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August 4, 2010

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Assistant Secretary of Labor for Occupational Safety and Health
OSHA Dockets Office
Docket No. OSHA-2010-0003
U.S. Department of Labor
Room N-2625
200 Constitution Avenue, N.W.
Washington, DC 20210

RE: Department of Labor; Occupational Safety and Health Administration; Docket No. OSHA-2010-0003; Infectious Diseases, Request for Information; (Vol. 75, No. 87), May 6, 2010.

Dear Dr. Michaels:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our 40,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Occupational Safety and Health Administration's (OSHA) Request for Information (RFI) on Infectious Diseases. We hope that our comments, and those of our members, will assist OSHA in making an informed and balanced decision as to whether further action is warranted.

America's hospitals are dedicated to the health and safety of patients and health care personnel. Protecting against and preventing the transmission of infectious diseases that result from occupational exposures are top priorities. The AHA encouraged hospitals to respond to the RFI and to share the steps they take to protect employees and patients against infectious diseases. While many of OSHA's questions require a hospital-specific response, we provide below responses to those questions for which there is a general practice common among most hospitals or where the question is more broadly directed to health care stakeholders.

The AHA believes that hospitals and health care systems have effective and comprehensive programs in place that integrate the need to protect patients and health care personnel, and that there is no need for an additional standard. The existing infection prevention and control standards, including their assessment and enforcement by regulatory, accrediting and certifying bodies, have proven to be functional and appropriate, and substantial resources are dedicated to their regular maintenance and improvement.



OVERARCHING COMMENTS

Health and safety of hospital personnel. The health and safety of patients and health care professionals are equally important and inter-related. Infection prevention measures to control transmission from infected patients to others are only successful if health care personnel also are protected; one directly impacts the other. Hospitals realize that protecting patients and personnel from exposures to infected individuals cannot wait for a diagnosis. Therefore, the cornerstone of hospitals' infection prevention and control (IPC) and employee health (EH) programs is education and training of new employees, as well as periodic refresher training, on the routine use of Standard Precautions.

Employee health programs. The EH program develops and implements systems for diagnosis, treatment and prevention of infectious diseases in health care personnel. The IPC and the EH programs typically work collaboratively to develop policies and procedures for health care personnel, such as placement evaluations, health and safety education, evaluation of potentially harmful infectious exposures and implementation of appropriate preventive measures, coordination of plans for managing outbreaks among personnel, provision of care to personnel for work-related illnesses or exposures, education on infection risks related to employment or special conditions, development of guidelines for work restrictions when an employee has an infectious disease, and maintenance of health records on all personnel.

EH programs also manage the OSHA occupational injury and illness reporting programs, including maintaining OSHA logs, and other relevant agencies' reportable disease processes. Another critical component of the EH programs is immunization. Many of the communicable diseases common to health care personnel are vaccine-preventable, and appropriate vaccine use protects both health care workers and patients. Immunization programs also are highly cost-effective.

Enforcement and accountability. We believe that OSHA has mischaracterized IPC and EH programs as "voluntary." These programs are essential for patient and personnel safety, and are mandated by the Centers for Medicare & Medicaid Services (CMS) and all accrediting agencies with deemed status from CMS, such as The Joint Commission and Det Norske Veritas. That is, in order to be considered participating providers and to receive reimbursement for services furnished to Medicare beneficiaries, hospitals must comply with IPC conditions of participation that are required and enforced by CMS, the accreditation organizations and state agencies involved in the survey and certification of hospitals. In addition, hospitals that are participating providers in Medicare and Medicaid but which do not comply with CMS standards, risk loss of their certification, or even their license, if CMS determines the facility has unsafe conditions related to infection control standards or life safety codes. CMS and other agencies' enforcement actions affect both patients and health care personnel. For example, CMS' infection control standards and interpretative guidelines explicitly address health care personnel health and safety.

We have attached a copy of CMS' comprehensive infection control interpretive guidelines for further examination. OSHA will see that the basis for CMS' standards is evidence-based guidelines from the Centers for Disease Control and Prevention (CDC), such as the *Guideline for Infection Control in Health Care Personnel* and *Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings*. Other specific guidelines utilized by CMS, accrediting organizations and state agencies address *M. tuberculosis*, hand hygiene, environmental infection control and many other guidelines critical for the health and safety of health care personnel, such as the CDC's

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Advisory Council on Immunization Practices recommendations for immunizations. Most of these CDC documents can be found at <http://www.cdc.gov/hicpac/pubs.html>.

Safety culture and the reduction of healthcare-acquired infections (HAI). The AHA strongly agrees with the importance that OSHA ascribes to developing a safety culture within health care facilities. Hospitals have expressed their commitment to a safety culture through many successful voluntary programs that demonstrate sustained HAI reductions. One excellent example is a program from the Keystone Center for Patient Safety and Quality of the Michigan Health & Hospital Association that has proven to reduce central-line associated bloodstream infections to nearly zero in intensive care units. As part of the Department of Health and Human Services' *Action Plan to Prevent Healthcare Associated Infections*, and with the AHA's leadership and involvement, the Agency for Healthcare Research and Quality is funding efforts to emulate Michigan's Keystone success story across the nation. More than 30 states participate in "On the CUSP: Stop HAI."

