

Significant Changes Coming for Ambulatory Surgery Center Medicare/Medicaid Certification

The Centers for Medicare and Medicaid Services published a Proposed Rule on August 31, 2007, to add three new and revise three existing Conditions for Coverage (“conditions”) governing Ambulatory Surgery Center (ASC) participation in Medicare and Medicaid. These would be the first significant non-payment related changes since 1982. The public comment period has closed and issuance of the final rule is pending.

The Proposed Rule reflects a shift away from a problem-focused, reactive regulatory approach to a quality assurance-focused, proactive approach. Given that the Proposed Rule is part of this larger shift in policy and given that final rules similar to the Proposed Rule have been implemented for other health care facilities, it is reasonable to expect this Proposed Rule for ASCs will become final without too many major substantive changes.

The proposed revised conditions are in the areas of:

1. Governing Body and Management
2. Evaluation of Quality (renamed “Quality Assessment and Performance Improvement, or “QAPI”)
3. Laboratory and Radiologic Services

The proposed new conditions are in the areas of:

1. Patient Rights
2. Infection Control
3. Patient Admission, Assessment and Discharge

Many of the detailed requirements will already be covered in the policies and procedures being followed by the ASC for one or more other purposes, such as accreditation and state licensure, maintaining insurance coverage, OSHA compliance, and other regulatory or business drivers. Therefore, the most effective way to ensure compliance with the new rule will be to check the specific requirements of each of the new and revised conditions against existing facility policies and procedures so that gaps can be identified and amendments or new policies and procedures or can be crafted and implemented where necessary. Each of the three proposed revised conditions and three proposed new conditions is discussed in turn below.

Governing Body and Management:

The proposed revised condition would change the existing governing body requirements to add direct oversight and accountability for the QAPI program discussed below. One specific substantive addition to the governing body requirements is responsibility for maintaining a written disaster preparedness plan to direct the emergency care of patients in the event of fire, natural disaster, functional failure of equipment, or other similar events.

QAPI:

The proposed revised condition would change the existing “evaluation of quality” system to one that includes an ongoing program to demonstrate measurable improvement in patient health outcomes and improves patient safety by using quality indicators or performance measures associated with improved health outcomes and with the identification of medical errors. The ASC would be expected to measure, analyze, and track quality indicators, including adverse patient events, infection control, and other aspects of performance that include process of care

and services furnished. Identified deficiencies would need to be corrected, with the effectiveness of corrective action evaluated and tracked.

Laboratory and Radiologic Services:

The proposed revised condition would split apart the existing combined laboratory and radiologic services provision into two separate provisions, leaving the substantive laboratory provisions the same and expanding the radiologic services conditions to require the ASC to meet the conditions of coverage for portable x-ray suppliers if the ASC is furnishing such services directly. Radiologic services provided under contract would have to be performed by an entity certified by Medicare as a supplier of portable x-ray services by meeting the conditions of coverage for portable x-ray services.

Patient Rights:

The proposed new condition contains a host of requirements for providing information to patients. These include disclosing the physician's financial interest in the ASC, if any, prior to the patient's first visit. They also include requirements that the ASC provide the patient or patient's representative with verbal and written notice of the patient's rights prior to providing care. There are specific requirements for what must be included in the rights, such as provisions regarding the procedures for resolving patient grievances and contact information for the federal Medicare ombudsman and state agency where patients can file complaints about the ASC. There are also patient notification requirements pertaining to advanced directives.

Infection Control:

The proposed new condition would augment the existing infection control program regulations with various requirements, including a requirement to follow an organized plan of action to identify infection control problems and implement corrective measures and preventive mechanisms where necessary.

Patient Admission, Assessment and Discharge:

The proposed new condition would augment the existing regulations requiring an evaluation of the patient for anesthesia risk before surgery, and proper recovery from anesthesia before discharge, with various requirements. The condition is primarily designed to protect an aging patient demographic, as older patients generally face greater risks undergoing anesthesia than do younger patients. Specific requirements include the pre-surgery comprehensive medical history and physical assessment taking place no more than 30 days prior to surgery and detailed requirements pertaining to contents and disposition of the history and assessment. There are post-surgery assessment standards and discharge standards containing various detailed requirements as well.

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