

WIPAG

WY Infection Prevention Orientation Manual

Section #17, Regulatory Compliance in Infection Control

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Section #17: Regulatory Compliance in Infection Control

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Objectives

At the completion of this section the IP will:

- recognize the source of Federal statutory requirements to identify, monitor, and prevent infections in long-term care (LTC) facilities
- understand the relationships between infection control activities and an overarching quality assessment, performance improvement (QAPI) program
- understand the process for surveying infection control compliance

NOTE: The stated objectives are specific for long-term care facilities. Infection control requirements for other healthcare facility types - for example, acute care and critical access hospitals, ambulatory surgery centers, home health agencies - can be found in the online references provided at the end of this section.

Number of hours

- Key Concepts and Methods – 2 hours

Overview

The Centers for Medicare & Medicaid Services (CMS), operating under the authority of the Code of Federal Regulations, Title 42, publish regulatory requirements that define minimum levels of quality care for healthcare facilities. Federal requirements are supplemented in some cases with additional, more stringent, requirements established by the State of Wyoming. It is the responsibility of the State Survey Agent, Healthcare Licensing & Surveys, to survey facilities and determine compliance with Federal and State rules for quality care to patients and residents.

This section presents an overview of regulatory compliance for infection control in a LTC setting. Infection control requirements exist in all healthcare facility types; LTC is used here to illustrate the elements of infection control from a surveyor perspective and describe the survey process to new IPs. Other facility types have similar regulatory requirements; refer to the links at the end of this section for information on regulatory compliance in other healthcare facilities.

The IP is critical to a facility's success in meeting compliance requirements for infection prevention, surveillance activities, environmental services, and employee health programs. Specific regulatory language for infection prevention varies between facility types, but the basic principles that apply in LTCs are consistent across all healthcare settings.

Key Concepts

A survey is an opportunity for an external agency to enter the facility and interact with staff and residents. The surveyor team's goal is to assess compliance with Federal and State requirements and identify areas where non-compliance has, or is likely to, result in an unsafe environment for residents. Yes, a survey is an inspection and, yes, it contributes to staff anxiety. Remember that most surveyors previously worked in healthcare facilities that were inspected - they have been on both sides of the fence and understand the stress of an inspection. Ask questions and use this time, and the surveyors'

experience, as a learning opportunity.

The survey process relies on 3 principal methods for gathering evidence: **observation** of facility practices, **review** of documentation, and **interview** with facility staff, residents, family members, and visitors. A survey is action oriented and focuses on observed practices as evidence that policies, procedures, and standards are understood and applied by facility staff. Observation is key to the survey process, substantiated by documentation and interview, to see how staff integrates training, established policies and procedures, and professional standards to achieve the facility's infection prevention goals.

To better understand the process of data collection used in the survey process, consider the ways these techniques might be applied when surveying an infection control program:

- **Observation:** Surveyors will watch staff and residents for evidence of infection prevention practices. This could include opportunities for hand hygiene, wound care, point-of-care testing such as with glucometers, use of personal protective equipment (PPE) in posted rooms, cleaning and disinfection of equipment and rooms, terminal cleaning after precautions are removed, use of clean and soiled utility rooms, medication pass, sharps and waste disposal, and injection practices. Observations will occur throughout the facility and across the entire day.
- **Review:** Surveyors will review policies and procedures outlining the infection control program, outcome and process surveillance activities, incidence reports, laboratory results, medical records, manufacturer's literature for products and equipment, instructions for use, precaution signage, medication records, clinical charts, and any other documentation needed to understand a facility's infection control practices.
- **Interview:** Surveyors will talk with staff, residents, family members, visitors, volunteers, and contractors to assess compliance with infection prevention practices. Interviews help clarify observations and substantiate staff awareness of policies, procedures, and practices.

Every healthcare facility type regulated under CMS must have the ability to identify and prevent infections. If an infection occurs, the LTC must be able to monitor the resident's condition, treatment, and progression to the point of clinical resolution. This monitoring activity is known as "surveillance" and is a critical component of compliance with CMS regulations.

Surveys are conducted in accordance with outcome-oriented survey protocols. The survey team will concentrate on resident outcomes in determining a facility's compliance with the Federal requirements rather than focusing exclusively on "process-oriented" requirements. In this case, outcomes include both actual and potential negative events for residents in the facility.

