

State Operations Manual

Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals

Infection Control Interpretive Guideline (IC IG)

A-0747

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§482.42 Condition of Participation: Infection Control

The hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases.

Interpretive Guidelines §482.42

This regulation requires the hospital to develop, implement, and maintain an active, hospital-wide program for the prevention, control, and investigation of infections and communicable diseases. The National Institute of Allergy and Infectious Diseases defines an infectious disease as a change from a state of health to a state in which part or all of a host's body cannot function normally because of the presence of an infectious agent or its product. An infectious agent is defined by the NIAID as a living or quasi-living organism or particle that causes an infectious disease, and includes bacteria, viruses, fungi, protozoa, helminthes, and prions. NIAID defines a communicable disease as a disease associated with an agent that can be transmitted from one host to another. (NIAID website glossary) According to the Centers for Disease Control and Prevention (CDC), healthcare-associated infections, i.e., infections that patients acquire during the course of receiving treatment for other conditions within a healthcare setting, are one of the top ten leading causes of death in the United States. The CDC estimates that there are 1.7 million healthcare-associated infections in American hospitals each year, with 99,000 associated deaths. (CDC website, Estimates of Healthcare-Associated Infections, date last modified May 30, 2007)

The hospital must provide and maintain a sanitary environment to avoid sources and transmission of infections and communicable diseases. All areas of the hospital must be clean and sanitary. This includes all hospital units, campuses and off-site locations. The infection prevention and control program must include appropriate monitoring of housekeeping, maintenance (including repair, renovation and construction activities), and other activities to ensure that the hospital maintains a sanitary environment. Examples of areas to monitor would include: food storage, preparation, serving and dish rooms, refrigerators, ice machines, air handlers, autoclave rooms, venting systems, inpatient rooms, treatment areas, labs, waste handling, surgical areas, supply storage, equipment cleaning, etc. The hospital's program for prevention, control and investigation of infections and communicable diseases should be conducted in accordance with nationally recognized infection control practices or guidelines, as well as applicable regulations of other federal or state agencies. Examples of

organizations that promulgate nationally recognized infection and communicable disease control guidelines, and/or recommendations include: the Centers for Disease Control and Prevention (CDC), the Association for Professionals in Infection Control and Epidemiology (APIC), the Society for Healthcare Epidemiology of America (SHEA), and the Association of periOperative Registered Nurses (AORN).

The U.S. Occupational Health and Safety Administration (OSHA) also issues federal regulations applicable to infection control practices.

In order to prevent, control and investigate infections and communicable diseases, the hospital's program must include an active surveillance component that covers both hospital patients and personnel working in the hospital. Surveillance includes infection detection, data collection and analysis, monitoring, and evaluation of preventive interventions.

The hospital must conduct surveillance on a hospital-wide basis in order to identify infectious risks or communicable disease problems at any particular location. This does not imply "total hospital surveillance," but it does mean that hospitals must have reliable sampling or other mechanisms in place to permit identifying and monitoring infections and communicable diseases occurring throughout the hospital's various locations or departments. The hospital must document its surveillance activities, including the measures selected for monitoring, and collection and analysis methods. Surveillance activities should be conducted in accordance with recognized infection control surveillance practices, such as, for example, those utilized by the CDC's National Healthcare Safety Net (NHSN).

The hospital must develop and implement appropriate infection control interventions to address issues identified through its detection activities, and then monitor the effectiveness of interventions through further data collection and analysis.

The hospital's infection prevention and control program must be integrated into its hospital-wide Quality Assurance and Performance Improvement (QAPI) program. (See 42 CFR 482.42(b)(1).)

