

Emily R. Studebaker, Esq.

Garvey Schubert Barer
1191 Second Avenue, Suite 1800
Seattle, WA 98101
Direct 206.816.1417
Mobile 206.406.2729
estudebaker@gsblaw.com

Medicare Conditions for Coverage Alert: Infection Control

In order to receive Medicare payment for surgical services furnished to program beneficiaries, an ambulatory surgical center (“ASC”) must meet certain specific requirements referred to as Conditions for Coverage and set forth at 42 C.F.R. 416, Subpart C. This alert discusses the Infection Control Condition for Coverage and the interpretive guidance related to infection control set forth in the Medicare State Operations Manual.

Background

The Infection Control Condition for Coverage requires an ASC to maintain an active program for the minimization of infections and communicable diseases. It provides:

The ASC must maintain an infection control program that seeks to minimize infections and communicable diseases.¹

An ASC’s infection control program must 1) provide a functional and sanitary environment for surgical services; 2) be based on nationally recognized infection control guidelines; 3) be directed by a designated health care professional with training in infection control; 4) be integrated into the ASC’s quality assurance performance improvement (“QAPI”) program; 5) be ongoing; 6) include actions to prevent, identify and manage infections and communicable diseases; and 7) include a mechanism to immediately implement corrective actions and preventive measures that improve the control of infection within the ASC.

During a Medicare certification survey, one surveyor is responsible for completion of the Infection Control Surveyor Worksheet (Exhibit 351 to the Medicare State Operations Manual) which is used by the surveyor in order to determine compliance with the Infection Control Condition for Coverage.²

Sanitary Environment

(a) Standard: Sanitary Environment.

The ASC must provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice.

An ASC must maintain a functional and sanitary environment for surgical services. This includes all areas of the ASC, including waiting areas, pre-surgical prep areas, recovery rooms, and operating and procedure rooms. The ASC must monitor housekeeping, maintenance and other activities such as repair, renovation, and construction to ensure a functional and sanitary environment. The ASC should develop and maintain policies and procedures for a functional and sanitary environment addressing the following:

- Ventilation and water quality control;
- Safe air handling systems in areas of special ventilation;
- Techniques for food sanitation (if employee food storage and eating areas are provided);

¹ 42 C.F.R. § 416.51. Appendix L to the Medicare State Operations Manual sets forth the “Guidance for Surveyors: Ambulatory Surgical Centers” and is available at www.cms.gov/GuidanceforLawsandRegulations/02_ASCs.asp.

² The Infection Control Surveyor Worksheet is available at www.cms.gov/manuals/downloads/som107_exhibit_351.pdf.

- Techniques for cleaning and disinfecting environmental surfaces, carpeting, and furniture;
- Techniques for disposal of regulated and non-regulated waste; and
- Techniques for pest control.

The ASC's infection control activities must be conducted in accordance with professionally recognized standards of infection control practice.³

Infection Control Program

(b) Standard: Infection control program.

The ASC must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases. In addition, the infection control and prevention program must include documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines. ...

An ASC's infection control program must have an active surveillance component that covers ASC patients and personnel working in the facility. Surveillance must include infection detection through ongoing data collection and analysis.

The ASC should select one or more sets of guidelines that enable it to address the following key functions of an effective infection control program:

- Development and implementation of infection control activities related to ASC personnel (which, for infection control purposes, includes all ASC medical staff, employees, and on-site contract workers);
- Mitigation of risks associated with healthcare-associated infections;
- Identifying infections;
- Monitoring compliance with policies, procedures, protocols and other infection control program requirements; and
- Program evaluation and revision of the program, when indicated.

The following provides a more detailed overview of the activities related to these key functions.

³ 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").

Development and Implementation of Infection Control Activities Related to ASC Personnel

An ASC should evaluate the immunization status of each member of its staff for designated infectious diseases. In addition, it should develop and maintain policies articulating the authority and circumstances under which the ASC screens its staff for infections likely to cause significant infectious disease or other risk to an exposed individual, and for reportable diseases, as required under local, state, or federal public health authority as well as policies articulating when infected ASC staff are restricted from providing direct patient care or are required to remain away from the facility entirely. The ASC should also require new employee and regular update training in preventing and controlling healthcare-associated infections ("HAI") and methods to prevent exposure to and transmission of infections and communicable diseases.

