When surveyors from the Centers for Medicare and Medicaid Services (CMS) arrived at Robinwood Surgery Center in Hagerstown, Maryland, at 2 pm one day last summer, the leaders were ready.

“The surveyors were very thorough. You won’t pass this if you don’t operate as a quality facility and follow all of the standards,” says the center’s director, Lana Gladhill, RN, noting the center passed with no deficiencies.

She and other leaders of ambulatory surgery centers (ASCs) shared their experiences from recent CMS surveys. The surveys, which are unannounced, assess compliance with the revised CMS conditions for coverage (CfCs) issued in May 2009, the first full update since 1982.

The surveyors follow the CMS interpretive guidelines for state surveyors, including a detailed 13-page worksheet of infection control practices. Infection control has been a major focus in the past year.

CMS issued an update of the interpretative guidelines on December 30, 2009. The guidelines were originally issued in May 2009. The most significant change is to specify that the exception to the advanced notice requirement for patients referred for surgery on the same day applies to all 3 advanced notice requirements—patient rights, advance directive, and physician ownership, the ASC Association reports. The exception for physician ownership was not included in the May 2009 guidelines.

More time in clinical areas

In many ways, the CMS survey is like other accreditation surveys, with scrutiny of personnel files, credentialing files, policies and procedures, and QI reports. But surveyors are also spending a lot of time in clinical areas.

“They are going through the facility and talking one-on-one with the clinical staff,” say Lee Anne Blackwell, RN, BSN, EMBA, CNOR, and Jan Allison, RN, of Surgical Care Affiliates, Birmingham, Alabama, which owns about 120 ASCs. About 13 of the centers have had a recent CMS survey.

Surveyors are observing care and following a patient through the process. Gladhill says that at her center, once the surveyors had permission from a patient, “they interviewed the patient and watched all of the interactions with the patient through the PACU” (postanesthesia care unit).

Infection control

As expected, surveyors are taking a close look at infection control.

“The surveyor really scrutinized our practices. She had a clipboard with the worksheet on it,” says Rosemary Lambie, RN, MEd, CNOR, nurse administrator of the SurgiCenter of Baltimore in Maryland.
Areas of focus include hand hygiene; instrument reprocessing, including flash sterilization; and injection safety, including proper aseptic technique.

**Infection control plan**
Surveyors ask to see the ASC’s infection control plan and documentation of the plan. The plan, according to the guidelines, should reflect that the facility follows recognized infection control guidelines, such as those from AORN, the Association for Professionals in Infection Control and Epidemiology (APIC), and the Centers for Disease Control and Prevention (CDC).

**Infection preventionist**
CMS requires that the infection control program be directed by a designated health care professional with training in infection control.

“They want to see evidence of ongoing training for the infection control nurse,” Allison says.

A simple way to ensure the infection preventionist receives the necessary training is for the person to join APIC, which offers reliable education on infection control.

“You can’t sit back,” adds Deb Oberholzer, RN, Robinwood’s infection control specialist. “You have to be proactive and seek out information from CMS, APIC, and the CDC, among others.”

**Staff education**
Staff and physicians must be kept up to date on infection control standards and developments.

“You have to share information. “You don’t know who the surveyors are going to ask, so the staff has to be aware of the latest information,” Gladhill notes.

An example is the Food and Drug Administration’s recent notice about the Steris System 1 processor, recommending that facilities make a transition to alternatives as soon as possible (www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm191585.htm).

At Robinwood, the OR manager meets with the staff every morning and includes updates on infection control. Annually, each staff member completes an online learning module on infection control, which includes a test. Completion of the module is documented.

**Hand hygiene**
Leaders say surveyors were particularly attentive to whether nurses, physicians, and other staff cleaned their hands when moving from one patient to another not only in the OR but also throughout the facility. Hands are a major path for disease transmission, and hand hygiene in health care has been notoriously lax.

“They watched the anesthesia providers to see if they cleaned their hands between touching the patient and other surfaces,” Lambie notes.

**Injection practices**
Injection safety is another strong emphasis. A number of disease outbreaks have been associated with lapses in aseptic practice, such as reinsertion into multidose syringes or using a single needle or syringe to give IV medications to multiple patients.

At SurgiCenter of Baltimore, the surveyor watched to see that anesthesia providers used an alcohol wipe on the port of medication vials and on the IV port every time they pushed a drug.
The surveyor also observed to make sure the remainder of a propofol vial was discarded after use on one patient.

