

## A-0338

### §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

1. This regulation requires the hospital to develop, implement, and maintain an *active, hospital-wide program which includes all facilities, departments, units, sections and locations for which the organization has administrative and/or medical responsibility under the facility's Medicare provider number, including those facilities remote from the institution's primary location*, for the prevention, control, and investigation of infections, *which includes but is not limited to healthcare-associated infections, and those communicable diseases in patients and hospital personnel (all employees including contractual employees and volunteers)*.
2. The hospital prevention and control program must have active **infection prevention and control** program that includes specific measures for prevention, early detection, control, *hospital personnel* education, and investigation of **infections and communicable diseases** in the hospital. There must be a mechanism to *periodically* evaluate the effectiveness of the program(s) and take corrective action when necessary. The program must include *documentation that is has considered, selected and implemented* nationally recognized infection control guidelines. *Examples of organizations that promulgate nationally recognized infection and communicable disease control guidelines, recommendations and/or regulations include:* the Centers for Disease Control and Prevention (CDC), the Occupational Health and Safety Administration (OSHA), 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)*.
3. The hospital infection *prevention and* control program must be hospital-wide, include all locations *for which the organization has administrative and/or medical responsibility, and* all departments and services.

*3a The hospital prevention and control program must include an active surveillance program for the prevention, control, and investigation of infections and communicable diseases occurring in patients and personnel, including both patient care and non-patient care personnel. The surveillance program must include documentation that the surveillance program (i.e., infection detection, data collection and analysis, monitoring, evaluation) selected for implementation is based on a nationally recognized system of*

*infection control surveillance such as the National Healthcare Safety Net (NHSN). The hospital must document its patient population risk assessment, selected measures, and evaluation of actions taken on an ongoing basis.*

*4. Quality Assessment and Performance Improvement (QAPI). In accordance with a QAPI approach, the hospital's infection and communicable disease prevention and control program must gather infection and communicable disease data from all its departments and locations 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 mechanisms in place for identifying and monitoring health-care associated infections or communicable diseases (communicable diseases include those reportable, those requested by health authorities, and those the hospital judges to have epidemiologic significance) occurring in any location or department. Additionally, the hospital must develop and implement adequate interventions to address identified issues, and monitor the effectiveness of interventions to control and prevent infection transmission to patients, staff, visitors, and volunteers.*

*5. SANITATION. The hospital must provide and maintain a sanitary environment to avoid sources and transmission of infections and communicable diseases. The infection prevention and control program must provide appropriate monitoring of housekeeping, maintenance (including repair, renovation and construction activities), and other activities to ensure that the hospital maintains a sanitary environment to avoid sources and transmission of infections and communicable diseases. Examples of areas to monitor to ensure that a sanitary environment is maintained 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. All areas must be clean and sanitary, and maintained in accordance with federal, state, and local regulations, codes, guidelines and recommendations. The type of monitoring needs to reflect national standards of practice, local state and federal requirements and recommendations.*

*6. AMBULATORY CARE. A characteristic of ambulatory care settings that presents unique challenges for adapting transmission prevention guidelines is that care is often episodic, patients remain in common areas for prolonged periods of time waiting to be seen by a healthcare provider or awaiting admission to the hospital, examination or treatment rooms are turned around quickly with minimal cleaning, and infectious patients may not be recognized immediately. Furthermore, immunocompromised patients often receive treatments in rooms where they are maintained for extended periods of time among other patients receiving similar treatment.*

*The hospital's infection prevention and control program must address ambulatory/outpatient issues at all locations including those physically remote from the facility's primary site and include measures for screening individuals with potentially contagious diseases during their initial patient encounter, and placing those individuals who may present risk to other patients, staff, or visitors for the transmission of infectious agents by the airborne or droplet route, as identified in guidelines promulgated by the*

*CDC and its Healthcare Infection Control Practices Advisory Committee. When such 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. In assessing the adequacy of infection control in ambulatory care settings, the program must also consider the types of patients for whom the facility routinely or emergently provides care (including highly immunosuppressed patient populations), risks of congregate settings; the adequacy of isolation and/or separation facilities; the adequacy and availability of toilet facilities and hand hygiene for staff, patients, and visitors; and cleaning and disinfection practices.*

