

§416.45

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

- (4) Cardiac defibrillator.
(5) Cardiac monitoring equipment.
(6) Tracheostomy set.
(7) Laryngoscopes and endotracheal tubes.
(8) Suction equipment.

(9) Emergency medical equipment and supplies specified by the medical staff.

(d) Standard: Emergency personnel. Personnel trained in the use of emergency equipment and in cardiopulmonary resuscitation must be available whenever there is a patient in the ASC.

[47 FR 34094, Aug. 5, 1982, amended at 53 FR 11508, Apr. 7, 1988; 54 FR 4026, Jan. 27, 1989; 68 FR 1385, Jan. 10, 2003; 69 FR 18803, Apr. 9, 2004; 70 FR 15237, Mar. 25, 2005]

EFFECTIVE DATE NOTE: At 71 FR 55339, Sept. 22, 2006, §416.44 was amended by revising paragraphs, (b)(5)(iii) and (iv)(F) and (G) and by adding paragraph (b)(5)(v), effective October 23, 2006. For the convenience of the user, the revised and added text is set forth as follows:

§416.44 Conditions for coverage-Environment.

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- (b) \* \* \*
(5) \* \* \*
(iii) The dispensers are installed in a manner that adequately protects against inappropriate access;
(iv) \* \* \*
(F) The dispensers shall not be installed over or directly adjacent to an ignition source;
(G) In locations with carpeted floor coverings, dispensers installed directly over carpeted surfaces shall be permitted only in sprinklered smoke compartments; and
(v) The dispensers are maintained in accordance with dispenser manufacturer guidelines.

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§416.45 Condition for coverage—Medical staff.

The medical staff of the ASC must be accountable to the governing body.

(a) Standard: Membership and clinical privileges. Members of the medical staff must be legally and professionally qualified for the positions to which

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they are appointed and for the performance of privileges granted. The ASC grants privileges in accordance with recommendations from qualified medical personnel.

(b) Standard: Reappraisals. Medical staff privileges must be periodically reappraised by the ASC. The scope of procedures performed in the ASC must be periodically reviewed and amended as appropriate.

(c) Standard: Other practitioners. If the ASC assigns patient care responsibilities to practitioners other than physicians, it must have established policies and procedures, approved by the governing body, for overseeing and evaluating their clinical activities.

§416.46 Condition for coverage—Nursing services.

The nursing services of the ASC must be directed and staffed to assure that the nursing needs of all patients are met.

(a) Standard: Organization and staffing. Patient care responsibilities must be delineated for all nursing service personnel. Nursing services must be provided in accordance with recognized standards of practice. There must be a registered nurse available for emergency treatment whenever there is a patient in the ASC.

(b) [Reserved]

§416.47 Condition for coverage—Medical records.

The ASC must maintain complete, comprehensive, and accurate medical records to ensure adequate patient care.

(a) Standard: Organization. The ASC must develop and maintain a system for the proper collection, storage, and use of patient records.

(b) Standard: Form and content of record. The ASC must maintain a medical record for each patient. Every record must be accurate, legible, and promptly completed. Medical records must include at least the following:

- (1) Patient identification.
(2) Significant medical history and results of physical examination.
(3) Pre-operative diagnostic studies (entered before surgery), if performed.