

# ELECTRONIC CODE OF FEDERAL REGULATIONS

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Title 42 → Chapter IV → Subchapter B → Part 416 → Subpart C → §416.44

Title 42: Public Health  
PART 416—AMBULATORY SURGICAL SERVICES  
Subpart C—Specific Conditions for Coverage

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## §416.44 Condition for coverage—Environment.

The ASC must have a safe and sanitary environment, properly constructed, equipped, and maintained to ensure the health and safety of patients.

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

(1) Each operating room must be designed and equipped so that the types of surgery conducted in the room are 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.

(b) *Standard: Safety from fire.* (1) Except as otherwise provided in this section, the ASC must be in compliance with the Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-4).

(2) In consideration of a recommendation by the State survey agency or Accrediting Organization, the Secretary, may waive, for periods deemed appropriate, specific provisions of the Life Safety Code, if the waiver does not constitute an unreasonable hardship upon an ASC, but only if the waiver will not adversely affect the health and safety of patients.

(3) The provisions of the Life Safety Code do not apply in a State if CMS finds that a fire and life safety code that is adopted by law adequately protects patients in an ASC.

(4) An ASC may place alcohol-based hand rub dispensers in its facility if the dispensers are in compliance with the Life Safety Code and adequately protect against inappropriate access.

(5) When a sprinkler system is shut down for more than 10 hours, the ASC must:

(i) Evacuate the building or portion of the building affected by the system outage until the system is back in service.

(ii) Establish a fire watch until the system is back in service.

(6) Beginning July 5, 2017, an ASC must be in compliance with Chapter 21.3.2.1, Doors to health care areas.

(c) *Standard: Building Safety.* Except as otherwise provided in this section, the ASC must meet and must proceed in accordance with the 2012 edition of the Health Care Facilities Code (NFPA 96).

Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5 and TIA 12-6).

(1) Chapters 7, 8, 12, and 13 of the adopted Health Care Facilities Code do not apply to an ASC.

(2) If application of the Health Care Facilities Code required under paragraph (c) of this section causes an unreasonable hardship for the ASC, CMS may waive specific provisions of the Health Care Facilities Code if the waiver does not adversely affect the health and safety of patients.

(d) *Standard: Emergency equipment.* The ASC medical staff and governing body of the ASC must periodically review and revise ASC policies and procedures to specify the types of emergency equipment required for use in the emergency room. The equipment must meet the following requirements:

- (1) Be immediately available for use during emergency situations.
- (2) Be appropriate for the facility's patient population.
- (3) Be maintained by appropriate personnel.

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

(f) The standards incorporated by reference in this section are approved for incorporation by reference by the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain these standards from the Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: <http://www.archives.gov/federal-register/code-of-federal-regulations/ibr-locations.html>. If any changes in this edition of the standards are published, CMS will publish a document in the FEDERAL REGISTER to announce the changes.

(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, [www.nfpa.org](http://www.nfpa.org)

(i) NFPA 99, Standards for Health Care Facilities Code of the National Fire Protection Association, August 11, 2011.

(ii) TIA 12-2 to NFPA 99, issued August 11, 2011.

(iii) TIA 12-3 to NFPA 99, issued August 9, 2012.

(iv) TIA 12-4 to NFPA 99, issued March 7, 2013.

(v) TIA 12-5 to NFPA 99, issued August 1, 2013.

(vi) TIA 12-6 to NFPA 99, issued March 3, 2014.

(vii) NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011;

(viii) TIA 12-1 to NFPA 101, issued August 11, 2011.

(ix) TIA 12-2 to NFPA 101, issued October 30, 2012.

(x) TIA 12-3 to NFPA 101, issued October 22, 2013.

(xi) TIA 12-4 to NFPA 101, issued October 22, 2013.

(2) [Reserved]

[47 FR 34094, Aug. 5, 1982, amended at 53 FR 11508, Apr. 7, 1988; 54 FR 4026, Jan. 27, 1989; 68 FR 13 18803, Apr. 9, 2004; 70 FR 15237, Mar. 25, 2005; 71 FR 55339, Sept. 22, 2006; 77 FR 29030, May 16, 20 81 FR 42548, June 30, 2016]

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