Dramatic reductions in HAIs seen in these types of initiatives are the result of health care personnel working together to minimize, and even eliminate, infections in patients. But again, these programs also reduce the risk of health care personnel exposure through high rates of compliance with hand hygiene and proper use of protective barriers. The Keystone initiative is based on regular input and measurement of the safety culture among the staff in care units throughout the hospital, using checklists to raise awareness of "doing the right thing all of the time." Such efforts translate into a greater overall focus on safety within health care facilities, whether through the use of barriers or through the safe use of devices. We have encouraged our members to share their individual successes with OSHA in their responses to the RFI.

Hospital safety management programs also foster a safety culture by focusing on health care personnel's interaction with the hospital environment, including preventing the transmission of infection. Hospitals devote much time and effort to facility-wide performance measurement and improvement. These programs include reduction of safety risks, addressing occupational illness and actions that will prevent all types of safety risks, including sharps injuries.

In conclusion, we are confident that, after reviewing the responses from the AHA and our members, OSHA will find that hospitals and health care systems have effective and comprehensive programs that integrate the need to protect patients and health care personnel, and that there is no need for an additional standard. In order to justify a new standard, OSHA must demonstrate that these comprehensive and stringently enforced programs are insufficient, and that gaps in the existing programs have led to measurable increases in occupationally acquired infections.

If you have any questions regarding our comments and attached responses, please contact me or Roslyne Schulman, director for policy development, at (202) 626-2273 or rschulman@aha.org.

Sincerely,

Rick Pollack
Executive Vice President

Enclosure

ATTACHMENT

AHA RESPONSES TO CERTAIN OSHA QUESTIONS

A. General

Question 3. One of the most important steps in determining how to effectively protect workers from infectious diseases is identifying who is at risk of exposure. What recommendations do you have for how to determine which employees are potentially exposed to contact, droplet, and airborne transmissible diseases in the type of workplace about which you are responding? How many of your total workers have a risk of exposure to such diseases during the performance of their job duties? What proportion of your workforce does this represent? What are the job titles or classification(s) of these workers? What are the job duties of these workers? To which diseases are they exposed?

AHA Response. Infection prevention and control (IPC) programs in acute-care hospitals take several key factors into consideration in determining who is at risk:

- Hospitals are concerned about the health and safety of all occupants of the facility, including patients, health care personnel and visitors. Therefore, the IPC programs must assess the risk of airborne, droplet and contact exposures for all occupants, and, as a result, a major focus is on environmental/engineering controls for the overall environment.
- A hospital's risk assessment must consider the population it serves in order to evaluate the types of communicable disease likely to be seen in the facility. Hospitals use the reportable communicable disease entries published weekly from local and state public health agencies, as well as the Centers for Disease Control and Prevention's (CDC) *Morbidity and Mortality Weekly Report* (MMWR). Therefore, specific risks may vary by locale. For example, for *Mycobacterium tuberculosis* (MTB), CDC guidelines state that because some communities have minimal risk, hospitals in those communities need neither carry out TB testing nor develop respiratory protection programs.
- General risks. All hospital personnel, whether they perform direct care or support services, are considered to be at some level of risk due to the basic principle of "universal precautions," meaning that all patients are considered to be potentially infectious. Therefore, standard precautions apply to all health care personnel and all receive basic education and training.
- Specific risks. The disease exposure risk for direct care personnel does not depend on whether they treat a primarily adult versus a pediatric/neonatal patient population. Instead, the risk assessment considers factors such as: whether the patient is suspected or known to have a communicable disease; type, frequency and duration/intensity of procedures which the direct care personnel will be performing; and degree of contact with the patient. For example, risks are generally considered to be higher for personnel working in the hospital's emergency department because they would be evaluating patients with potentially communicable diseases (e.g., tuberculosis) and the emergency department staff often is responsible for furnishing higher-risk pulmonary procedures such as bronchoscopies. As noted in our overarching comments, IPC programs place major emphasis on prevention and routine use of Standard Precautions. The IPC

programs address potential risks by department/procedures and indicate if specific additional personal protective equipment (PPE) should be used in addition to Standard Precautions.

With regard to OSHA's question about the job duties of workers and the diseases to which they are exposed, the AHA believes that exposure control plans typically reflect similar specific job titles or classifications developed for the OSHA bloodborne pathogen standard as well as for the CDC's influenza vaccination recommendations, which reference direct care personnel, personnel with frequent contact and support services personnel managing contaminated equipment. With regard to specific disease exposures, as noted above, hospitals' risk assessments will reflect the diseases prevalent in the community, whether airborne (e.g., MTB), large droplet (e.g., influenza, norovirus) or contact transmissible diseases (e.g., scabies and various bacterial infections). IPC programs place major emphasis on prevention and routine use of Standard Precautions.

Question 4. Workplaces vary in the types of infectious diseases and the number of infected individuals encountered. OSHA is interested in the types of diseases that your workplace encounters and how often they are encountered. Please describe your workplace's experience with infectious diseases over the past 10 years (e.g., which diseases, how often).

AHA Response. This question of "experience" is ambiguous and may be interpreted differently by some as meaning employees or patient admissions. For example, some may sum up the past 10 years of infectious disease classifications coded in medical records. Others may use hospitals' copies of state-required forms for each type of recorded reportable disease sent to their local health department. Yet others may use reportable disease logs for employees only (e.g., OSHA Form 300A) as reported to the local health department. Finally, some may only report exposures to infectious diseases, not actual diseases. We encourage OSHA to consider this ambiguity when reviewing responses to this question.