SPECIAL CHALLENGES IN INFECTION CONTROL

MULTI-DRUG RESISTANT ORGANISMS (MDROs)

According to the Centers for Disease Control's (CDC) publication, Management of Multi-drug Resistant Organisms in Healthcare Settings 2006, <http://www.cdc.gov/ncidod/dhqp/pdf/ar/mrdoGuideline2006.pdf>, MDROs are microorganisms that are resistant to one or more antimicrobial agents. Options for treating patients with MDRO infections are very limited, resulting in increased mortality, as well as increased hospital length of stay and costs. During the last several decades the prevalence of MDROs in hospitals has increased steadily. Hospitals are encouraged to have mechanisms in place for the early identification of patients with targeted MDROs prevalent in their hospital and community, and for the prevention of transmission of such MDROs. When ongoing transmission of targeted MDROs in the hospital is identified, the infection prevention and control program should use this event to identify potential breaches in infection control practice.

AMBULATORY CARE

The ambulatory care setting, including emergency departments, presents unique challenges for infection control, because: patients remain in common areas, often for prolonged periods of time, until they can be seen by a healthcare practitioner; examination or treatment rooms are turned around quickly with minimal cleaning; and infectious patients may not be recognized immediately. Furthermore, immuno-compromised patients may receive treatments in rooms among other patients who pose risks of infection.

The hospital's infection prevention and control program should be designed with these ambulatory care setting challenges in mind. After assessing the likely level of risk in its various ambulatory care settings, including off-site settings, a hospital might identify particular settings, such as the emergency department, where it would be appropriate to employ measures for screening individuals with potentially contagious diseases during their initial patient encounter, and taking appropriate control measures for those individuals who may present risk for the transmission of infectious agents by the airborne or droplet route. Guidelines promulgated by the CDC's Healthcare Infection Control Practices Advisory Committee (HICPAC) are a resource for hospitals in developing their infection control program for ambulatory care. For example, when potentially infectious individuals are identified, prevention measures should include prompt physical separation wherever possible, implementation of respiratory hygiene/cough etiquette protocols, and/or appropriate isolation precautions based on the routes of transmission of the suspected infection.

COMMUNICABLE DISEASE OUTBREAKS

Community-wide outbreaks of communicable diseases (such as measles, SARS, or influenza) present many of the same issues and require many of the same considerations and strategies as other hospital infectious disease threats. If a communicable disease outbreak occurs, an understanding of the epidemiology, likely modes of transmission, and clinical course of the disease is essential for responding to and managing the event. Among the infection control issues that may need to be addressed are:

- Preventing transmission among patients, healthcare personnel, and visitors;
- Identifying persons who may be infected and exposed;
- Providing treatment or prophylaxis to large numbers of people; and
- Logistics issues (staff, medical supplies, resupply, continued operations, and capacity).

Pandemics, or very widespread and clinically serious outbreaks of an infection, present additional challenges due to the widespread effect on the availability of back-up resources that would typically be available to address an outbreak confined to a smaller geographic area. Additionally, the duration of a pandemic may present special challenges for staffing, supplies, resupply, etc. Hospitals should work with local, State, and Federal public health agencies to identify likely communicable disease threats and develop appropriate preparedness and response strategies.

BIOTERRORISM

Healthcare facilities would confront a set of issues similar to naturally occurring communicable disease threats when dealing with a suspected bioterrorism event. The required response is likely to differ based on whether exposure is a result of a biological release or person-to-person transmission. A variety of sources offer guidance for the management of persons exposed to likely agents of

bioterrorism, including Federal agency websites (e.g., <http://www.ahrq.gov/prep>; <http://www.usamrid.army.mil/publications/index.html>; <http://www.bt.cdc.gov>) Because of the many similarities between man-made and naturally occurring threats, an all-hazards approach to developing emergency response plans is preferred, and hospitals are encouraged to work with their State and local emergency response agencies to develop their plans.

The hospital must be in compliance with the Occupational Health and Safety Administration's Bloodborne Pathogens regulation at 29 CFR 1910.1030.

