingerstick safety, please refer to:*

- *https://www.cdc.gov/injectionsafety/fingerstick-devicesbgm.html*
- *https://www.cdc.gov/injectionsafety/providers/blood-glucose-monitoring_faqs.html*

Blood Glucose Meters

Blood glucose meters, can become contaminated with blood and, if used for multiple residents, must be cleaned and disinfected after each use according to manufacturer's instructions for multi-patient use. Additionally, staff must ***not*** *carry blood glucose meters in pockets.*
The FDA has released guidance for manufacturers regarding appropriate products and procedures for cleaning and disinfection of blood glucose meters. This guidance can be found at the FDA's website:
http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm227935.htm
An excerpt from this guidance reads:

> *"The disinfection solvent you choose should be effective against HIV, Hepatitis C, and Hepatitis B virus. Outbreak episodes have been largely due to transmission of Hepatitis B and C viruses. However, of the two, Hepatitis B virus is the most difficult to kill. Please note that 70% ethanol solutions are not effective against viral bloodborne pathogens and the use of 10% bleach solutions may lead to physical degradation of your device." A list of Environmental Protection Agency (EPA) registered disinfectants can be found at the following website: https://www.epa.gov/pesticide-registration/selected-epa-registered-disinfectants.*

Furthermore, "healthcare personnel should consult the manufacturers of blood glucose meters in use at their facilities to determine what products, meeting the criteria specified by the FDA, are compatible with their meter prior to using any EPA-registered disinfectant for disinfection

purposes. If manufacturers are unable to provide this information then the meter should not be used for multiple patients."[60]

Blood glucose meters dedicated for single-resident use should be stored in a manner that will protect against inadvertent use of the device for additional residents and also cross-contamination via contact with other meters or equipment.

***NOTE:** If the facility failed to clean and disinfect, per device manufacturer's instructions, and blood glucose meters are used for more than one resident, surveyors must cite this tag and utilize the guidelines in Appendix Q as it may constitute immediate jeopardy.*

For more information on point-of-care testing, refer to CDC's website at: https://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html

Safe Medication Administration

All injectable medications must be prepared and administered in accordance with safe injection practices, including but not limited to the following:

- *Injections are prepared using aseptic technique in a clean area, free from potential sources of contamination (e.g., blood, body fluids, contaminated equipment);*
- *Needles and syringes are used for only one resident (this includes manufactured prefilled syringes and cartridge devices such as insulin pens).*

  ***NOTE:** If it is identified that needles or syringes are used for more than one resident, surveyors must cite noncompliance at this tag and utilize the guidelines in Appendix Q for immediate jeopardy. The SA must notify the appropriate state public health authority of the deficient practice;*

- *Medication containers are entered with a new needle and a new syringe, even when obtaining additional doses for the same resident. If noncompliance is found, further investigation is warranted.*

  ***NOTE:** If the medication container is used for more than one resident, a new needle and/or syringe was not used with each access, and the container was then used for another resident, surveyors must cite noncompliance at this tag and utilize the guidelines in Appendix Q for immediate jeopardy. The SA must notify the appropriate state public health authority of the deficient practice;*

- *Single dose (single-use) medication vials, ampules, and bags or bottles of intravenous solution are used for only one resident;*
- *Medication administration tubing and connectors are used for only one resident.*

  ***NOTE:** Surveyors must cite at this tag if noncompliance is identified and utilize the guidelines in Appendix Q for immediate jeopardy. The SA must notify the appropriate state*

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60 Centers for Disease Control and Prevention. (2016). *Frequently asked questions (FAQs) regarding assisted blood glucose monitoring and insulin administration.* Accessed on June 9, 2017 from https://www.cdc.gov/injectionsafety/providers/blood-glucose-monitoring_faqs.html

public health authority of the deficient practice; and

- *Multi-dose vials to be used for more than one resident are kept in a centralized medication area (e.g., medication room or cart) and do not enter the immediate resident treatment area (e.g., resident room). If multi-dose vials enter the immediate resident treatment area, they should be discarded immediately after use.*

  ***NOTE**: For more information on multi-dose vials, please refer to: https://www.cdc.gov/injectionsafety/providers/provider_faqs_multivials.html*