Question 5. OSHA is interested in data and information that will further assist in characterizing workers' occupational exposure to contact, droplet, and airborne transmissible infectious diseases.

a) OSHA encourages the submission of your workplace or your industry's experience with these diseases and the impact of infectious diseases on your workers (e.g., type and number of exposure incidents, occupationally-acquired infectious diseases, days of work missed, and fatalities).

AHA Response. Due to the ambiguity around the term "experience," we urge OSHA to take into consideration the various sources of information that hospitals could provide. The implication, though not stated explicitly, is that the data requested are from the OSHA Form 300A, used to collect and report occupationally-acquired disease. However, some data submitted by hospitals may be limited to exposures and not include disease outcomes.

b) Please provide information about any database that collects and aggregates data on occupationally-acquired infectious diseases (e.g., Federal, State, provider network, or academic).

AHA Response. It is not clear whether OSHA is interested primarily in databases that collect data electronically or databases that collect data manually would also be of interest to OSHA. Beyond the data generated by OSHA Form 300A, that may be collected either way, other electronic systems

include the CDC's National Healthcare Safety Network (NHSN) module for health care personnel exposures and a number of commercial stand-alone databases for tracking sharps-related incidents and immunization status/vaccination rates.

c) Please provide any additional information, including peer-reviewed studies, which addresses occupational exposure to infectious agents that you think OSHA should consider.

AHA Response. We recommend that OSHA review the CDC's "*Guidelines for Infection Control in Healthcare Personnel, 1998.*" The CDC's Healthcare Infection Control Practices Advisory Committee (HICPAC) is in the process of updating this guideline. However, the current guidelines contain multiple citations of studies involving infectious agents for which prevention/treatment strategies were put into place and tested.

Question 6. Infection control (IC) programs are currently the primary means of controlling occupational exposure to infectious agents. However, these programs are largely voluntary. OSHA is particularly interested in case studies that highlight experience in the implementation and effectiveness of IC programs in protecting workers against infectious diseases (e.g., the extent to which employers are fully implementing and consistently following their written IC programs).

AHA Response. We believe that OSHA has mischaracterized IPC programs as "voluntary" since hospitals, ambulatory care centers, other care-delivery sites and related entities understand that such programs are not only essential for safety, but mandated by CMS and by all accrediting agencies with deemed status from CMS, such as The Joint Commission and Det Norske Veritas. That is, in order to be considered participating providers and receive reimbursement for services furnished to Medicare beneficiaries, hospitals are required to comply with IPC conditions of participation mandated and enforced by CMS, the accreditation organizations and state agencies involved in the survey and certification of hospitals. In addition, hospitals that are Medicare and Medicaid participating providers but do not comply with CMS standards, risk losing their certification or even their license, if CMS determines the facility has unsafe conditions related to infection control standards or life safety codes. CMS and other agencies' enforcement actions affect both patients and health care personnel. Therefore, CMS infection control standards and interpretative guidelines explicitly address health care personnel health and safety. We have attached a copy of CMS' comprehensive infection control interpretative guidelines, which address all aspects of an IPC program including the issue of protecting health care personnel.

a) For example, has your workplace had instances where a significant increase in infections (among either patients or workers) required more rigorous implementation of your IC program? If so, please describe any factors that contributed to the increase and what steps your workplace took to address the situation.

AHA Response. The CDC guidelines anticipate occasional clusters of infections or outbreaks. In addressing such clusters, hospitals start with the CDC Guidelines' "transmission-based" section recommendations that are outlined in Tier I. That is, they determine whether the basic Standard Precautions have been implemented properly, such as through the measurement of adherence to hand hygiene protocols and the use of barriers, thereby ensuring basic practices are at high rates of compliance. Then hospitals make a determination about the need to move to Tier II, which involves additional steps to bring the outbreak under control, even as the cause of the cluster or outbreak is investigated.

b) Please provide any studies that demonstrate the difference in infection rates between situations where the IC program had lapsed and situations where rigorous implementation of control measures was instituted.

AHA Response. The cause of the cluster or outbreak may not necessarily be a “lapse” in the IC program, but sometimes results from a single unexpected source from the environment, identified during the investigation. The hospital’s initial response will always be to take steps to protect patients and health care personnel in order to stop further transmission until the cause is known. Hospital personnel follow recommendations contained in the CDC’s isolation guidelines and in its multi-drug resistant organism (MDRO) guidelines in these situations.

Question 7. While OSHA has a Bloodborne Pathogens standard (Sec. 1910.1030), the Agency does not have a comprehensive standard that addresses occupational exposure to contact, droplet, and airborne transmissible diseases. The Agency has other standards [(e.g., Respiratory Protection (Sec. 1910.134) and General Personal Protective Equipment (Sec. 1910.132)] that may apply and, in some situations, Section 5(a)(1) of the OSH Act (the General Duty Clause) would apply. OSHA is interested in commenter’s insights regarding the adequacy of existing OSHA requirements to protect workers against occupational exposure to infectious agents.

