

October 30, 2007

Centers for Medicare & Medicaid Services,  
Department of Health and Human Services,  
Attention: CMS-3887-P,  
P.O. Box 8017,  
Baltimore, MD 21244-8017.

Re: Medicare and Medicaid Programs; Ambulatory Surgical Centers, Conditions for Coverage, Proposed Rule CMS-3887-P; Comments on § 416.51 Conditions for coverage— Infection Control.

The Association for Professionals in Infection Control and Epidemiology (APIC) and the Society for Healthcare Epidemiology of America (SHEA) collectively represent more than 14,000 infectious disease and infection control authorities in our nation's healthcare facilities. As organizations with considerable expertise in the prevention, detection, control and treatment of healthcare-associated infections (HAIs), we wish to respond jointly to your questions regarding the proposed conditions for coverage focused on the area of infection control for ambulatory surgical centers (ASCs) as outlined in the document *CMS-3887-P*.

We applaud the foresight of CMS in this arena, as we have a shared vision of preventing HAIs. Elevating HAI prevention and infection control to the level of a condition and noting that infection control is "an essential health and quality standard" reinforces the critical importance of infection prevention in terms of patient safety and quality of care.

We endorse the integration of the infection prevention and control program (IC) into the ASC's Quality Assurance Performance Improvement Requirement (QAPI) and the emphasis on integration of

*"knowledge gained from past and current experiences to modify policies, procedures or practice that would lead to improvements for those problematic areas identified and monitored as part of the QAPI program."*

An IC program must be dynamic and utilize assessment of prior events to improve patient care and eliminate HAIs.

While we support many of the basic tenets of the proposed rule, we also have some suggestions we hope will facilitate early planning as CMS finalizes and implements the proposed rule and considers interpretive guidelines for the final rule.

## **I. Background**

Infection prevention is increasingly important in non-acute settings such as ASCs, which are experiencing continued growth in volumes of surgeries that are performed. We believe every effort should be made to eliminate HAIs in all healthcare settings by applying evidence-based approaches as healthcare facilities care for sicker patients in an increasingly complex environment. We agree with the intent of the proposed changes; however, we do have some concerns regarding several specific concepts and statements made as part of the background and provisions of the proposed rule as outlined below:

### **Provisions**

## **II. Provisions of the Proposed Regulation, Section 5. Condition for Coverage—Infection Control (§ 416.51)**

### **Designated IC staff**

We agree the designation of a specific individual to serve as the ASC's infection control officer (ICO) is essential. Studies such as the landmark Study on the Efficacy of Nosocomial Infection Control (SENIC)<sup>1</sup> have shown an active infection prevention and control program with a dedicated infection control professional (ICP) can lead to a significant reduction in HAI rates in general and surgical site infection (SSI) rates in particular.<sup>2</sup> The variety of issues and responsibilities the ICO will face in an ASC setting underscores the importance of adequate training including an up-to-date knowledge base encompassing all areas that will impact the ASC patient.

### **Qualifications and current competency**

Per the background in the proposed rule,

*“the infection control program would operate under the direction of that designated individual [i.e. the infection control officer] who would be accountable for the investigation and resolution of infection and communicable disease incidents. In addition, the infection control program would be required to follow an organized plan of action to identify infection control problems and implement corrective measures and preventive mechanisms when necessary.”*

We would suggest the ICO should be referred to as an “infection control professional” or ICP. The ASC must designate in writing an individual or group of individuals, qualified through ongoing education, training, experience, or certification<sup>3</sup> as an infection control professional or professionals. CDC has defined an “infection control professional” as “a person whose primary training is in either nursing, medical technology, microbiology, or epidemiology and who has acquired specialized training in infection control.” Verification of ongoing education and training should also be required. The number of ICPs or the number of ICP hours devoted to the infection prevention and control program should not be based on patient census alone, but rather should be determined by an annual risk assessment considering such factors as the scope of the program, characteristics of the patient population, complexity of the ASC and activities that will be carried out,

techniques available for performing essential tasks, risks entailed in the care, treatment, and services provided, and unique or urgent needs of the ASC.

### **Infection prevention program resources**

There must be adequate, dedicated resources allocated to implement and evaluate measures to prevent and control ASC- and community-associated infections and to identify and investigate infections and communicable diseases. Resource allocation should be based on an annual risk assessment.

In order to maintain an active program for the prevention, control, and investigation of infections and communicable diseases, the scope of actual responsibilities and activities for the ASC's ICP is much more extensive than currently exist in many ASCs today.

**An effective infection control program** should at a minimum, address the following elements: (see Appendix I for more detail)

- Patient and staff prevention and control measures
- A safe and sanitary environment
- Staff/volunteer health, education, and training
- Regulatory and community agency responsibilities
- Annual program evaluation and revision to further the overall program goal of elimination of HAIs.

