

§416.43

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which a non-physician administers the anesthesia, unless exempted in accordance with paragraph (d) of this section, the anesthetist must be under the supervision of the operating physician, and in the case of an anesthesiologist's assistant, under the supervision of an anesthesiologist.

(c) *Standard: Discharge.* All patients are discharged in the company of a responsible adult, except those exempted by the attending physician.

(d) *Standard: State exemption.* (1) An ASC may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (b)(2) of this section, if the State in which the ASC is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision of CRNAs. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law.

(2) The request for exemption and recognition of State laws, and the withdrawal of the request may be submitted at any time, and are effective upon submission.

[57 FR 33899, July 31, 1992, as amended at 66 FR 56768, Nov. 13, 2001.]

§416.43 Condition for coverage—Evaluation of quality.

The ASC, with the active participation of the medical staff, must conduct an ongoing, comprehensive self-assessment of the quality of care provided, including medical necessity of procedures performed and appropriateness of care, and use findings, when appropriate, in the revision of center policies and consideration of clinical privileges.

§416.44 Condition for coverage—Environment.

The ASC must have a safe and sanitary environment, properly constructed, equipped, and maintained to

protect the health and safety of patients.

(a) *Standard: Physical environment.* The ASC must provide a functional and sanitary environment for the provision of surgical services.

(1) Each operating room must be designed and equipped so that the types of surgery conducted can be performed in a manner that protects the lives and assures the physical safety of all individuals in the area.

(2) The ASC must have a separate recovery room and waiting area.

(3) The ASC must establish a program for identifying and preventing infections, maintaining a sanitary environment, and reporting the results to appropriate authorities.

(b) *Standard: Safety from fire.* (1) Except as provided in paragraphs (b) (2) and (3) of this section, the ASC must meet the provisions of the 1985 edition of the Life Safety Code of the National Fire Protection Association (which is incorporated by reference)¹ that are applicable to ambulatory surgical centers.

(2) In consideration of a recommendation by the State survey agency, CMS may waive, for periods deemed appropriate, specific provisions of the Life Safety Code which, if rigidly applied, would result in unreasonable hardship upon an ASC, but only if the waiver will not adversely affect the health and safety of the patients.

(3) Any ASC that, on May 9, 1988, complies with the requirements of the 1981 edition of the Life Safety Code, with or without waivers, will be considered to be in compliance with this standard, so long as the ASC continues to remain in compliance with that edition of the Life Safety Code.

(c) *Standard: Emergency equipment.* Emergency equipment available to the operating rooms must include at least the following:

(1) Emergency call system.

(2) Oxygen.

(3) Mechanical ventilatory assistance equipment including airways, manual breathing bag, and ventilator.

(4) Cardiac defibrillator.

(5) Cardiac monitoring equipment.

¹See footnote to §405.1134(a) of this chapter.