Survey Procedures §482.42

- Survey of the Infection Control Condition of Participation (CoP) should be coordinated by one surveyor. However, each surveyor should assess the hospital's compliance with the Infection Control CoP as he/she conducts his/her survey assignments.
- Determine whether there are hospital-wide policies and procedures for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases of patients and hospital personnel, including contract workers and volunteers. Determine whether the infection control program can identify all hospital locations and that the policies and procedures take the various hospital locations into account.
- Determine whether the policies and procedures are implemented correctly in an active infection control program.
- Determine whether the program is hospital-wide and program specific in gathering and assessing infection and communicable disease data. Review the parameters of the active surveillance program to determine whether it is consistent with infection control standards of practice and suitable to the scope and complexity of the hospital's services.
- Throughout the hospital, observe the sanitary condition of the environment of care, noting the cleanliness of patient rooms, floors, horizontal surfaces, patient equipment, air inlets, mechanical rooms, food service activities, treatment and procedure areas, surgical areas, central supply, storage areas, etc.
- Determine whether the hospital's infection prevention and control program is integrated into its hospital-wide QAPI program.

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§482.42(a) Standard: Organization and Policies

A person or persons must be designated as infection control officer or officers to develop and implement policies governing control of infections and communicable diseases.

Interpretive Guidelines §482.42(a)

Hospital infection control officers are often referred to as "hospital epidemiologists (HEs)" or "infection control professionals (ICPs)." CDC has defined "infection control professional" as "a

person whose primary training is in either nursing, medical technology, microbiology, or epidemiology and who has acquired specialized training in infection control.”

The hospital must designate in writing an individual or group of individuals as its infection control officer or officers. In designating infection control officers hospitals should assure that the individuals so designated are qualified through education, training, experience, or certification (such as that offered by the Certification Board of Infection Control and Epidemiology Inc. (CBIC), or by the specialty boards in adult or pediatric infectious diseases offered for physicians by the American Board of Internal Medicine (for internists) and the American Board of Pediatrics (for pediatricians)). Infection control officers should maintain their qualifications through ongoing education and training, which can be demonstrated by participation in infection control courses, or in local and national meetings organized by recognized professional societies, such as APIC and SHEA.

CMS does not specify either the number of infection control officers to be designated or the number of infection control officer hours that must be devoted to the infection prevention and control programs. However, resources must be adequate to accomplish the tasks required for the infection control program. A prudent hospital would consider patient census, characteristics of the patient population, and complexity of the healthcare services it offers in determining the size and scope of the resources it commits to infection control. The CDC’s HICPAC as well as professional infection control organizations such as the APIC and the SHEA publish studies and recommendations on resource allocation that hospitals may find useful.

The infection control officer(s) must develop and implement policies governing the control of infections and communicable diseases. Infection control policies should address the roles and responsibilities for infection control within the hospital; how the various hospital committees and departments interface with the infection control program; and how to prevent infectious/communicable diseases; and how to report infectious/communicable diseases to the infection control program.

Survey Procedures §482.42(a)

- Determine whether an infection control officer(s) is designated and has the responsibility for the infection prevention and control program.
- Review the personnel file of the infection control officer(s) to determine whether he/she is qualified through ongoing education, training, experience, or certification to oversee the infection control program.
- Determine whether the infection control officer(s) have developed and implemented hospital infection control policies.

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§482.42(a)(1) - The infection control officer or officers must develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel.

Interpretive Guidelines §482.42(a)(1)

The infection control officer or officers must develop, implement and evaluate measures governing the identification, investigation, reporting, prevention and control of infections and communicable diseases within the hospital, including both healthcare-associated infections and community-acquired infections. Infection control policies should be specific to each department, service, and location, including off-site locations, and be evaluated and revised when indicated. The successful development, implementation and evaluation of a hospital-wide infection prevention and control program requires frequent collaboration with persons administratively and clinically responsible for inpatient and outpatient departments and services, as well as, non-patient-care support staff, such as maintenance and housekeeping staff.