### **Staff training and current competency**

Another area of concern focuses upon the baseline expectations for infection control training of ASC personnel. The background of the proposed rule states that:

*“the proposed infection control condition allows flexibility for ASCs to determine how to meet these objectives. This includes the flexibility to determine how much training in infection control is necessary for the ASCs personnel.”*

While we agree each ASC, as a part of its regular infection control risk assessment, should have the flexibility to determine which areas of infection control require emphasis as a part of personnel training, a minimum standard of training in the basic essential concepts of infection control should be required.

In the background and provisions of the proposed rule it is noted that CMS

*“considered requiring ASCs to meet CDC and Occupational Safety and Health Administration (OSHA) standards for providing an environment to avoid infections and communicable disease. However, such a requirement would raise questions as to which CDC or OSHA standards must be met. Moreover, where dual sets of professionally recognized standards exist, we would not wish to restrict ASC flexibility by mandating compliance with a particular body of standards. Therefore, we are not mandating that ASCs follow any specific set of infection control guidelines.”*

While we understand the concern of potentially conflicting guidelines, we would suggest that ICPs must consider all related regulations and standards, including OSHA standards to protect health care professionals as well as CDC and other IC guidelines addressing patient safety. We would propose the above paragraph be modified to state:

"the Infection Prevention and Control program must include documentation that it has considered, selected, and implemented nationally recognized infection control guidelines."

Examples of organizations that promulgate nationally recognized infection control guidelines include, but are not limited to: the CDC/Healthcare Infection Control Practices Advisory Committee (HICPAC), the Occupational Health and Safety Administration (OSHA), the Association for Professionals in Infection Control and Epidemiology (APIC), the Society for Healthcare Epidemiology of America (SHEA), the Association of periOperative Registered Nurses (AORN) and the Association for the Advancement of Medical Instrumentation (AAMI).<sup>4-7</sup>

### **Cleaning, Disinfection and Sterilization**

Another important concern lies in the proposed expectations for ASC instrument and equipment sterilization and cleaning. Namely, the proposed rule does **not**

*"propos[e] to include a prescriptive requirement that mandates a specific method of cleaning and sterilization of equipment utilized in ASC procedures. We would require each ASC to be responsible for creating and implementing its own policies and procedures for proper instrument cleaning and maintenance of the sterilization equipment to prevent patient exposure to infectious organisms by ensuring all equipment is properly cleaned and sterilized."*

We agree with CMS if the intent is to *not dictate* use of a particular method or piece of equipment. However, we are concerned this language implies that more lenient and ASC-determined policies and procedures for equipment and instrument cleaning, disinfection and sterilization are acceptable, which has the potential to place patients at increased risk in the event minimum standards are not met. Instead, the ASC should select approved and scientifically based methods/equipment for cleaning, disinfection and sterilization as outlined in nationally recognized guidelines. The approach should be no different than that used in standard operating rooms, since inpatient and outpatient surgery should provide a single standard of care.

### **III. Collection of Information Requirements**

Given the broad range of responsibilities of the ICP at the ASC, we are also concerned regarding the estimate of the information collection burden of the Infection Control Provision; namely, the Infection Control Provision is estimated **not** to require any further burden in terms of information collection. The time and effort devoted to conduct the necessary activities for an active infection control program could be substantial. This will include, but not be limited to, development of an active IC program and annual risk assessment and evaluation of program effectiveness as detailed in Appendix I. Although we agree strongly with the premise that ASCs should have a dedicated and active IC program, we feel the true burden associated with this requirement may have been underestimated.

### **IMPACT**

## V. Regulatory Impact Analysis, 5. Anticipated Effects of the Infection Control Provision (§416.51)

Given the potential issues and responsibilities the ASC's ICP may face as noted above, we are also concerned about the perceived necessary training for the ICP. As per the proposed rule,

*“the designated person would need to engage in continuing education in infection control on a frequent or at least an annual basis. We estimate that an ASC would spend approximately \$500 per calendar year on infection control training for the designated individual. This cost was based on the quantity of technical information that we believe is appropriate to be included in an infection control program. The cost also includes the time spent by the ASC infection control officer (the trainee), the cost for a qualified trainer and the training materials. We estimate that the course would run 4 hours.”*

Knowledge regarding infection prevention and control practices, regulatory and accreditation standards, and epidemiologic principles essential for an ICP are not a formal part of standard nursing education and training.<sup>8</sup> Specialized instruction in basic infection control training is thus required.<sup>9, 10</sup> We feel the proposed cost of \$500/year is a better indicator of the cost of *continuing* education in IC following initial training. The estimated time commitment for such training currently noted in the CMS proposal (4 hours) appears less than is needed to merely ensure ongoing familiarity with new regulatory requirements and infection prevention guidelines. Thus, the impact of the new rule may have larger cost implications for the ACS than originally estimated.