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.*** *Facility staff must follow manufacturer's instructions for administration. Regurgitation of blood into the insulin cartridge after injection will create a risk of bloodborne pathogen transmission if the pen is used for more than one resident, even when the needle is changed. The FDA makes the following recommendations to prevent transmission of bloodborne 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 and other identifiers to verify that the correct pen is used on the correct resident; and*
- *Facilities should review their policies and procedures and educate their staff regarding safe use of insulin pens.*

***NOTE:** Sharing insulin pens, or similar devices, between residents is similar to reusing needles or syringes for more than one resident. If noncompliance is found, surveyors must cite at this tag and utilize the guidelines in Appendix Q for immediate jeopardy. The SA must notify the appropriate state public health authority of the finding.*

For more information on insulin pens, please refer to: https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/ucm133352.htm

Accessing Vascular Devices

Vascular access devices, especially central venous catheters (CVC), increase the risk for local and systemic infections as well as additional complications such as septic thrombophlebitis. Intravascular access devices such as implanted ports may be accessed multiple times per day, for hemodynamic measurements or to obtain samples for laboratory analysis, thus increasing the risk of contamination and subsequent clinical infection. Limiting access to CVCs for only the primary purpose may help reduce the risk of infection. The following CDC guidelines are provided as a reference for current standards of practice for the care of CVCs:

- *http://www.cdc.gov/HAI/settings/outpatient/basic-infection-control-prevention-plan-2011/central-venous-catheters.html*
- *http://www.cdc.gov/dialysis/PDFs/collaborative/Hemodialysis-Central-Venous-Catheter-STH-Protocol.pdf*

- *http://www.cdc.gov/dialysis/PDFs/collaborative/Catheter-Exit-Site-Care-Observations.pdf*
- *http://www.cdc.gov/hicpac/pdf/guidelines/bsi-guidelines-2011.pdf*

SYSTEM OF RECORDING IPCP INCIDENTS

A facility must develop and implement a system for recording incidents identified under the facility's IPCP and the corrective actions taken by the facility based on the investigation of the incidents. A facility-identified incident (e.g., HAI) may include the spread of disease due to errors in infection prevention and control. The facility's system should include defining, identifying, analyzing, and reporting incidents related to failures in infection control practices to the director of nursing, medical director, and the QAA committee. These may include but are not limited to the following:

- *Identification of methods by which the facility would obtain information on incidents from residents, family, and direct care/direct access staff;*
- *A description of how the facility addresses and investigates the incident(s);*
- *Measures to be implemented for the prevention of incidents or potential incidents as they relate to infection prevention and control;*
- *Development and implementation of corrective actions;*
- *Monitoring for the effectiveness of its implemented changes; and*
- *Methods for feedback to appropriate individuals involved in the failed practices.*

LINENS

Laundry Services

The facility must develop and follow practices on handling, storing, processing, and transporting laundry. The facility must monitor to ensure that the laundry practices are implemented, any deviations from practices must be identified, and corrective actions are put in place.

Laundry includes resident's personal clothing, linens, (i.e., sheets, blankets, pillows), towels, washcloths, and items from departments such as nursing, dietary, rehabilitative services, beauty shops, and environmental services. Laundry services may be provided onsite or the facility may have a written agreement in place for offsite laundry services. Regardless of the location where the laundry is processed, the facility must ensure that all laundry is handled, stored, processed and transported in a safe and sanitary method.

Handling Laundry

The facility staff should handle all used laundry as potentially contaminated and use standard precautions (i.e., gloves). Alternatively, if not all used linens are handled as potentially contaminated, staff would provide separation with special identification of bags and containers for contaminated linens with labels, color coding, or other alternative means of separation of the laundry for appropriate handling and processing. The facility should use the following practices:

- *Contaminated laundry is bagged or contained at the point of collection (i.e., location where it was used);* [58]
- *Leak-resistant containers or bags are used for linens or textiles contaminated with blood or body substances;*[58]
- *Sorting and rinsing of contaminated laundry at the point of use, hallways, or other open resident care spaces is prohibited; and* [58]

- *Staff should handle soiled textiles/linens with minimum agitation to avoid the contamination of air, surfaces, and persons.* [58]

Transport of Laundry

The facility practices must include how staff will handle and transport the laundry with appropriate measures to prevent cross-contamination. This includes but is not limited to the following:

- *Contaminated linen and laundry bags are not held close to the body or squeezed when transporting;*[45]
- *No special precautions (i.e., double bagging) or categorizing for linen originating in transmission-based precaution rooms is necessary;*[58]
- *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;*[45]
- *Contaminated linen carts must be cleaned and disinfected whenever visibly soiled and according to a schedule developed by the facility;*[41]
- *Separate carts must be used for transporting clean and contaminated linen. If this is not possible, the contaminated linen cart should be thoroughly cleaned and disinfected per facility protocol before being used to move clean linens; and* [58]
- *Clean linens must be transported by methods that ensure cleanliness and protect from dust and soil during intra or inter-facility loading, transport, and unloading.* [58]

Linen Storage

Facility practices must address linen storage, and should include but are not limited to:

- *Covers are not needed on contaminated textile hampers in resident care areas (unless state licensing rules require them); and* [58]
- *Clean linen must always be kept separate from contaminated linen. The use of separate rooms, closets, or other designated spaces with a closing door provides the most secure methods for reducing the risk of accidental contamination.*[61]

Processing Laundry Including the Use of Laundry Equipment and Detergents in the Facility

The facility must have a process to clean laundry. Detergent and water physically remove many microorganisms from the linen through dilution during the wash cycle. Advances in laundry equipment 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. *Washing/drying processes includes the use of manufacturer's instructions for use (IFU) for laundry additives and equipment maintenance. The facility staff must prevent contamination of laundry in processing areas. The facility has laundry practices that includes but are not limited to the following:*

- *Availability and use of hand hygiene products, as well as appropriate PPE (i.e., gloves and gowns) while sorting and handling contaminated linens;* [58]
- *The receiving area for contaminated textiles is clearly separated from clean laundry areas. Workflow should prevent cross-contamination;* [58]

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61 Healthcare Laundry Accreditation Council. (2015). *Checklist: Accreditation standards 2016 edition.* Accessed on June 9, 2017 from http://media.wix.com/ugd/076879_24e999ab2b484cac8c3c30ee9af77cc0.pdf

- *If using fans in laundry processing areas, prevent cross-contamination of clean linens from air blowing from soiled processing areas (i.e., the ventilation should not flow from soiled processing areas to clean laundry areas);* [58]
- Laundry equipment (e.g., washing machines, dryers) is used and maintained according to the manufacturer's IFU to prevent microbial contamination of the system; [58]
- Damp laundry is not left in machines overnight; [58]
- *Laundry detergents, rinse aids or other additives are used according to the manufacturer's IFU's;* [58]

NOTE: *Facilities should communicate information regarding allergies that may impact how an individual resident's laundry is processed.*

- Ozone cleaning systems are acceptable for processing laundry;
- If laundry chutes are used, they are 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); [58] and
- *The facility should be using the fabric manufacturer's recommended laundry cycles, water temperatures and chemical detergent products:*
  - Recommendations for laundry processed in hot water temperatures is 160ºF (71ºC) for 25 minutes;[58] and
  - For laundry that is not hot water compatible, low temperature washing at 71 to 77 ºF (22-25 ºC) plus a 125-part-per-million (ppm) chlorine bleach rinse has been found to be effective and comparable to high temperature wash cycles.[58]

NOTE*: The facility is not required to monitor water temperatures during laundry processing cycles, unless specified by state rules.* 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. *The facility should refer to the manufacturer's recommendations for the use of the detergent and items being laundered.*

Offsite Professional Laundry Services

If linen is sent off-site to a professional laundry, the facility has practices that address how the service will be provided, including how linen is processed and handled to prevent contamination from dust and dirt during loading and transport. The facility should assure that this laundry service meets healthcare industry laundry standards.

Mattresses and Pillows

Standard *permeable* 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. ***NOTE****: Bed and bath linens must be maintained in good condition (Refer to §483.10(i) Safe environment, F584, for further information).*

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The facility must have practices that address the methods for cleaning and disinfecting items that are to be used for another resident after an individual resident's use such as but not limited to the following:[58]

- Mattress covers with tears or holes are replaced;
- Moisture resistant mattress covers are cleaned and disinfected between use for different residents with an EPA-approved germicidal detergent to help prevent the spread of infections;
- Fabric mattress covers are laundered between use for different residents;
- Pillow covers and washable pillows are laundered in a hot water laundry cycle between use for different residents or when they become contaminated with body substances; and
- Mattresses are discarded if bodily fluids have penetrated into the mattress fabric.

ANNUAL REVIEW OF IPCP

The facility's IPCP and its standards, policies and procedures must be reviewed at least annually to ensure effectiveness and that they are in accordance with current standards of practice for preventing and controlling infections; the IPCP must be updated as necessary. In addition, the facility population and characteristics may change over time, and the facility assessment may identify components of the IPCP that must be changed accordingly.