AHA Response. Although hospitals comply with the OSHA Bloodborne Pathogen standard, the General Industry Respiratory Protection standard and other applicable standards as required, the impact of these requirements in terms of worker protection is difficult to determine in isolation from the impact of other practices that hospitals engage in as a result of compliance with the evidence-based CDC guidelines and CMS requirements. For instance, while hospitals are aware of and compliant with the OSHA Bloodborne Pathogen standard, the substantial reduction in hepatitis B infections among health care personnel is primarily a result of the high level of efficacy of the hepatitis B vaccine (HBV) and hospital attention to the CDC guideline recommendations related to “universal precautions” and safe use of sharps devices. Another example relates to the OSHA General Industry Respiratory Protection Standard. While hospitals that utilize particulate respirators, primarily N-95 respirators, are compliant with the OSHA standard, it is important to note that the CDC Tuberculosis guidelines also address respiratory protection as part of the facility’s overall risk assessment. This CDC guideline continues to be the key resource for hospitals. In addition, the OSHA standard is actually referenced in the CMS Infection Control Interpretive Guideline attached at the end of our comment letter. Further, hospitals view the OSHA General Duty clause as comparable to CMS’ general requirement for a “safe and sanitary” environment. This requirement is enforced when CMS surveyors determine that a serious violation to a Life Safety code requirement has occurred in a hospital.

Question 8. California OSHA recently issued a standard for occupational exposure to "Aerosol" Transmissible Diseases (ATD) that covers infectious diseases transmitted through the airborne and droplet routes. IC programs that are established in most healthcare settings address exposure to contact, droplet, and airborne transmissible diseases. Please explain whether the Agency’s deliberations on occupational exposure to infectious diseases should focus on only droplet and airborne transmission or if contact transmissible diseases should also be included.

AHA Response. The AHA did not understand the need or justification for California’s ATD standard given that the studies examined by OSHA and stakeholders failed to demonstrate that the

rate of TB in health care personnel was any higher than the TB rate in the general population. CDC droplet precautions (as described in the CDC's isolation guidelines) are implemented to prevent all exposures, including in health care personnel, and are enforced by other agencies. Contact transmission, the most common mode of transmission, is equally important. A great deal of education and training time is spent on prevention, and CDC guidelines are already enforced by various agencies. We believe that current CDC guidelines, enforced by other agencies, are adequate and another standard would be duplicative and burdensome for health care facilities.

Question 9. If the Agency pursues rulemaking and promulgates a standard, jurisdictions with OSHA-approved State plans will be required to cover workers who OSHA determines are at occupational risk for exposure to infectious agents, including public employees. State and local governments are defined very broadly, and would typically include such entities as a university hospital associated with a State university as well as public hospitals and health clinics. What public sector healthcare or healthcare-related workers are at increased risk for occupational exposure to infectious agents? Please describe conditions unique to any of these occupations that are not seen in the private sector. Please describe any other issues specific to OSHA-approved State plans that the Agency should consider.

AHA Response. University contracts that involve the rotations of students through hospital training already include the same requirements for health assessment that apply to other settings, such as requiring proof of HBV vaccination, as well as training to reduce occupational exposure.

B. Infection Prevention and Control Plan

Question 10. CDC/HICPAC's 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings recommends an IC program for addressing the transmission of airborne and other infectious diseases. In certain settings, CMS and The Joint Commission require that health care facilities have such programs. If you are subject to the CMS or Joint Commission requirements or otherwise have an IC program, please provide information on the elements of this program (e.g., early identification of infectious patients, implementation of transmission-based control measures, HCW training) and how the program works.

AHA Response. Hospital infection prevention and control programs are comprehensive and each key element, including occupational health elements, must meet the detailed requirement of the CMS infection control interpretive guidelines. These interpretive guidelines require hospital infection prevention and control programs to be based on CDC's evidence-based guidelines.

Question 11. In most cases, an IC program is managed by an infection control preventionist or other designated person. For example, the CDC/HICPAC guidelines recommend that the IC program be managed by individuals with training in infection control. Who manages your program? What percentage of this individual's time is spent managing the IC program?

AHA Response. The management of IC programs varies based on facility size and resources. For example, in small or rural hospitals and critical access hospitals (CAHs), the same person may direct both the IPC and EH program.

***Question 12.** For the IC program(s) established in your workplace, please describe, in detail, the resource requirements and associated costs, if available, expended to initiate the program(s) and conduct the program(s) annually. Please estimate, in percentage terms where possible, the extent to which the components or elements in your program(s) are typical of those practiced throughout your industry.*

AHA Response. The personnel and non-personnel resources and associated costs for IC programs vary widely and are generally proportional to the size, sophistication, case mix, and estimated risk of the populations served by the hospital. Personnel and non-personnel resources would likely include:

- Personnel resources:
 - Infection preventionist/infection control manager;
 - Hospital epidemiologist (or access to a clinician);
 - Surveillance technicians (in larger institutions);
 - Employee health program support (varies by size of facility);
 - Administrative support; and
 - Computer support personnel.

- Non-personnel resources:
 - Office space, computer equipment and supplies and other related equipment;
 - Microbiology laboratory support, including reference laboratory and pathology support; (In small or rural hospitals, such as CAHs, such laboratory support is often obtained under arrangement from another laboratory); and
 - Education and training support necessary to achieve and maintain competency, including tuition and related travel costs, as necessary.