### Proposed Rule, § 416.51 Conditions for coverage— Infection Control

Our preceding remarks were intended to provide background on the scope of an ASC infection and prevention program, the breadth and depth of the knowledge and skills needed by the designated ICP (ICO) and support for more extensive training resources needed for staffing an effective program. These remarks may be useful consideration in future interpretive guidelines for this new standard. We have appended relevant supporting documentation and recommendations that CMS may also find helpful as it drafts Interpretive Guidelines to any final rule.

With regard to the actual proposed rule, we recommend minor wording changes as noted below in **bold**. The specific notation that the program should be “active” mirrors language found in the rules that cover hospitals "Conditions of Participation: Infection Control" [§482.42; §482.42(a); §482.42(a) (1) and §482.42(a) (2)] and emphasizes the need to continually assess and evaluate the program to identify risk areas and keep pace with changing standards and guidelines.

*The Ambulatory Surgical Center (ASC) must maintain an **active** infection **prevention and control** program for patients and ASC staff that seeks to minimize infections and communicable diseases.*

- (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.*
- (b) Standard: Infection **prevention and control** program. The ASC must maintain an **active** program designed to prevent, control, and investigate infections and communicable diseases. The program is--*

- (1) Under the direction of a designated and qualified professional who has **sufficient knowledge, skills, and training in infection control to manage an effective infection prevention and control program**
- (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, **investigating**, and managing infections and communicable diseases and for immediately implementing corrective and preventive measures that result in improvement.

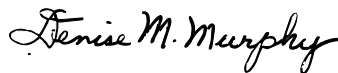
**(c) Standard: Responsibility of Chief Executive Officer, Medical Staff and Director of OR Services**

**The chief executive officer, medical staff and director of OR services must—**

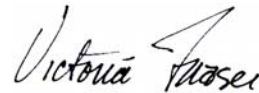
- (1) **Ensure that the quality assessment and performance improvement program address problems identified by the infection control professional or professional(s) and**
- (2) **Be responsible for the implementation of successful corrective action plans in affected problem areas**

In summary, we strongly support the enhanced focus by CMS on infection prevention and control in ASCs, and we appreciate the opportunity to comment on this proposed rule. We are eager to offer our infection control expertise and participate with CMS in the development of the final rule and, more specifically, in the development of the interpretive guidelines pertaining to the rule once finalized. We are committed to improving the safety of healthcare and the prevention of HAIs, and we look forward to working with CMS toward this goal.

Sincerely,



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APIC President



Victoria J. Fraser, MD  
SHEA President

1. Haley RW, Culver DH, White JW, et al. The efficacy of infection surveillance and control programs in preventing nosocomial infections in US hospitals. *Am J Epidemiol* 1985; 121:182-205.
2. McConkey SJ, L'Ecuyer PB, Murphy DM, Leet TL, Sundt TM, Fraser VJ. Results of a comprehensive infection control program for reducing surgical-site infections in coronary artery bypass surgery. *Infect Control Hosp Epidemiol* 1999; 20:533-8.
3. Certification Board in Infection Control and Epidemiology Incorporated. Accessed on October 22, 2007 at [www.cbic.org](http://www.cbic.org).
4. Mangram AJ, Horan TC, Pearson ML, Silver LC, Jarvis WR. Guideline for prevention of surgical site infection, 1999. Hospital Infection Control Practices Advisory Committee. *Infect Control Hosp Epidemiol* 1999;20(4):250-78. Accessed on October 25, 2007 at <http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/SSI.pdf>.
5. Sehulster L, Chinn RY. Guidelines for environmental infection control in health-care facilities. Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC). *MMWR Recomm Rep* 2003;52 (RR-10):1-42. Accessed on October 25, 2007 at [http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Enviro\\_guide\\_03.pdf](http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Enviro_guide_03.pdf).

6. Centers for Disease Control and Prevention. Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007. Accessed on October 23, 2007 at <http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Isolation2007.pdf>.
7. Occupational Safety & Health Administration. Standard on Bloodborne Pathogens (1930.1030), 1993, revised 2003. Accessed on August 23, 2005 at [www.osha.gov/SLTC/bloodbornepathogens/standards.html](http://www.osha.gov/SLTC/bloodbornepathogens/standards.html).
8. SHEA/CDC Training Courses in Healthcare Epidemiology. Accessed on October 23, 2007 at [http://www.shea-online.org/about/she\\_a\\_courses.cfm](http://www.shea-online.org/about/she_a_courses.cfm).
9. Horan-Murphy E BB, Chenoweth C, et al. APIC/CHICA-Canada infection control and epidemiology: Professional and practice standards. Am J Infect Control 1999;27:47-51. Accessed Oct 23, 2007 at <http://www.apic.org/Content/NavigationMenu/PracticeGuidance/Standards/Standards.htm>.
10. Association for Professionals in Infection Control and Epidemiology. EPI Courses - Education for the Prevention of Infection. Accessed on October 22, 2007 at [http://www.apic.org/scriptcontent/custom/education/ice\\_courses.cfm?section=education](http://www.apic.org/scriptcontent/custom/education/ice_courses.cfm?section=education).