*7. MULTI-DRUG RESISTANT ORGANISMS (MDROs). The hospital must have mechanisms in place for the early identification of patients with targeted MDROs (as defined in the CDC Isolation Guidelines) and for the prevention of transmission of such MDROs. With the increasing incidence and prevalence of MDROs, all hospitals must have an active multidisciplinary program to identify epidemiologically significant MDROs prevalent in their hospital and community, implement appropriate control measures, where indicated and assess the effectiveness of the control program on an ongoing basis. When ongoing transmission of targeted MDRO in the hospital is identified, the infection prevention and control program should use this event to identify potential breaches in infection control practice. A comprehensive program for the control of MDROs should include, but not be limited to, a multidisciplinary approach to the evaluation and control of antibiotic utilization.*

*8. COMMUNICABLE DISEASE OUTBREAKS. Community-wide communicable disease outbreaks, epidemics and pandemics (such as measles, SAR's, or Pandemic Flu) 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*
- Logistic issues (staff, medical supplies, resupply, continued operations, and capacity).*

*Pandemics, such as pandemic flu, present additional challenges due to the wide spread impact upon state and federal resources, resources that would typically be available to address a community-wide disaster may not be readily available. Additionally, the duration of a pandemic may extend over months or years, thus presenting special challenges in regard to staffing, supplies, resupply, and all aspects of resource*

*management. Hospitals should work with local, state, and federal health authorities in order to identify likely communicable disease threats and to develop appropriate preparedness strategies that would be implemented in the event of such occurrences.*

*9. BIOTERRORISM. Healthcare facilities confront a similar set of issues when dealing with a suspected bioterrorism event as compared with other communicable disease threats. If a bioterrorism event occurs, an understanding of the epidemiology, likely modes of transmission, and clinical course of the disease through a carefully drafted and periodically updated plan that provides disease-specific guidance to healthcare, administrative, and support personnel are essential for responding to and managing the bioterrorism 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; protecting the environment; and logistical issues associated with sufficient securing of all environments, providing barrier protection, and providing appropriate staffing (e.g., vaccinated healthcare personnel for care of patients with suspected or proven small pox). The response is likely to differ based on whether exposure is a result of a biological release or person-to-person transmission. Hospitals should maintain current information on bioterrorism threats, identify resources for quickly obtaining information, and have mechanisms in place to rapidly disseminate such information when and where needed.*

*A variety of sources offer guidance for the management of persons exposed to likely agents of bioterrorism. Federal agency websites (e.g., [www.usamrid.army.mil/publications/index.html](http://www.usamrid.army.mil/publications/index.html); [www.bt.cdc.gov](http://www.bt.cdc.gov)) and state and county health department web sites should be consulted for the most up-to-date information.*

*10. The hospital's infection **prevention and** control program must be integrated into its hospital-wide Quality Assurance and Performance Improvement (QAPI) program*

*11. An active hospital-wide prevention and control program would include at a minimum that the hospital has and implements policies, procedures and protocols that are based on national guidelines and address the following:*

- Definition of *healthcare-associated* infections and communicable diseases *in accordance with CDC guidelines;*
- Measures for identifying, investigating, and reporting *healthcare-associated infections* and communicable diseases;
- *Measures for the early identification of patients who require isolation in accordance with CDC guidelines;*
- Measures for preventing, **identifying and** investigating post-operative infections *following inpatient, same day and, outpatient surgery.*