INVESTIGATIVE SUMMARY

Surveyors would use the Infection Control Facility Task to determine compliance with the infection control part of the survey. One surveyor should coordinate the review of the facility's overall infection prevention and control program (IPCP), however, each member of the survey team should assess for compliance throughout the entire survey when observing his/her assigned areas and tasks. The IPCP must be facility-wide and include all departments and contracted services. The surveyor should corroborate any concerns observed through interviews and record and/or document review.

Observations

Specific observations for the provision of infection prevention and control practices such as following standard precautions (e.g., hand hygiene and the appropriate use of PPE) should be made by all team members throughout the survey. Observe care of a resident on transmission-based precautions, if any, to determine if implemented appropriately based on precaution type (i.e., contact, droplet, airborne). If concerns are identified, expand the sample to include more residents with transmission-based precautions.

Observe laundry services throughout the survey (e.g., resident and laundry rooms) to determine whether staff handle, store, and transport linens appropriately.

Interviews

Surveyors should interview appropriate facility staff regarding the IPCP. In addition, any potential concerns should be followed up with interviews and record reviews as needed.

KEY ELEMENTS OF NONCOMPLIANCE

*To cite deficient practice at F880, the surveyor's investigation will generally show that the facility failed to do **any one** or more of the following:*

- *Establish and maintain an IPCP designed to provide a safe, sanitary, and comfortable environment and to help prevent development and transmission of disease and infection;*
- *The IPCP must be reviewed at least annually and updated as necessary;*
- *Implement a system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases for all residents, staff, volunteers, visitors, and other individuals providing services under a contractual arrangement, based on the facility assessment (see §483.70(e)) and follows accepted national standards;*
- *Develop and implement written IPCP standards, policies, and procedures that are current and based on national standards. These must include:*
  - *When and to whom possible incidents of communicable diseases should be reported;*
  - *Developing and implementing a system of surveillance to identify infections or communicable diseases;*
  - *How to use standard precautions (to include appropriate hand hygiene) and how and when to use transmission-based precautions (i.e., "isolation precautions"); and/or*
  - *Prohibiting staff with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit disease.*
- *Assure that staff handle, store, process and transport laundry to prevent the spread of infection; and/or*
- *Maintain a system for recording identified incidents, and taking appropriate corrective actions.*

DEFICIENCY CATEGORIZATION

Examples of Severity Level 4 Non-Compliance: Immediate Jeopardy to Resident Health or Safety include but are not limited to:

- The facility failed to follow standard precautions during the performance of routine testing of blood glucose. The facility reused fingerstick devices for more than one resident. This practice of reusing fingerstick devices for more than one resident created an immediate jeopardy to resident health by potentially exposing residents who required blood glucose testing to the spread of bloodborne infections in the facility.
- The facility failed to investigate, document surveillance of, and implement preventative measures to address an outbreak of gastrointestinal illness among residents in one unit of the facility. As a result, several residents in an adjoining unit became seriously ill with diarrheal illnesses resulting in dehydration.
- *Facility staff failed to handle soiled linens using safe and sanitary techniques. A resident was observed to have an acute onset of vomiting and diarrhea resulting in soiled clothing and linens. The nursing staff removed the soiled/contaminated clothing and linens, rinsed them out in the bathroom sink, and placed the wet/soiled linen onto the floor. The bathroom was shared with a roommate who utilized the sink for oral hygiene purposes and stored his/her toothbrush and glass on the sink. The roommate, subsequently developed vomiting and diarrhea, with the development of severe dehydration, resulting in hospitalization.*

An Example of Severity Level 3 Non-Compliance: Actual Harm that is not Immediate Jeopardy includes but is not limited to:

- *The facility failed to identify and prevent the spread of infestation when a case of scabies (i.e., a highly contagious skin condition caused by the itch mite Sarcoptes scabiei) was*

not diagnosed or adequately treated, and the resident was not placed on transmission-based precautions. Resident A was admitted with an undiagnosed, reddened, itchy pin-point rash which spread, became infected, and disrupted the resident's sleep. A month later, multiple residents developed a red, pin-point rash with severe itching, which was not present prior to resident A being admitted. The facility failed to identify through assessment and therefore, implement control measures to prevent the transmission of scabies among multiple residents in the facility, causing the residents physical harm. In addition to the physical harm, the residents experienced psychosocial harm due to anxiety and loss of sleep from severe itching and lack of timely diagnosis.