Methods

Excerpts from the Federal regulatory code are presented in this section to illustrate the scope of regulatory compliance for LTC facilities. The best source of current Federal compliance information can be found at the "Regulations and Guidance" section of the CMS website (www.cms.gov) or as linked from the Healthcare & Licensing webpage (www.health.wyo.gov/ohls). In addition to the regulatory language shown below, the summation of regulatory requirements includes several pages of Interpretive Guidelines. These guidelines are not regulatory in the sense they specifically embody the Federal Code, but instead serve as an expanded source of definitions, examples, references, and explanatory discussion of regulatory requirements for infection control.

Exercise #1: Using one of the links listed above, find and review the regulatory requirements for infection control programs in a LTC facility (F441). Review the 24 pages of interpretive guidelines for references. Source: Code of Federal Regulations, Title 42, Chapter IV, Subchapter G, Part 483; State Operations Manual (SOM), Appendix PP, Guidance to Surveyors for Long-Term Care Facilities

NOTE: Federal regulations are updated as practices evolve, standards change, and legal decisions refine the law; the following excerpts are current at the time of writing, but will change over time. Facilities are responsible for compliance with current requirements.

The intent of the regulation is to ensure facilities develop, implement, and maintain an infection prevention and control program in order to recognize and prevent the onset and spread of infection within the facility. The overall emphasis is on maintaining a safe and sanitary environment for residents. The infection control program must:

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

The regulatory language and stated intent outline the fundamental compliance requirements for LTC facilities. The stated requirements address the need for outcome and process surveillance activities, staff and visitor training, compliance monitoring, problem-solving (investigation and intervention), employing transmission-based precautions, and reporting diseases and conditions as required by the Wyoming Department of Health.

Surveyors review surveillance activities across two distinct components: outcome (monitoring existing infections and events) and processes (actions to prevent infection or transmission of infectious materials). They gather evidence from all areas of the facility to evaluate the adequacy and efficacy of surveillance activities. This means that all facility personnel can expect to be observed and interviewed by surveyors on infection prevention practices. The infection control program must ensure that all staff understand and apply preventive practices, such as hand hygiene, cleaning and disinfecting, isolation and transmission-based precautions, and waste disposal. Additional specialized practices, such as medication administration and wound care, are evaluated as they apply to facility residents.

Surveillance activities must be documented. This is often represented by a log or worksheet used to capture information on active (symptomatic) infections, microbiology culture results, therapeutic interventions, use of transmission-based precautions, line listings of multidrug-resistant organisms (MDROs), and clinical resolution. Each of these elements is important in tracking infections and developing strategies to prevent spread to other residents and staff. Surveyors will review these data to ensure records are complete, accurate, and follow facility policies and procedures for surveillance activities.

The facility's policies and procedures for infection control activities should be based on nationally

recognized standards and practices. There is no regulatory mandate that specifies only guidelines from the Centers for Disease Control and Prevention (CDC) or recommendations of the Association in Infection Control and Epidemiology (APIC) must be used. However, surveyors will observe staff practices and evaluate these practices against current standards of practice, which are often based on CDC and APIC guidance. The facility must have a substantive foundation for its infection control program.

Surveyors review the facility's data collection processes and evaluate the timeliness and accuracy of data collection. Data collection is often a mix of active and passive techniques; regulatory compliance does not prescribe how surveillance data is collected, only that it be accurate, complete, and sufficient for the complexity of infection control challenges at a facility.

One of the most commonly cited deficiencies for surveillance activities based on national survey statistics is the absence of a complete and accurate method for tracking infections or epidemiologically significant events in a LTC. In Wyoming, this is often demonstrated by a lack of appropriate data collection (or not following an established data collection plan), inaccurate data, missing (or misunderstood) microbiology cultures or other laboratory diagnostic information, or failure to monitor an infection or event to resolution.

Monitoring compliance (process surveillance) is also frequently cited for non-compliance, both nationally and in Wyoming LTCs. Observations and documentation often demonstrate discrete monitoring of the nursing care staff, but overlook non-direct care staff, environmental infection control, laundry and linen, and employee health. Non-compliance is most often discovered when surveyors find that support services do not understand the necessity for hand hygiene or how to apply acceptable practices when confronted with a precautions-posted room.