Implicit in the infection control officer(s)' responsibility for measures to identify, investigate, report, prevent and control infections and communicable diseases are the following activities:

- Maintenance of a sanitary hospital environment;
- Development and implementation of infection control measures related to hospital personnel; hospital staff, for infection control purposes, includes all hospital staff, contract workers (e.g., agency nurses, housekeeping staff, etc), and volunteers;
- Mitigation of risks associated with patient infections present upon admission:
- Mitigation of risks contributing to healthcare-associated infections:
- Active surveillance;
- Monitoring compliance with all policies, procedures, protocols and other infection control program requirements;
- Program evaluation and revision of the program, when indicated;
- Coordination as required by law with federal, state, and local emergency preparedness and health authorities to address communicable disease threats, bioterrorism, and outbreaks;
- Complying with the reportable disease requirements of the local health authority; For example, a hospital with a comprehensive hospital-wide infection control program should have and implement policies and procedures, based as much as possible on national guidelines, that address the following:
- Maintenance of a sanitary physical environment:

Ventilation and water quality control issues, including measures taken to maintain a safe environment during internal or external construction/renovation;

- Maintaining safe air handling systems in areas of special ventilation, such as operating rooms, intensive care units, and airborne infection isolation rooms;
- Techniques for food sanitation;

- Techniques for cleaning and disinfecting environmental surfaces, carpeting and furniture;
- Techniques for textiles reprocessing, storage and distribution;
- Techniques for disposal of regulated and non-regulated waste; and
- Techniques for pest control.
- Hospital staff-related measures:
 - Measures – and authority - for evaluating hospital staff immunization status for designated infectious diseases, as recommended by the CDC and its Advisory Committee on Immunization Practices (ACIP);
 - Policies articulating the authority and circumstances under which the hospital screens hospital staff for infections likely to cause significant infectious disease or other risk to the exposed individual, and for reportable diseases, as required under local, state, or federal public health authority;
 - Policies articulating when infected hospital staff are restricted from providing direct patient care and/or are required to remain away from the healthcare facility entirely;
 - New employee and regular update training in preventing and controlling healthcare-associated infections and methods to prevent exposure to and transmission of infections and communicable diseases;
 - Measures to evaluate staff and volunteers exposed to patients with infections and communicable disease;
- Mitigation of risks associated with patient infections present upon admission:
 - Measures for the early identification of patients who require isolation in accordance with CDC guidelines;
- Appropriate use of personal protective equipment including gowns, gloves, masks and eye protection devices;
 - Use and techniques for “isolation” precautions as recommended by the CDC.
- Mitigation of risks contributing to healthcare-associated infections:
 - Surgery-related infection risk mitigation measures:

- Implementing appropriate prophylaxis to prevent surgical site infection (SSI), such as a protocol to assure that antibiotic prophylaxis to prevent surgical site infection for appropriate procedures is administered at the appropriate time, done with an appropriate antibiotic, and discontinued appropriately after surgery;
 - Addressing aseptic technique practices used in surgery and invasive procedures performed outside the operating room, including sterilization of instruments;
- Other hospital healthcare-associated infection risk mitigation measures:
 - Promotion of handwashing hygiene among staff and employees, including utilization of alcohol-based hand sanitizers;
 - Measures specific to prevention of infections caused by organisms that are antibiotic-resistant;
 - Measures specific to prevention of device-associated bloodstream infection (BSI), such as a protocol for reducing infections of central venous catheters specifying aseptic precautions for line insertions, care of inserted lines, and prompt removal when a line is no longer needed;
 - Measures specific to prevention of other device-associated infections, e.g., those associated with ventilators, tube feeding, indwelling urinary catheters, etc;
 - Isolation procedures and requirements for highly immuno-suppressed patients who require a protective environment. Care techniques for tracheostomy care, respiratory therapy, burns and other situations that reduce a patient's resistance to infection;
 - Requiring disinfectants, antiseptics, and germicides to be used in accordance with the manufacturers' instructions;
 - Appropriate use of facility and medical equipment, including negative and positive pressure isolation room equipment, portable air filtration equipment, treatment booths and enclosed beds, UV lights, and other equipment used to control the spread of infectious agents;
 - Adherence to nationally recognized infection prevention and control precautions, such as current CDC guidelines and recommendations, for infections/communicable diseases identified as present in the hospital; and
 - Educating patients, visitors, caregivers, and staff, as appropriate, about infections and communicable diseases and methods to reduce transmission in the hospital and in the community;
- Active surveillance:
 - Methods for obtaining and reviewing data on infections/communicable diseases selected for monitoring;

- Methods for monitoring and evaluating practices of asepsis;
- Authority and indications for obtaining microbiological cultures from patients and the environment as indicated.
- Provisions to monitor compliance with all policies, procedures, protocols and other infection control program requirements;
- Provision for program evaluation and revision of the program, when indicated;
- Policies and procedures developed in coordination with federal, state, and local emergency preparedness and health authorities to address communicable disease threats, bioterrorism, and outbreaks; and
- Procedures for meeting the reporting requirements of the local health authority.