Mitigation of Risks Associated with Healthcare-Associated Infections

An ASC should take the following surgery-related infection risk mitigation measures:

- Implementing appropriate prophylaxis to prevent surgical site infection, such as protocol to assure that antibiotic prophylaxis to prevent SSI for appropriate procedures is administered at the appropriate time, done with an appropriate antibiotic, and discontinued appropriately after surgery; and
- Addressing aseptic technique practices used in surgery, including sterilization or high-level disinfection of instruments, as appropriate.

In addition, the Medicare State Operations Manual indicates that an ASC should take other HAI risk mitigation measures such as the following:

- Promotion of hand hygiene among staff and employees, including utilization of alcohol-based hand sanitizers;
- Measures specific to the prevention of infections caused by organisms that are antibiotic-resistant;
- Measures specific to safe practices for injecting medications and saline or other infusates;
- Requiring disinfectants and germicides to be used in accordance with the manufacturers' instructions;
- Appropriate use of facility and medical equipment, including air filtration equipment, UV lights, and other equipment used to control the spread of infectious agents;
- Educating patients, visitors, and staff, as appropriate, about infections and communicable

diseases and methods to reduce transmission in the ASC and in the community.

Identifying Infections

An ASC must conduct monitoring activities throughout the entire facility in order to identify infection risks or communicable disease problems. The ASC should document its monitoring activities. Monitoring includes follow-up of patients after discharge, in order to gather evidence of whether the patients develop an infection associated with their stay in the ASC. The ASC must also 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.

Monitoring Compliance with Policies, Procedures, Protocols and Other Infection Control Program Requirements

An ASC must take steps to determine whether its staff adheres to its infection control policies and procedures.

Program Evaluation and Revision of Infection Control Program

An ASC's infection control program must be an integral part of the ASC's quality assessment and performance improvement program.⁴

Infection Control Program

(b) Standard: Infection control program.

... The program is --

(1) Under the direction of a designated and qualified professional who has training in infection control;

(2) An integral part of the ASC's quality assessment and performance improvement program; and

(3) Responsible for providing a plan of action for preventing, identifying, and managing infections and communicable diseases and for immediately implementing corrective and preventive measures that result in improvement.

An ASC must designate in writing, a qualified licensed health care professional who will lead the facility's infection control program. The individual must have training in the principles and methods of

⁴ More information regarding QAPI requirements is available at www.cascacolorado.com.

infection control.⁵ The individual selected to lead the ASC's infection control program must maintain his or her qualifications through ongoing education and training.⁶

The ASC's infection control professional must develop and implement a comprehensive plan that includes actions to prevent, identify and manage infections and communicable diseases within the ASC. The plan must include mechanisms that result in immediate action to implement preventive or corrective measures that improve the ASC's infection control outcomes. It also must be specific to each particular area of the ASC, including the waiting rooms, the recovery rooms, and the surgical areas.

The infection control professional must assure that the program's plan addresses the following activities: 1) maintenance of a sanitary environment; 2) development and implementation of infection control measures related to ASC personnel; 3) mitigation of risks associated with patient infections present upon admission; 4) mitigation of risks contributing to HAI; 5) active surveillance; 6) monitoring compliance with all policies, procedures, protocols, and other infection control program requirements; 7) plan evaluation and revision of the plan, when indicated; 8) coordination as required by law with federal, state, and local emergency preparedness and health authorities to address communicable and infectious disease threats and outbreaks; and 9) compliance with reportable disease requirements of the local health authority.

This article has been prepared by Emily R. Studebaker of Garvey Schubert Barer. It is not a substitute for legal advice or individual analysis of a particular legal matter. Transmission and receipt of this publication does not create an attorney-client relationship.

⁵ Certification in infection control, such as that offered by the Certification Board of Infection Control and Epidemiology Inc. ("CIBC"), while highly desirable, is not required. However, the ASC must be able to provide documentation that the individual has training that qualifies the individual to lead an infection control program.

⁶ The individual's ongoing education and training can be demonstrated by his or her participation in infection control courses, or in local and national meetings organized by recognized professional societies, such as APIC and SHEA.