“She stayed in the room until she saw the anesthesia provider discard the bottle,” Lambie says, adding that this results in a lot of the expensive drug being wasted. Propofol is labeled for single use, but the smallest vial is 20 mL. Recently, Lambie says, the drug has been on back order, and at times the center has been able to get only 50 mL or 100 mL vials.

“We are throwing away tens of thousands of dollars of propofol,” she says, noting the manufacturer has little incentive to sell smaller vials.

Propofol has no preservatives and can support the growth of microorganisms, says the manufacturer, Astra Zeneca.

Sterilization, disinfection

Blackwell and Allison say surveyors are also spending a lot of time watching activities in reprocessing areas.

Blackwell says she thinks surveyors have a better understanding of flash sterilization than in the past. “They are not immediately citing a facility if they see flash sterilization. But they want to see that you have appropriate processes for cleaning and transporting instruments to the sterile field with an appropriate container system.”

CMS issued a memo on flash sterilization in September 2009, instructing surveyors on how to distinguish appropriate from inappropriate use of flash sterilization.

Manufacturers’ instructions for reprocessing are another big area. The Joint Commission stressed the importance of manufacturers’ instructions in its update on steam sterilization in June 2009.

“When we do education, we remind our facilities that it’s important to have the manuals with manufacturers’ instructions available,” Blackwell says.

That includes instructions for cleaning products. For example, a surveyor or might stop at the sink where an employee is using an enzymatic detergent for cleaning instruments to ask how the employee knows how much detergent to add to the water. Surveyors are also likely to quiz the staff about which personal protective equipment they are supposed to wear for the various products they use.

Point-of-care devices

At Robinwood, surveyors asked about infection control practices for point-of-use devices such as glucometers and wanted to make sure finger-stick devices weren’t being used for multiple patients. Surveyors also check for disinfection of reusable items like blood pressure cuffs and stethoscopes.

Advanced patient notice

A requirement that has raised questions and challenges is the expectation that ASCs provide patients with notice in advance of the date of the procedure about patient rights, physician financial interests in the ASC, and advance directives.

“This has been a toughie, and we’re still working through the challenges,” says Blackwell. One question is what to do if a patient indicates he or she has an advance directive but does not bring it on the day of surgery.

“We understand we have to provide the patient with an advance directive form if the patient requests one, and it must be the state-approved form. But we are not sure what to do if patients have an advance directive, are
instructed to provide the ASC with a copy, and then don’t.” She notes that one center was cited for not having the advance directive on the chart of a patient who indicated he or she had executed a directive.

Gladhill says, “They were very specific about notifying the patient of the bill of rights and the advance directive, which we have in place.” Her center provides the required information in a patient packet distributed by the surgeon’s office before the day of surgery. Some Surgical Care Affiliates centers post the information on their websites and provide patients with a password to access it or send the notices by e-mail if the patient prefers.

“It doesn’t matter to the surveyor how the information is communicated, as long as the patient receives it in advance,” Blackwell says.

In one detail, at Robinwood, the surveyors said the Medicare beneficiary ombudsman’s phone number should be added to the patient’s advance notice as well as to the ASC’s website.

**Radiology credentialing**

Another CMS requirement ASCs find challenging is that their radiology services must meet the same standards as hospitals, including credentialing and privileging of the radiologists. ASCs have asked whether this is necessary if they don’t employ their own radiologists but contract with a radiology group and provide only limited services, such as verifying the placement of a screw during a fracture repair.

The ASC Association and ASC Coalition asked CMS about this issue in a letter raising questions and concerns about the interpretive guidelines. CMS responded in October 2009, rejecting their request that the supervising radiologist not be required to be a member of the medical staff.

In response to arguments that this would be a burden to ASCs, CMS said, “We do not anticipate requiring the supervising radiologist to be a member of the medical staff will cause extreme burden to the ASC primarily because a consulting radiologist who supervises an ASC’s radiologic services must be properly credentialed and have clinical privileges granted by the ASC, even if that radiologist is not a member of the ASC’s medical staff.”

Lambie asked the surveyor to clarify what is expected when the radiology group is contracted, as her center does. She says the surveyor told her it isn’t necessary for the ASC to separately credential and privilege the radiology group because the radiologists are not employees. Instead, the surveyor said there should be language in the contract to say the radiology group will provide the center with qualified personnel, which would include credentialing and privileging. Lambie adds that this interpretation may vary by surveyor and by state.

—Pat Patterson

Revised CMS interpretive guidelines were issued in December 2009. The guidelines and other CMS documents are available from the ASC Association at www.ascassociation.org

**References**