Exercise #2: Based on your facility policies, and interviews with pertinent staff, answer the following questions.

- 1. How does your environmental services staff document terminal cleaning, after a room has been under transmission-based precautions?*
- 2. Is staff aware of requirements for special environmental cleaning, for example, after Clostridium difficile infection?*
- 3. If you were asked how you monitor this type of environmental infection control, what documentation can you provide?*

In a similar fashion, surveyors review in-service training and employee orientation to ensure infection control is a part of the required education for staff. Involve all facility staff in infection control education opportunities and be sure they understand how the training applies to the tasks they perform.

Infection prevention is a challenging task in the long-term care setting and achieving compliance requires a facility-wide effort. Surveyors will watch resident care, environmental services, food preparation, precaution-posted rooms (when present), laundry services, housekeeping, and medication passes in the LTC and evaluate observed practices against regulatory requirements. This is an important concept for new IPs. Infection control is a team process and all staff must be aware of, and follow, standards detailed in applicable policies and procedures. The survey team will interview not just clinical staff, but also support services, to assess their level of understanding and compliance.

It is not uncommon to discover staff members who are not aware of infection prevention practices, or who have a conceptual awareness of the requirements, but do not understand their application. For example, nursing personnel can usually recite requirements for selected transmission-based precautions and recognize the signage, but might fail to properly use PPE. A similar situation observed on survey involves staff using a disinfectant product; they understand the need to disinfect an environmental surface, but fail to use minimum wet exposure times required for disinfecting action.

Process surveillance might be cited as non-compliant at LTCs, particularly when the facility's infection control activities are exclusively focused on residents with active infection or those on antibiotic therapy, i.e., outcome only events. While tracking infections and antibiotics (outcome surveillance) is a critical element of a surveillance program, it is not the only area of infection prevention required by regulation. A surveyor might ask the IP or other staff member to identify processes in the facility that are necessary to prevent transmission of infection. These might include hand hygiene, safe injection practices, perineal care, wound therapy, food preparation, cleaning and disinfection of equipment and environmental surfaces, and following posted transmission-based precautions. The infection control program is expected, and required, to actively monitor staff compliance with essential processes to prevent the spread of infection.

If implementing hand hygiene monitoring as a process surveillance activity, consider how to ensure monitoring includes all areas within the facility. The IP might find it helpful to complete a risk assessment to identify areas and procedures that require a high frequency of hand hygiene or have particularly stringent requirements for hand washing, then focus surveillance efforts on these high risk areas. Risk assessment of infection prevention is not specifically addressed in the LTC regulations. However, surveyors use a similar process to evaluate facility hand hygiene compliance and monitor staff practices when hand washing is an appropriate step within a task.

Exercise #3: Consider a task, such as serving food trays to residents that eat in their rooms, and make a list of infection prevention processes associated with the task. Then observe the task being performed. Do additional infection prevention practices become apparent when you watch the task being performed? Please explain below.

Can you think of a similar technique that you could use to evaluate the facility-wide hand hygiene compliance rate? Please describe below.

The survey team reviews the facility's surveillance activities for evidence of both outcome and process surveillance. The IP will be asked to explain how the facility collects data, what tools are used to collect data, how the resultant data is analyzed, and how surveillance activities integrate into the facility's overarching quality assessment, performance improvement (QAPI) program.

Surveillance activities are data-driven and should provide an objective, quantifiable assessment of infection control and prevention in the facility. Surveillance data is typically compiled for reporting to the facility-wide QAPI program. Surveyors will ask for these reports or feeder data for QAPI review.

If a facility is non-compliant in the area of infection control, there must be a focused effort to identify and develop quality indicators and performance improvement strategies to identify, implement, evaluate, and sustain corrective actions. The QAPI indicators should be relevant to compliance concerns, ensure corrective interventions are assessed for effectiveness, and implement new interventions as necessary. For example, if non-compliance with hand hygiene practices are cited on a survey or is a repeat deficiency from previous surveys, the QAPI program is reasonably expected to identify the extent of hand hygiene problems, develop and implement interventions to improve and sustain appropriate hand hygiene practices, and monitor the effectiveness of the corrective interventions.