***Question 13.** In your industry, for the IC programs established in your workplace or for IC programs in other workplaces of which you are aware, are there any components or features that may present economic difficulties to small businesses? Please describe and characterize in detail these components and why they might present difficulties for small businesses.*

AHA Response. Small rural hospitals and CAHs are financially vulnerable organizations that have difficulty absorbing additional costs. Our particular concern involves CAHs and other small hospitals that already comply with the CDC guidelines and associated CMS/accreditation standards, but which would be required, under a new OSHA infectious disease standard, to bear the additional cost and burden of putting into place and maintaining an OSHA compliance program for what is likely to be a redundant standard.

***Question 14.** Periodic evaluation of IC program effectiveness is recommended by CDC/HICPAC and required by The Joint Commission and CMS for most types of facilities under their jurisdiction. Please describe how your workplace or industry evaluates the effectiveness of its IC program, including the methods and criteria used. How often does your workplace evaluate its program? Please describe the results your program has achieved (e.g., if there has been a decrease in patient and/or worker infections). Please describe any specific problems and/or successes that have been encountered in the implementation and operation of the program.*

AHA Response. CMS conditions of participation and accrediting agency standards call for a minimum of annual and/or periodic evaluations that involve risk re-assessments and making

necessary changes when new or revised hospital programs affect IC surveillance goals and strategies. Many hospital IC programs also undertake quarterly reviews of trends and issues for the organization's Board of Trustees, utilizing the hospital's quality, safety or infection control committees, and reporting on measurable performance improvement outcomes, including explicit employee health measures. It is important to reiterate that the successes in reducing HAIs also lower exposure risks to employees.

C. Methods of Control

Question 17. CDC/HICPAC, CMS, and The Joint Commission provide a variety of approaches that employers can implement to reduce or eliminate workers' exposure to infectious agents. For example, a well-structured IC program can include: immunizations for vaccine-preventable diseases, isolation precautions to prevent exposures to infectious agents, training, personal protective equipment, management of workers' risk of exposure to infected persons, including post exposure prophylaxis, and work restrictions for exposed or infected personnel. Please describe the types of problems/obstacles your workplace or industry encountered with implementing specific control measures. Please include a discussion of each control measure, the problem/obstacle encountered, the affected worker group, and any particularly effective solutions your workplace or industry has implemented to address the obstacle/problem.

AHA Response. Supply chain limitations have been a major obstacle for hospitals with regard to implementing control measures. For example, in recent years, supplies of seasonal influenza vaccine have been either short or delayed due to manufacturing problems and regulatory actions by federal agencies. In the 2009 H1N1 pandemic, the delay in availability of vaccine for immunizing health care workers was a result of the emergence of a novel H1N1 virus strain in the Spring of 2009 and the competing demand on manufacturing capacity from the parallel production of seasonal influenza vaccine. However, the obstacles are not limited to vaccines. This past year hospitals experienced supply chain shortages of many other supplies linked to the response to the pandemic, including N-95 particulate respirators, surgical and procedure masks, hand sanitizer, and injection supplies and equipment.

Limited U.S. manufacturing capacity of essential items, unreliable raw material supply chains and economic conditions and market incentives that lead to "just in time" inventory strategies for health care facilities are at the heart of these obstacles. Solutions to these supply chain issues would likely involve increasing U.S. manufacturing capacity for essential supplies and equipment, using more efficient and effective manufacturing processes, and locating alternate sources for raw materials needed to manufacture essential items.

Another obstacle to putting into place effective control measures, particularly for seasonal and pandemic influenza vaccination campaigns, relates to conflicting messages sent by leaders within the health care system. The AHA believes that in order to improve influenza vaccination rates among health care personnel, hospitals need strong internal leadership that supports annual vaccinations and provides clear, fact-based and timely education and communication initiatives. But strong hospital leadership is only part of the equation for improving vaccination rates among health care workers.

Hospitals frequently have found that certain unions representing health care workers have sought to delay or block the implementation of employee vaccination programs. Vaccination rates of health care workers could be improved with union support of hospitals' vaccination policies and programs.

Question 18. When developing and implementing infection control measures in your workplace, are there any recommended controls that you have found to be ineffective or unnecessary in controlling infectious diseases? If so, please explain how you arrived at this conclusion.

AHA Response. The AHA believes the use of the CDC guidelines provide sufficient flexibility to identify and use the most effective controls for any given situation. The guidelines are evidence-based and supported by clinical experience.

Question 20. CDC/HICPAC's 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings addresses the need for a safety culture and its role in improving a workplace's IC program (e.g., worker adherence to safe work practices). Please describe the policies and actions undertaken in your workplace or industry to develop and maintain a culture of worker safety. Please describe any means that have been particularly effective in fostering a safety culture and any problems or obstacles that have been encountered in developing and/or maintaining the safety culture.

AHA Response. The nation's hospitals recognize the importance of developing a safety culture involving teams working together toward reducing HAIs in patients and reduced exposures and transmission to patients and health care personnel alike. Hospitals have expressed their commitment to a safety culture through many successful voluntary programs that demonstrate sustained HAI reductions. One excellent example is the program from the Keystone Center for Patient Safety and Quality of the Michigan Health & Hospital Association that has proven to reduce central-line associated bloodstream infections to nearly zero in intensive care units. As part of the Department of Health and Human Services' *Action Plan to Prevent Healthcare Associated Infections* and with the AHA's leadership and involvement, the Agency for Healthcare Research and Quality (AHRQ) is funding efforts to emulate Michigan's Keystone success story across the nation. More than 30 states are participating in "On the CUSP: Stop HAI."