- Measures for assessing and identifying patients and hospital personnel, *including* contract staff (e.g., agency nurses, housekeeping staff) and volunteers, at risk for infections and communicable diseases;
- Methods for obtaining *and reviewing* reports of *monitored* infections and communicable diseases on inpatients, outpatients, and health care workers, including all hospital personnel, contract staff (e.g., agency nurses, housekeeping staff, etc) and volunteers, in a timely manner;
- Measures for the prevention of infections, especially infections caused by organisms that are antibiotic-resistant or in other ways epidemiologically *significant*; device-*associated* infections e.g., those associated with intravascular devices, ventilators, tube feeding, indwelling urinary catheters, etc; surgical site infections; and those infections associated with tracheostomy care, respiratory therapy, burns, immunosuppressed patients, and other factors which compromise a patient's resistance to infection;
- *Measures for the prevention of device-associated bloodstream infection (BSI) such as a protocol for reducing infections of central venous catheters by specifying aseptic precautions for line insertions, care of inserted lines, and prompt removal when a line is no longer needed;*
- *Measures for 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;*
- *Measures addressing aseptic technique practices used in surgery and invasive procedures performed outside the operating room;*
- Measures for prevention of communicable disease outbreaks, such as airborne, food borne, blood borne, and other *diseases as defined by local, state and federal recommendations, guidelines, regulations, and laws;*
- Provision of a safe environment consistent with nationally recognized infection *prevention and* control precautions, such as the current CDC *guidelines and* recommendations for the identified infection and/or communicable disease;
- Isolation procedures and requirements for *highly* immunosuppressed patients who *require a protective environment, as defined by CDC recommendations.*
- Use and techniques for standard *and other categories of patient care (“isolation”)* precautions *as recommended by the CDC recommendations.*

- *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;*
- Methods for monitoring and evaluating practices of asepsis;
- *Measures that prevent the transmission of infectious agents associated with the physical environment that address ventilation and water quality control issues including measures taken to maintain a safe environment during internal or external construction and renovation;*
- *Maintaining safe air handling systems in areas of special ventilation such as protective environments if required in accordance with CDC guidelines, operating rooms, intensive care units, and airborne infection isolation rooms;*
- Techniques for hand *hygiene*, respiratory protection, asepsis, sterilization, disinfection, food sanitation, housekeeping, liquid and solid waste disposal, *sharps* disposal, separation of clean items from dirty items, as well as other means for limiting contamination of the environment;
- Authority and indications for obtaining microbiological cultures from patients *and the environment as indicated;*
- A requirement that disinfectants, antiseptics, and germicides be used in accordance with the manufacturers' instructions to avoid harming patients, *healthcare personnel and the environment of care;*
- *Maintaining a sanitary environment including cleaning and disinfecting environmental surfaces, carpeting and furniture; textiles reprocessing, storage and distribution; regulated and non-regulated waste; and pest control;*
- *New employee orientation and annual training in preventing and controlling healthcare-associated infections and methods to prevent exposure and transmission of infections and communicable diseases;*
- *Appropriate use of personal protective equipment including gowns, gloves, masks and eye protection devices;*
- Measures and *authority* for the screening and evaluation of health care workers, including all hospital staff, contract workers (e.g., agency nurses, housekeeping staff, etc), and volunteers, for *infections and communicable diseases as indicated*, and for the evaluation of staff and volunteers exposed to patients with *infections and communicable disease as indicated (for the purposes of this statement, infections and communicable diseases refer to infections and communicable diseases likely to cause significant infectious or other risk to the exposed*

*individual as identified by the hospital or federal, state or local public health authorities, or those defined as reportable by local, state, or federal public health authorities;*

- Employee health policies regarding infectious diseases and when infected or ill employees, including contract workers and volunteers, *must be restricted from providing direct* patient care and/or *must be required to remain away from the healthcare facility entirely;*
- *Measures for screening or evaluating immunization status for designated infectious diseases in employees and other healthcare providers and personnel, as recommended by the CDC and its Advisory Committee on Immunization Practices (ACIP);*
- A procedure for meeting the reporting requirements of the local health authority;
- Procedures for working with local, state, and federal health authorities in emergency preparedness situations;
- Policies and procedures developed in coordination with federal, state, and local emergency preparedness and health authorities to address communicable disease threats, *bioterrorism*, and outbreaks;
- *Provisions for methods to monitor compliance with all policies, procedures, protocols and other infection control program requirements; and*
- Provision for program evaluation and revision of the program, when indicated.

