



Medicare Conditions for Coverage: Laboratory and Radiologic Services

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 Laboratory and Radiologic Services Condition for Coverage and includes a discussion of the hospital Conditions of Participation for radiologic services, which is incorporated into this condition.

Background

The Laboratory and Radiologic Services Condition for Coverage sets forth separate standards for laboratory and radiologic services.¹ Lack of substantial compliance with either standard is a basis for citing an ASC for a condition-level deficiency. Each standard is discussed in detail below.

Laboratory Services

(a) Standard: Laboratory Services.

If the ASC performs laboratory services, it must meet the requirements of part 493 of this chapter. If the ASC does not provide its own laboratory services, it must have procedures for obtaining routine and emergency laboratory services from a certified laboratory in accordance with Part 493 of this chapter. The referral laboratory must be certified in the appropriate specialties and subspecialties of service to perform the referred tests in accordance with the requirements of Part 493 of this chapter.

An ASC performing laboratory services must meet the requirements of 42 C.F.R. § 493, the regulations implementing the Clinical Laboratory Improvement Amendments of 1988 (“CLIA”).² If the ASC does not provide its own laboratory services, it must have procedures for obtaining laboratory services from a laboratory certified in accordance with 42 C.F.R. § 493.

An ASC should adopt and maintain policies and procedures that list the kinds of laboratory services that are provided directly by the ASC as well as services that are provided through a contractual agreement with a third party. These policies and procedures should address the following: 1) laboratory services that are provided by the ASC; 2) well-defined arrangements with outside laboratory service providers; 3) routine procedures for requesting laboratory tests; and 4) language that requires the incorporation of laboratory reports into patient records.

Radiologic Services

(b) Standard: Radiologic Services.

(1) The ASC must have procedures for obtaining radiological services from a Medicare approved facility to meet the needs of patients.

¹ 42 C.F.R. § 416.49. See also Appendix L to the Medicare State Operations Manual which sets forth the “Guidance for Surveyors: Ambulatory Surgical Centers” and is available at www.cms.gov/GuidanceforLawsandRegulations/02_ASCs.asp.

² Information regarding these requirements is available at www.cms.gov/clia/.

Emily R. Studebaker

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

(2) Radiologic services must meet the hospital conditions of participation for radiologic services specified in §482.26 of this chapter.

If an ASC uses radiologic services as an integral part of the surgical procedures it performs, the radiologic services must be provided in a manner that complies with the requirements for radiologic services in the hospital Conditions of Participation.³ If the ASC does not provide these radiologic services directly, *i.e.*, utilizing its own staff, then it must obtain the services through a contractual agreement from a Medicare-participating facility.

Radiologic services considered integral to the procedure itself are those imaging services performed immediately before, during or after the procedure that are medically necessary to the completion of the procedure.⁴

Hospital Condition of Participation for Radiologic Services

The following is a discussion of the requirements for radiologic services set forth in the hospital Conditions of Participation. Radiologic services provided by or on behalf of an ASC must meet these requirements.

The hospital must maintain, or have available, diagnostic radiologic services. If therapeutic services are also provided, they, as well as the diagnostic services, must meet professionally approved standards for safety and personnel qualifications.

The hospital must maintain or have available diagnostic radiological services according to the needs of its patients.

The services must be provided in accordance with acceptable standards of practice and must meet professionally approved standards for safety and personnel qualifications.⁵ The scope and complexity

³ 42 C.F.R. § 482.26. *See also* Appendix A to the Medicare State Operations Manual which sets forth the “Survey Protocol, Regulations and Interpretive Guidelines for Hospitals.”

⁴ If an ASC does not perform any procedures where radiological services are integral to the procedure, then the ASC is not required to have arrangements for obtaining radiological services.

⁵ Acceptable standards of practice include maintaining compliance with applicable federal and state laws, regulations and guidelines governing radiological services as well as any standards and recommendations promoted by nationally recognized professional organizations.

of services offered should be specified in writing and approved by the medical staff and governing body. In addition, the hospital’s radiologic services, including any contracted services, must be integrated into its hospital-wide Quality Assurance and Performance Improvement program.

(a) Standard: Radiologic Services.

The hospital must maintain, or have available, radiologic services according to the needs of the patients.

The scope and complexity of radiologic services provided must meet the needs of the patients. Radiologic services may be provided by the hospital directly or through a contractual arrangement. The same standards apply whether the service is provided by the hospital directly or under contract. Diagnostic radiological services provided under contract may be provided either on the hospital premises or in an adjacent or other nearby, readily accessible facility.