Dramatic reductions in HAIs seen in these types of initiatives are the result of health care personnel working together to minimize, and even eliminate, infections in patients. But again, these programs also reduce the risk of health care personnel exposure through high rates of compliance with hand hygiene and proper use of protective barriers. The Keystone initiative is based on regular input and measurement of the safety culture among the staff in care units throughout the hospital, using checklists to raise awareness of "doing the right thing all of the time." Such efforts translate into a greater overall focus on safety within health care facilities, whether through the use of barriers or through the safe use of devices.

Hospital safety management programs also foster a safety culture by focusing on the health care personnel's interaction with the hospital environment, including preventing the transmission of infection. Hospitals devote significant time and effort on facility-wide performance measurement and improvement. These programs include reduction of safety risks, addressing occupational illness and actions that will prevent all types of safety risks, including sharps injuries. The Joint Commission focuses heavily on hospitals' safety programs that engage employees in a culture of safety.

Question 21. Poor adherence to infection control measures (e.g., failure to use necessary PPE or to follow recommended hand hygiene practices) can be one indicator of the breakdown of an IC

program. Please describe what actions have been undertaken in your workplace or industry to assess and enforce adherence to infection control measures. What obstacles has your workplace encountered in maintaining adherence and are there any particularly successful ways you have found to maintain adherence (e.g., training initiatives, worker incentives)? Please discuss any underlying factors that you feel may affect non-compliance with current infection control guidelines and standards in your facility.

AHA Response. Hand hygiene is generally included in all “checklists” used to reduce HAIs and also is closely monitored as a major quality measure in organizations. Hospitals use the CDC’s hand hygiene guidelines. Also, CMS and the hospital accrediting organizations place great focus on hand hygiene as well and closely observe actual practice on scheduled and non-scheduled surveys. Hospitals are creative in their methods to aim for 100 percent adherence for both patient and worker protection. For example, “Speak Up” campaigns encourage patients and families to inquire whether a health caregiver has washed his/her hands, and the increased availability of alcohol-based hand rubs and well-placed sinks also are major tools in adherence.

Question 22. The use of proper PPE is an essential component of an effective IC program. For example, CDC/HICPAC recommends that facemasks (e.g., surgical masks) be worn by workers when droplet precautions are implemented and respirators be worn under certain circumstances when airborne precautions are in place. Please describe how your workplace determines when a facemask (e.g., surgical mask) is used for worker protection and when a respirator is used for worker protection. How does your workplace determine which employees use a facemask and which use a respirator? If your workplace uses different types of respirators, please describe what types and when they are used.

AHA Response. The AHA has encouraged hospitals to comply with OSHA’s respiratory protection standard when airborne precautions are in use and as recommended in the CDC guidelines. In recent years, the two main situations requiring respirator use involve TB and the 2009 H1N1 pandemic and both were addressed through CDC guidelines.

The CDC TB guidelines recommend a risk assessment be conducted and, if the criteria are met, the hospitals must implement worker TB evaluation as well as institute a full respiratory protection program. This includes education, fit-testing of respirators, and training on how to do a fit-check after donning of a respirator. The interim CDC *Guideline for Infection Control in Healthcare Settings*, issued at the outset of the 2009 H1N1 pandemic, led to a far greater number of health care personnel requiring education, training and fit-testing. Due to widespread respirator shortages as the pandemic progressed, staff performing procedures generating short range aerosols were given priority for N95 respirators. However, those hospitals which had sufficient supplies of respirators used them in accordance with the CDC guidelines. Once the revised guidance for prevention of influenza is finalized by the CDC, the AHA expects that hospitals will comply with recommendations for the use of facemasks for routine care and N95 respirators only for the listed procedures generating short-range aerosols.

Question 23. NIOSH regulates the testing and certification of respiratory protective equipment, has established minimum performance standards, and conducts independent testing and verification of all respirators prior to certification. The Food and Drug Administration (FDA) approval process for facemasks does not have established minimum performance standards and allows manufacturer submitted data. As noted in a 2009 IOM report, a 2008 study that examined the filter performance

of nine different types of facemasks using the sodium chloride NIOSH challenge test, found wide variation in penetration (4 percent to 90 percent) of smaller aerosol particles. Therefore, the protective properties of different manufacturers' facemasks may vary. Is there a need for a more rigorous certification/approval process for facemasks and additional independent verification of personal protective properties of devices?

AHA Response. A single standard for facemask performance would be of value. However, while we are aware of the cited IOM report, we also are aware of related information on testing facemasks and respirators shared at subsequent IOM meetings and NIOSH workshops that raised questions about whether aerosolized saline is an appropriate particle surrogate for aerosolized human mucous. The AHA recommends that OSHA work with FDA for further input on this issue.

Question 24. Some HCWs have medical conditions or are receiving treatments that impair their ability to resist infection. These HCWs may be unable to develop protective immune responses after vaccination. What is your workplace or industry doing to educate its workers about these conditions? What approaches are being used/should be used to address the special needs of HCWs with these conditions?

AHA Response. There are many employee privacy and confidentiality issues that must be considered in this situation. Hospitals assess a prospective employee's laboratory results during pre-employment reviews, and would provide, in this situation, additional one-on-one counseling sessions on the importance of understanding and adhering to Standard Precautions. The hospital's employee health program will accommodate these workers as much as possible but there is no known "safe" unit in hospitals for assignment. As a basic premise, all patients in the hospital are considered to be potentially infectious. Any asymptomatic patients may be incubating infections and exposing others with an infectious disease agent such as influenza or varicella. In addition to Standard Precautions, such employees are urged to always report potential exposures so that they can be assessed, tested and receive appropriate prophylaxis.

