The Centers for Medicare and Medicaid Services (CMS) published the long-awaited final revision of the ambulatory surgery center (ASC) conditions for coverage (CfCs) on Oct 30, 2008. The CfCs spell out the rules for ASCs participating in Medicare. They were issued as part of a larger rule that includes updates to the ASC and hospital outpatient payment systems and changes to the ASC list of covered procedures. The rule was scheduled to appear in the Nov 18, 2008, Federal Register.

The changes are effective Jan 1, 2009. Comments on designated parts of the final rule will be accepted until Dec 29, 2008.

This is the first major overhaul of the CfCs since the original ASC rules were adopted in 1982. Since then, the number of ASCs participating in Medicare has mushroomed to 5,100.

Compliance with the CfCs is checked either by state survey agencies or 1 of the 4 national accrediting bodies: the Joint Commission, American Association for Accreditation of Ambulatory Surgical Facilities (AAAASF), Accreditation Association for Ambulatory Health Care (AAAHC), or American Osteopathic Association (AOA).

The final CfCs have some notable revisions from the proposed rule published in August 2007. The ASC Association, which plans to issue a detailed analysis, pointed in particular to a less restrictive definition of ASCs than was in the proposed rule issued in August 2007.

**Definition of an ASC**

The revised more flexible wording defines an ASC as a “distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which services are not expected to exceed 24 hours following admission.”

This definition will allow patients to stay in the ASC for 23 hours and 59 minutes starting at the time of admission. That will create a 24-hour rolling clock that will allow ASCs to perform procedures later in the day or to perform procedures that require a longer recovery time.

In contrast, the proposed rule would have defined an ASC as caring for patients who do not require an “overnight stay,” defined as a stay past 11:59 pm on the day of surgery that required “active monitoring” by “qualified medical personnel.”

**Strengthening patient rights**

The CfCs strengthen patient rights regarding physician disclosure of financial interests in the ASC, advance directives, the grievance process, and confidentiality of clinical records. CMS is retaining proposed requirements that:

- patient rights be posted in the ASC
- patients be informed of their rights orally and in writing.

In addition, CMS kept the proposed requirement that patients be notified about physician ownership in the ASC in advance of the date of their procedure. ASCs said this would be burdensome because patients often don’t come to the ASC before their day of surgery. CMS said it was not specifying how the notice must be given. For example, the notice could be included in the information packet patients receive.
before their procedure. The packet might have a form with a check box to indicate whether the patient’s surgeon has a financial interest in the facility.

CMS also kept the requirement about giving patients information about advance directives, even though ASC patients have elective surgery. “We believe ASC health care personnel should discuss the use of advance directives with patients and their designated family members,” CMS says, because this is becoming a standard of practice.

Regarding patient complaints, the final rule requires ASCs to report only complaints or grievances that are substantiated to state and/or local authorities. The proposed language would also have required reporting unsubstantiated complaints.

CMS did decide to do away with a separate CfC for confidentiality of clinical records, referring instead to the privacy rules in HIPAA (Health Insurance Portability and Accountability Act).

Quality assessment and improvement

The final CfCs for quality improvement are basically the same as proposed. These rules impose stronger obligations on ASC governing bodies to oversee the quality assessment and performance improvement (QAPI) program, while allowing ASCs flexibility to use their own information to assess and improve patient services, outcomes, and satisfaction. CMS notes that these requirements bring the CfCs up to date with what the accrediting bodies already require.

The QAPI standards require ASCs to have an ongoing program that would:
• be able to show measurable improvement in quality outcome and safety indicators
• collect and analyze data to identify PI opportunities
• set priorities for PI activities
• reflect the scope and complexity of the ASC’s services and activities.

The ASC’s governing body would be responsible and accountable for the QAPI program. One change makes the final rule more specific, saying ASCs must allocate adequate “staff, time, information systems, and training” to the QAPI program, rather than using the more general term “resources.”

Patient admission, assessment, and discharge

With the expansion of procedures being performed in ASCs, CMS said it believes stronger requirements are needed for patient assessment and recovery. Core objectives of these requirements are to ensure:
• the patient can tolerate surgery
• the patient’s anesthesia risk and recovery are properly evaluated
• the patient’s postoperative recovery is adequately evaluated
• the patient receives effective discharge planning
• the patient is successfully discharged from the ASC.

Admission and assessment

This section says a patient must have a comprehensive history and physical not more than 30 days before the scheduled surgery. On admission to the ASC, each patient must have a presurgical assessment that includes, at a minimum, an update documenting any changes in the patient’s condition, including documentation of any allergies to drugs and biologicals. The history and physical must be in the patient’s medical record prior to the surgical procedure.

In one change, CMS dropped the requirement that the assessment include the patient’s “mental ability” to undergo surgery because this may be beyond the scope of the surgical team.

Postsurgical assessment

The final language says RNs with postop experience, in addition to physicians or other qualified practitioners, can assess and document the patient’s postoperative condition.

On discharge orders, the final language states the ASC must: “Ensure each
patient has a discharge order signed by the physician who performed the surgery or procedure in accordance with applicable state health and safety laws, standards of practice, and ASC policy.” Dropped was additional language, which would have required that “the discharge order must indicate that the patient has been evaluated for proper anesthesia and medical recovery.”

In addition, the ASC must: “Ensure all patients are discharged in the company of a responsible adult, except patients exempted by the attending physician.”

CMS did not make the proposed requirement that ASCs must ensure “the patient has a safe transition to home and that the postsurgical needs are met.” The agency agreed with commenters who said the language was too broad and might be interpreted to mean the ASC had responsibility after the patient left the facility.

Radiology services
In response to public comments, CMS decided to scrap onerous requirements for radiology services. ASCs had been concerned that the proposed changes would severely restrict their ability to perform procedures that require imaging and impose other impractical requirements.

CMS instead decided to keep the existing radiology services requirements applying to ASCs that are in the hospital conditions of participation. These include requirements for safety, equipment maintenance, and personnel qualifications.

Infection control
The final CICs emphasize the importance of infection control practices, requiring ASCs to maintain an infection control program. In a wording change, CMS added the requirement that the infection control program must include documentation that the ASC has implemented “nationally recognized infection control guidelines,” such as those of the Centers for Disease Control and Prevention.

Disaster plan
The final CICs require ASCs to adopt a disaster preparedness plan, as proposed. ASCs will need to coordinate the plan with state and local agencies, conduct annual drills, and “promptly implement” (rather than “immediately implement,” as proposed) any changes needed to improve the plan.

The ASC Association will be providing an analysis on its website at www.ascassociation.org.