- *The facility failed to ensure that linens were handled and processed in a manner to prevent the spread of pediculosis (i.e., head lice) after a resident (resident A) in a semi private room was diagnosed with pediculosis. Staff were aware of the presence of pediculosis, but did not handle the resident's linens or clothing appropriately, removing bed linens and placing them on the roommate's chairs and other furnishings. The resident's roommate (resident B) became infested with pediculosis. The resident's roommate was non-verbal and unable to express that he had intense itching and began to scratch himself.*

An Example of Severity Level 2 Non-Compliance: No Actual Harm with Potential for more than Minimal Harm that is not Immediate Jeopardy includes but is not limited to:

- *The facility failed to ensure that its staff demonstrates proper use of gloves with hand hygiene between residents to prevent the spread of infections. The nurse administered medications to a resident via a gastric tube and while wearing the same gloves proceeded to administer oral medications to another resident. The nurse did not remove the used gloves nor perform hand hygiene between the two residents.*
- *The facility failed to implement appropriate measures for the transport of contaminated linens. As a result, the potential exists for transmission of organisms from contaminated uniforms to residents during the delivery of care. A nursing assistant was observed removing bed linens contaminated with urine and fecal material without the use of gloves, and carrying the contaminated linens against his/her uniform down the hall to the laundry bin. The nursing assistant proceeded to assist the resident's roommate with transferring to his/her chair, and his/her uniform made contact with the resident's skin and clothing.*
- *The facility failed to ensure that a staff member implemented appropriate processes related to handling and storing wound care supplies. As a result, the potential existed for transmission of organisms between residents who received dressing changes. A staff member who was providing wound care, was observed to place dressing supplies on one resident's bedding and after completing the dressing change, placed the supplies, which are used for other residents, in the unit's dressing cart.*

An Example of Severity Level 1 Non-Compliance: No actual harm with potential for minimal harm includes but is not limited to:

- *The facility failed to ensure that the IPCP program was reviewed annually. The survey was conducted and it was determined that the facility last reviewed the IPCP at 14 months instead of annually (i.e., 12 months). There were no infection control findings outside of annual review and documentation.*

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POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION
For staff competency concerns, refer to the following F tags:

- *F725 or 726, §483.35(a),(c) for Nursing Services;*
- *F741, §483.40 for any Behavioral Health staff caring for residents with dementia or a history of trauma and/or post-traumatic stress disorder;*
- *F801, §483.60(a) for Food and Nutrition staff; and*
- *F839, §483.70(f), Administration for any other staff not referenced above.*

If the surveyor has concerns about 1) the overuse of transmission-based ("isolation") precautions, 2) the inappropriate transferring of rooms unnecessarily; or 3) the inappropriate use of PPE such as gloves when used unnecessarily, where residents indicate they are "untouchable," dirty or unclean, review under §483.10(a)(1), F550, Resident Rights (Dignity) or §483.24, F675, Quality of Life.

For concerns related to possible involuntary seclusion, refer to §483.12 (a)(1), F603.

Data from injectable, scheduled drug tracking should be regularly reviewed and discrepancies or unusual access patterns are investigated including whether residents should be screened for exposure to bloodborne pathogens (refer to 483.45, F755, Pharmacy Services for further information on reconciliation concerns).

For concerns related to the QAA committee's responsibility to identify or correct quality deficiencies, which may include systemic infection control concerns, refer to 483.75(g)(2)(ii), F867, QAA Activities.

For concerns related to the medical director's role in responsibility for care, refer to §483.70(h), F841, Medical Director.

F881
§483.*80(a) Infection prevention and control program.*
The facility must establish an infection prevention and control program (IPCP) that must include, at a minimum, the following elements:

§483.*80(a)(3) An antibiotic stewardship program that includes antibiotic use protocols and a system to monitor antibiotic use.*

INTENT
The intent of this regulation is to ensure that the facility:

- *Develops and implements protocols to optimize the treatment of infections by ensuring that residents who require an antibiotic, are prescribed the appropriate antibiotic;*
- *Reduces the risk of adverse events, including the development of antibiotic-resistant organisms, from unnecessary or inappropriate antibiotic use; and*
- *Develops, promotes, and implements a facility-wide system to monitor the use of antibiotics.*