D. Vaccination and Post-Exposure Prophylaxis

Question 25. In the Bloodborne Pathogens standard (Sec. 1910.1030), OSHA requires that hepatitis B vaccinations be made available to employees occupationally exposed to blood or other body fluids. It should be noted that while employers are required to offer the vaccine, employees are permitted to decline it. CDC/Advisory Committee for Immunization Practices (ACIP) recommends a number of other vaccines for various groups of HCWs including: influenza (both seasonal and the 2009 H1N1); measles, mumps, rubella (MMR); varicella; tetanus, diphtheria, pertussis; (Td/Tdap); and meningococcal vaccines. What vaccinations, other than hepatitis B, do you consider to be necessary to protect workers from occupational exposure to infectious agents? Who should receive these vaccinations, and why? Does your workplace offer vaccines other than the hepatitis B vaccine to workers and how do you determine who is offered these vaccines?

AHA Response. The CDC guidelines emphasize the importance of these vaccines, many of which are childhood vaccines required by school systems; others are boosters such as Tdap. The CMS infection control interpretive guidelines also require that the state surveyors review this information. A recent publication [Wei SC, et al. Clin Infectious Dis Aug 1: 2010; 51(3):315-321] demonstrates the effectiveness of Tdap in protecting against pertussis in a school, even in an outbreak setting.

Most employee health programs have policies requiring a thorough immunization history for employees. Employee health policies also require testing for antibodies to HBV and other diseases, such as varicella (if the employee does not have proof of immunity). This would apply to all personnel. If the individual is lacking immunity, some hospitals may administer the vaccines in-house or refer the employee to local public health for vaccinations. The AHA encourages hospitals to follow ACIP guidelines for health care personnel vaccination. These guidelines are currently being updated.

Question 26. The Bloodborne Pathogens standard (Sec. 1910.1030) requires that employers follow certain administrative and recordkeeping procedures (e.g., signing a declination statement; placing an employee's vaccination status in his/her medical record). Does your workplace or industry use similar administrative and recordkeeping procedures for vaccines other than hepatitis B? If not, please describe what administrative and recordkeeping procedures are or should be used.

AHA Response. As a matter of policy, hospitals maintain a record of prior and/or current immunization.

Question 27. Post-exposure prophylaxis (PEP) and evaluation for bloodborne pathogen exposures, such as hepatitis B and HIV, are addressed in the Bloodborne Pathogens standard [Sec. 1910.1030(f)]. OSHA is interested in post-exposure evaluation and PEP for other infectious diseases. Please describe the current PEP and evaluation practices in your workplace. For what infectious agent exposures should workers be provided with PEP and/or evaluation? Please describe the disease, its associated PEP, and the PEP efficacy.

AHA Response. Hospitals focus on ensuring that health care personnel are immunized against infections that are vaccine-preventable, including influenza. Beyond that, hospitals follow CDC guidelines for the proper treatment or PEP, depending on the type of infectious agent exposure.

Question 28. In some instances, a vaccine may be available for a disease but a worker may decline vaccination. Please describe procedures in your workplace that ensure workers who have declined vaccination have access to necessary PEP.

AHA Response. As noted earlier, hospitals offer appropriate PEP to all exposed employees, regardless of vaccine status.

Question 29. In order to appropriately evaluate the health status of a worker, some basic health information is needed. CDC/HICPAC recommends a personnel health service program for infection control that includes a number of components including: pre-placement evaluations, evaluation and treatment of exposure-related illnesses, and work restriction or work-exclusion policies for exposed HCWs. OSHA is interested in the prevalence, content and efficacy of such personnel health service programs.

a) *What should be included in a pre-placement medical evaluation for a worker who will be exposed to infectious agents? Please describe the possible components of the medical history and physical exam and specific tests (e.g., TB skin test, spirometry, blood tests). How are pre-placement medical evaluations of workers addressed in your workplace? What do these evaluations include? If pre-placement medical evaluations are used in your workplace, have*

they been effective, and what metrics are used to evaluate effectiveness? Give the rationale, including references if available.

AHA Response. Hospitals follow CDC's *Guidelines for Infection Control for Healthcare Personnel* and a medical history and a physical exam are included in their pre-placement programs. Elements include, for example, past infectious disease history, exposures, vaccines and tests for TB (if appropriate per CDC TB guidelines), vaccine titers, and overall health and fitness for the job being sought.

b) What type of ongoing medical surveillance or periodic medical evaluations should be provided for exposed workers? Please describe the possible components of such surveillance or evaluations. How often should periodic medical evaluations be conducted? In what situations should medical evaluations or surveillance be performed (e.g., return-to-work, fitness for duty)? How are periodic medical evaluations addressed in your workplace?

AHA Response. Comprehensive IPC programs involve surveillance by infection preventionists and/or the employee health program to ensure the provision of recommended follow-up treatment or testing following an exposure assessments. The "return to work" policies and procedures also are closely followed to ensure it is safe for employees to return.

E. Communication of Hazards

Question 31. Both initial and periodic worker training are recognized as important components of an effective IC program. Initial training provides information that workers need to protect themselves against exposures to hazards while periodic training refreshes worker knowledge, reinforces the importance of the IC program and provides a means of introducing new information and procedures.