Survey Procedures §482.42(a)(1)

- Determine whether the hospital has an active, hospital-wide infection control program reflecting the infection control officer responsibilities specified in the interpretive guidelines. Specifically, surveyors should determine whether the hospital:
 - Maintains a sanitary environment;
 - Develops and implements infection control measures related to hospital personnel;
 - Mitigates risks associated with patient infections present upon admission;
 - Mitigates risks contributing to healthcare-associated infections (for example, observe whether staff exhibit good handwashing hygiene);
 - Conducts active surveillance;
 - Monitors compliance with all infection control program requirements;
 - Evaluates the infection control program regularly and revises it, when indicated;
 - Coordinates as required by law with federal, state, and local emergency preparedness and health authorities to address communicable disease threats, bioterrorism, and outbreaks; and

Complies with the reportable disease requirements of the local health authority.

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§482.42(a)(2) - The infection control officer or officers must maintain a log of incidents related to infections and communicable diseases.

Interpretive Guidelines §482.42(a)(2)

The infection control officer(s) must maintain a **log of incidents related to infections and communicable diseases**, including healthcare-associated infections (HAI) and infections identified through employee health services. The log identifies incidents of infection and communicable disease throughout the hospital and documents infections and communicable diseases in patients and staff (patient care staff and non-patient care staff, including employees, contract staff and volunteers). Since hospitals may be required by law or contract to protect health care information related to its employees as confidential, the hospital may take appropriate steps, such as using codes instead of names in the log, with a separate document that enables linking codes and names, to address incidents associated with communicable disease occurrence among the staff.

"Incidents related to infections and communicable diseases" would include events falling into any of the following categories. Hospitals are not required to organize their logs according to these categories, but they are encouraged to capture all of the types of incidents described below. Multiple entries for an incident that falls into several categories is not required, e.g., a patient recorded as a reportable case of tuberculosis need not be listed again as a patient requiring airborne infection isolation.

- Healthcare-associated infections identified by the hospital, including surgical site infections (SSI) following either inpatient or outpatient procedures;
- Patients or staff with identified communicable diseases that local, state, or federal health agencies require be reported;
- Patients or staff identified by laboratory culture as colonized or infected with multi drug-resistant organisms (MDROs), as defined by the organization's Infection Prevention and Control Program;
- Patients who meet CDC criteria for requiring isolation precautions (other than "Standard Precautions" or a protective environment) during their hospitalization;
- Patients or staff with signs and symptoms that have been requested be reported or recorded by local, State, or Federal health agencies; and
- Staff or patients who are known or suspected to be infected with epidemiologically-significant pathogens that are identified by the hospital or local, State, or Federal health agencies.

The log may be a paper log or in electronic format, but regardless of the format, the information must at all times be safe/secure from unauthorized access, up-to-date, and accessible and readily retrievable by authorized personnel.

Survey Procedures §482.42(a)(2)

- Determine whether the infection control officer(s) maintains a log of incidents related to infections and communicable diseases, including those identified through employee health services.
 - Determine whether the log captures the types of incidents discussed above. Failure to track incidents in one or more of the above categories is not, in itself, evidence of a deficiency, but may be cited to support a documented failure in infection control practices if the failure to log incidents was pertinent to the documented failure.
 - Determine whether the log is current and can be readily accessed and information readily retrieved by the hospital's infection control officer(s) and other appropriate staff, as required by local, state, or federal agencies consistent with existing local, state, and federal laws regarding the confidentiality of and access to privileged medical information.
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