(b) Standard: Safety for patients and personnel.

The radiologic services, particularly ionizing radiology procedures, must be free from hazards for patients and personnel.

(1) Proper safety precautions must be maintained against radiation hazards. This includes adequate shielding for patients, personnel, and facilities, as well as appropriate storage, use, and disposal of radioactive materials.

(2) Periodic inspection of equipment must be made and hazards identified must be promptly corrected.

(3) Radiation workers must be checked periodically, by the use of exposure meters or badge tests, for amount of radiation exposure.

(4) Radiologic services must be provided only on the order of practitioners with clinical privileges or, consistent with State law, of other practitioners authorized by the medical staff and the governing body to order the services.

The hospital must adopt and implement policies and procedures that provide safety for patients and personnel. The hospital policies must contain safety standards for at least: 1) adequate shielding for patients, personnel and facilities; 2) labeling of radioactive materials, waste, and hazardous areas; 3) transportation of radioactive materials between locations within the hospital; 4) security of radioactive materials, including determining who may have access to radioactive materials and controlling access to radioactive materials; 5) testing of equipment for radiation hazards; 6) maintenance of personal radiation monitoring devices; 7) proper storage of radiation monitoring badges when not in use; 8) storage of radio nuclides and radio

pharmaceuticals as well as radioactive waste; 9) disposal of radio nuclides, unused radio pharmaceuticals, and radioactive waste; and 10) methods of identifying pregnant patients. The hospital must implement and ensure compliance with its established safety standards.

In addition, the hospital must have policies and procedures in place to ensure that periodic inspections of radiology equipment are conducted and that problems identified are corrected in a timely manner. The hospital must ensure that equipment is inspected in accordance with manufacturer's instructions, federal and state laws, regulations, and guidelines, and hospital policy. The hospital must have a system in place to correct hazards.

The requirement that "radiation workers must be checked periodically, by use of exposure meters or badge tests, for amount of radiation exposure" would include radiologic services personnel as well as other hospital employees who may be regularly exposed to radiation due to working near radiation sources.

(c) Standard: Personnel.

(1) A qualified full-time, part-time, or consulting radiologist must supervise the ionizing radiology services and must interpret only those radiologic tests that are determined by the medical staff to require a radiologist's specialized knowledge. For purposes of this section, a radiologist is a doctor of medicine or osteopathy who is qualified by education and experience in radiology.

(2) Only personnel designated as qualified by the medical staff may use the radiologic equipment and administer procedures.

The medical staff must establish the qualifications necessary for radiologist appointment to the medical staff.

There must be written policies developed and approved by the medical staff to designate which radiological tests require interpretation by a radiologist. When telemedicine is used, and the radiologist who interprets radiological tests and the patient are located in different states, the radiologist interpreting the radiological test must be licensed and/or meet the other applicable standards that are required by state or local laws in both the state where the practitioner is located and the state where the patient is located.

Supervision of the radiology services may only be performed by a radiologist who is a member of the medical staff. Supervision should include at least the following: 1) ensuring that radiology reports are

signed by the practitioner who interpreted them; 2) assigning duties to radiology personnel appropriate to their level of training, experience, and licensure, if applicable; 3) enforcing infection control standards; 4) ensuring that emergency care is provided to patients who experience an adverse reaction to diagnostic agents in the radiology service; 5) ensuring that files, scans, and other image records are kept in a secure area and are readily retrievable; and 6) training radiology staff on how to operate the equipment safely, how to perform tests offered by the facility and on the management of emergency radiation hazards and accidents. There should be written policies, developed and approved by the medical staff, consistent with state law, to designate which personnel are qualified to use the radiological equipment and administer procedures.

(d) Standard: Records of radiologic services must be maintained.

(1) The radiologist or other practitioner who performs radiology services must sign reports of his or her interpretations.

(2) The hospital must maintain the following for at least 5 years:

(i) Copies of reports and printouts.

(ii) Films, scans, and other image records, as appropriate.

The hospital must maintain records for all radiology procedures performed. At a minimum, the records should include copies of reports and printouts, and any films, scans or other image records, as appropriate. The hospital should have written policies and procedures that protect the privacy of radiology records. Patient radiology records are considered patient medical records and the hospital must comply with 42 C.F.R. § 482.24. It requires that medical records for any care, procedure, treatment, or test provided or conducted within the past five years must be secure, properly stored, accessible and promptly retrievable.

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.