#### **Survey Procedures §482.42**

- Survey of the Infection Control *Condition of Participation* (CoP) should be coordinated by one surveyor. However, each surveyor as he/she conducts his/her survey assignments should assess the hospital's compliance with the Infection Control CoP.
- Verify that there is a system (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 that this system is an active program, that it is both hospital-wide and program-specific, and that it is implemented correctly.
- *Verify that the hospital-wide system gathers and assesses infection and communicable disease data from all departments, all locations for which the*

*organization has administrative and/or medical responsibility and all inpatient and outpatient services.*

- Throughout the hospital, observe the *cleanliness and 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.*
- Verify that the hospital's infection prevention and control program is integrated into its hospital-wide QAPI program.

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## **A-0339**

### **§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)**

12. *Hospital infection control officers are often referred to as “hospital epidemiologists (HEs)” or “infection control professionals (ICPs)”.* The hospital must designate in writing an individual or group of individuals, qualified through *ongoing* education, training, experience, or certification (*such as offered by the Certifying Board in Infection Control Professional (CBIC)*), as an infection control officer or officers *or 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. 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”.* Verification of ongoing education and training can be demonstrated by participation in infection control courses, local, and national meetings organized by recognized professional societies such as APIC and SHEA.

13. *The number of infection control officers or the number of infection control officer hours devoted to the infection prevention and control programs should not be based on patient census alone, but rather should be determined by the scope of the program, characteristics of the patient population, complexity of the healthcare system, techniques available for performing essential tasks, and unique or urgent needs of the hospital.*

14. *There must be adequate, dedicated resources allocated to identify and investigate infections and communicable diseases and to implement and evaluate measures to prevent and control hospital- and community-associated infections. Resource allocation should be based on the complexity of the hospital's organization including inpatient and*

*outpatient services, the risks entailed in the care, treatment, and services provided, the hospital's patient population, and the complexity of the activities that will be carried out;*

*15. It is recommended that resource allocation be based on recommendations and studies published by the Centers for Disease Control and Prevention's Healthcare Infection Control Practices Advisory Committee and professional organizations such as the APIC and the SHEA.*

16. The infection control officer(s) must develop and implement policies governing the control of infections and communicable diseases.

#### **Survey Procedures §482.42(a)**

- Interview the infection control officer(s) regarding the hospital's infection prevention and control program, hospital issues regarding infection *prevention and control*, and to verify and evaluate integration of the hospital infection prevention and control program into the hospital's QAPI program.
- Verify that 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 verify that he/she is qualified through ongoing education, training, experience, or certification to oversee the infection control program.
- Verify that appropriate policies and procedures have been developed and implemented governing the control of infections and communicable diseases.

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#### **A-0340**

**§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)**

*17. The infection control officer or officers must develop, implement and evaluate measures governing the identification, investigation, reporting, prevention and control of health care- and community-associated infections and communicable diseases within the hospital. Infection control policies must be specific to each department, service, and location 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.*

*18. The risk of developing a hospital-associated infection will vary based on the geographic location of the hospital, the types of programs and services provided and the characteristics of the population served. An effective infection prevention and control program should have the ability and resources to adapt to rapidly changing infection-related risk or communicable disease threat factors occurring in hospitalized patients and in the community population.*

*19. The surveillance program must be able to rapidly identify infectious and communicable diseases which result from an act of bioterrorism or the emergence of a new communicable or non-communicable infectious disease.*

The infection control officer(s) is responsible for:

- Implementing policies governing asepsis, sterilization, and infection control;
- Developing a system for identifying, investigating, reporting, and preventing the spread of infections and communicable diseases among patients and hospital personnel, including contract staff and volunteers;
- Identifying, investigating and reporting infections and outbreaks of communicable diseases among patients and hospital personnel, including contract staff, *visitors* and volunteers, especially those occurring in clusters;
- Preventing and controlling the spread of infections and communicable diseases among patients and staff;
- *Providing oversight of risk assessment and implementation of infection and communicable disease prevention measures associated with construction and renovation;*
- Providing hospital-wide orientation and in-service education programs regarding the hospital's infection prevention and control program;

- Cooperating with other departments and services in the performance of quality assurance and performance improvement activities;
- Cooperating with disease control activities of the local, *state and federal* health authority; and
- Cooperating with federal, state and local emergency preparedness and public health officials to develop and implement emergency preparedness programs *for* bioterrorism and communicable disease threats.