- a) What information should be included in initial training for workers who may be exposed to infectious agents? What is the best format for providing initial training to these workers (e.g., specifying a minimum number of hours of training, specifying training content based on job tasks, specifying that training be adequate to demonstrate specified competencies, by a combination of these methods or by some other method)?*
- b) How frequently does your workplace provide workers with refresher training on its IC program? What information should be included in periodic refresher training for workers who may be exposed to infectious agents?*
- c) What is the best format for providing periodic training to these workers (e.g., specifying a minimum number of hours of training, specifying training content based on job tasks, specifying that training be adequate to demonstrate specified competencies, by a combination of these methods or by some other method)?*
- d) Should refresher training be provided based on lack of competency, or be provided at regular time intervals regardless of demonstrated competency?*

AHA Response. Hospitals follow the CDC guidelines and routinely offer initial and at least annual training on infectious disease beyond MTB and bloodborne infections. They also routinely offer training utilizing the most recent evidence-based information to ensure that the information provided to health care personnel is timely and relevant.

F. Recordkeeping

Question 32. Please describe the worker health surveillance system used in your workplace. Does the system include tracking of occupational exposures to infectious agents and/or occupationally-acquired infectious diseases? Please describe the procedures used by your workplace to determine whether an infectious disease is considered to have been occupationally-acquired. How is the worker health surveillance information collected under the system used in your IC program? Please describe the factors that affect the success implementation of such surveillance systems.

AHA Response. Hospitals follow the CDC guidelines and investigate each reported exposure using the latest information and updates from CDC to determine, for each specific disease, whether the exposure was an occupational- or community-based exposure. As recommended in CDC guidelines, employees are tracked for appropriate follow-up, using testing as needed.

Question 33. The OSHA requirements for recording and reporting occupational injuries and illnesses contain an exemption for the common cold and flu (Sec. 1904.5(b)(2)(viii)). However, the Agency has determined that, if certain criteria are met, occupationally-acquired 2009 H1N1 pandemic influenza is recordable (OSHA Directive CPL-02-02-075). As OSHA more broadly considers the issue of occupational exposure to infectious agents, what are the implications, if any, for the Agency's existing recording and reporting requirements under Sec. 1904?

AHA Response. OSHA's criteria appear to refer to initial reporting of individual cases of infection during the beginning of a pandemic. Now that the H1N1 virus is incorporated into the seasonal influenza vaccine, we believe that H1N1 should now fall under the common cold and flu exemption, especially since the CDC has in place its sentinel surveillance systems for measuring seasonal influenza cases in offices and emergency departments. However, the incorporation of H1N1 into the seasonal influenza vaccine does put a new emphasis on the importance of health care personnel and others receiving seasonal vaccination.

Further, the AHA is concerned about the increased burden that would fall on hospitals for reporting additional infectious agents, for example MRSA, when it is very difficult to determine colonization and to distinguish occupationally-acquired infection versus community-acquired infection. We are also concerned about conflicting reporting requirements that would arise if OSHA begins to require additional reporting of infections not typically required by state reporting systems, not supported by evidence, or for which PEP is effective.

G. Economic Impacts and Benefits

Question 34. As the Agency considers possible actions to address the prevention and control of infectious diseases (e.g., prospective standards or guidelines), what are the potential economic impacts associated with the promulgation of a standard specific to the hazards of infectious diseases? Describe these impacts in terms of benefits from the reduction of incidents and illnesses; effects on revenue and profit; and any other relevant impact measure. If you have any estimates of the costs of controlling infectious disease hazards, please provide them.

AHA Response. As discussed throughout our comments and responses, the AHA does not see any additional benefit from the imposition of a highly redundant set of requirements by OSHA. We believe that there would be a considerable financial burden involved in documenting compliance for a standard with such an unproven benefit.

Question 36. What are the potential benefits of more widespread compliance with infection control guidelines? How can OSHA best assure such compliance takes place?

AHA Response. The AHA does not believe that it is necessary for OSHA to develop an additional standard that will only serve to duplicate much of what is already in place. Existing infection prevention and control standards, including their assessment and enforcement by regulatory, accrediting and certifying bodies, have proven to be functional and appropriate, with substantial resources dedicated to their regular maintenance and improvement. In order to justify a new standard, the burden remains on OSHA to demonstrate that these comprehensive and stringently enforced programs are insufficient, and that gaps in the existing programs have led to measurable increases in occupationally acquired infections.

H. Impacts on Small Entities

Question 38. How, and to what extent, would small entities in your industry be affected by a potential comprehensive OSHA infectious diseases standard regulating occupational exposure to infectious agents? Do special circumstances exist that make controlling infectious diseases more difficult or more costly for small entities than for large entities? Describe these circumstances.

AHA Response. Small rural hospitals and CAHs are financially vulnerable organizations that have difficulty absorbing additional costs. Our particular concern involves CAHs and other small hospitals that already comply with the CDC guidelines and associated CMS/accreditation standards, but which would be required, under a new OSHA infectious disease standard, to bear the additional cost and burden of putting into place and maintaining an OSHA compliance program for what is likely to be a redundant standard that would provide no additional benefit.

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.

A-0748

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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.

A-0749

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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 immunosuppressed 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.

A-0750

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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.
-