Other Issues

The onsite survey team is a valuable resource; ask questions of the surveyors and engage them in a professional exchange. Despite the inevitable anxiety that arrives with the survey team, the survey process can be a substantive learning opportunity.

One of the greatest challenges for IPs, as viewed from a surveyor's perspective, is the frequency of turn-over in the IP position and a concomitant lack of training and education opportunities for new IPs. If an IP lacks a substantive background in infection control and surveillance activities, they might find compliance requirements unfamiliar and difficult to achieve. If an IP's time is spread across multiple job requirements, surveillance might appear as an insurmountable task with overwhelming demands on their time and energy.

The increased incidence of MDROs in healthcare facilities poses a particular challenge for LTC IPs. Ask healthcare provider staff, pharmacy consultants, and reference laboratories to explain unusual

microbiology culture results and susceptibility patterns. Communicate closely with providers to determine when precautions might be effective in reducing transmission risk and when such precautions can be reduced or removed. It is important for the LTC IP to establish a close liaison with the IPs at hospitals that provide acute care for residents from their facility. For example, does the local hospital perform screening for methicillin-resistant *Staphylococcus aureus* on admission from LTC? If so, how does the LTC facility get these results and what does the information mean to the overall infection prevention program? Can the hospital IP assist you in tracking down microbiology culture results for residents following an acute care stay?

IPs should take advantage of their network, IPs across the state, as other IPs have solved the very problems that an individual facility might now be facing. Solutions, or at least an approach to a solution, might be within the professional IP network. It is imperative that the IP become familiar with national standards, guidelines, and recommendations such as those published by the CDC, the APIC, and the Wyoming Health Department.

Remember, too, that the surveyor office is a resource. They do not provide consultative assistance, but are available to answer questions and assist with interpretation of compliance requirements. An IP should make the survey office part of their IP network.

Resources

Helpful/Related Readings

- Grota P, Allen V, Boston KM, et al, eds. *APIC Text of Infection Control & Epidemiology*. 4th Edition. Washington, D.C.: Association for Professionals in Infection Control and Epidemiology, Inc.; 2014.
 - Chapter 4, Accrediting and Regulatory Agencies, by K Boston
 - Chapter 61, Long Term Care, by M Bodily-Bartrum, J Franck, L Spaulding and J Zeller
- Lautenbach E, Woeltje KF, and Malani PN, eds. *SHEA Practical Healthcare Epidemiology* (3rd Edition). University of Chicago Press, Chicago, IL: 2010
 - Chapter 31 An Overview of Important Regulatory and Accrediting Agencies, by J Bartley, T Lundstrom, M Nettleman and G Pugliese
 - Chapter 32, Government Mandates and Infection Control, by SG Weber, pages 422-432
- Schweon S, Burdsall D, Hanchett M, et al. *Infection Preventionist's Guide to Long-Term Care*. Washington, D.C.: Association for Professionals in Infection Control and Epidemiology, Inc.; 2013.
 - Chapter 2, Regulatory Surveys and CMS F tag 441 Compliance, by D Patterson Burdsall

Helpful Contacts (in WY or US)

- Wyoming State Survey Agency, Healthcare Licensing & Surveys, Aging Division, Wyoming Department of Health, 307-777-7123

Related Websites/Organizations

- Centers for Medicare & Medicaid Services (CMS), Regulations & Guidance www.cms.gov/Regulations-and-Guidance/Regulations-and-Guidance.html
 - For General Acute Care Hospitals, www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf

- For Acute Psychiatric Hospitals, www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/Downloads/som107ap_aa_psyc_hospitals.pdf
- For Critical Access Hospitals, www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap_w_cah.pdf
- Healthcare Licensing & Surveys, Aging Division, Wyoming Department of Health www.health.wyo.gov/ohls/index.html
- Wyoming State Rules and Regulations based on healthcare facility type, Healthcare licensing & Surveys, Aging Division, Wyoming Department of Health, www.health.wyo.gov/ohls/ruleslist.html
- Wyoming Department of Health, Infectious Disease Epidemiology Unit, Healthcare-Associated Infection Prevention www.health.wyo.gov/phsd/epiid/HAIgeneral.html
- Mountain-Pacific Quality Health – Wyoming www.mpqhf.com/wyoming/index.php



WIPAG welcomes your comments and feedback on these sections.
For comments or inquiries, please contact:

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