## 20. Survey Procedures §482.42(a)(1)

- Determine that the infection control officer(s) is responsible for the elements specified in the interpretive guidelines.
- Determine *which committee(s) (infection control, QAPI, etc.) is/are responsible for the infection control program and compliance activities in the hospital.* Review committee minutes *and other documentation* to evaluate compliance with *recommendations, guidelines, regulations and other* requirements.

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## A-0341

### §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)

21. The infection control officer(s) must maintain a **log of incidents related to infections and communicable diseases**, including those identified through employee health services. The log identifies *healthcare associated infections (HAI) related to* incidents of infection and communicable disease and documents infections and communicable diseases *in* patients and staff (patient care staff, non-patient care staff, including employees, contract staff and volunteers). *Since hospitals may be required to separate confidential health care information related to its employees, the* hospital may utilize an appendix to the log to address incidents associated with communicable disease occurrence among the staff.

*22. For the purposes of this requirement to maintain a log of incidents related to infections and communicable diseases, “incidents related to infections and communicable diseases” includes any one of the following (Duplicate recording 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 organization;*

- *Surgical site infections (SSI) following either inpatient or outpatient procedures that are identified by the organization including those SSI identified in patients released or discharged from the hospital soon after surgery;*
- *Patients or staff with identified communicable diseases that local, state, or federal health agencies request, recommend or require be reported;*
- *Patients or staff identified by laboratory culture as colonized or infected with targeted 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.*

*23. The hospital must maintain the log of incidents related to infections and communicable diseases as described herein. The log may be a paper log or in electronic format (formatted in multiple subcomponents), but regardless of the format, the information must be safe/secure, up to date, accessible, and readily retrievable, at all times.*

**Survey Procedures §482.42(a)(2)**

- *Verify that the infection control officer(s) maintains a log of incidents related to infections and communicable diseases as defined above, including those identified through employee health services.*
- *Verify that 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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**A-0342**

**§482.42(b) Standard: Responsibilities of Chief Executive Officer, Medical Staff, and Director of Nursing Services**

**The chief executive officer, the medical staff, and the director of nursing must--**

**(1) Ensure that the hospital-wide quality assurance program and training programs address problems identified by the infection control officer or officers; and**

**(2) Be responsible for the implementation of successful corrective action plans in affected problem areas.**

**Interpretive Guidelines §482.42(b)**

**24.** The chief executive officer (CEO), the medical staff and the director of nursing (DON) must ensure that the hospital-wide Quality Assessment and Performance Improvement (QAPI) program and staff in-service training programs address problems identified through the infection prevention and control program.

*Evidence has accumulated that organizational characteristics (e.g., adequacy of staffing levels and composition, establishment and maintenance of a safety culture and the consistent adherence by healthcare workers to recommended infection control practices such as hand hygiene) are important factors in preventing transmission of infectious agents in healthcare settings. These observations have led to a heightened emphasis on the importance of administrative involvement in development and support of infection prevention and control programs.*

*Education on the principles and practices for preventing transmission of infectious agents during healthcare begins ideally during training in the health professions and should be provided to anyone who has an opportunity for contact with patients or medical equipment (e.g., nursing and medical staff, therapists and technicians such as those involved in respiratory, physical, and occupational, radiology and cardiology technicians, phlebotomists; housekeeping and maintenance staff; and all other students and trainees in healthcare professions.*

The CEO, the medical staff, and the DON are responsible for implementing corrective action plans to address problems identified by the infection control officer(s). These plans should be evaluated for effectiveness and revised if needed, and documentation concerning corrective actions and outcomes should be maintained.

*Key administrative measures include adherence monitoring, assessment and correction of system failures that contribute to healthcare-associated infections, and providing feedback to healthcare personnel and senior administrators. The positive influence of institutional leadership has been demonstrated repeatedly.*

**Survey Procedures §482.42(b)**

- Determine that the hospital's QAPI program and staff in-service training programs address problems identified by the infection control officer(s).
  - Determine that problems identified are reported to the medical staff, nursing and administration, and addressed in the hospital's quality assurance and in-service training programs.
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