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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; 73 FR 68812, Nov. 18, 2008; 79 FR 27153, May 12, 2014; 84 FR 63202, Nov. 15, 2019]

§ 416.43 Conditions for coverage—Quality assessment and performance improvement.

The ASC must develop, implement and maintain an ongoing, data-driven quality assessment and performance improvement (QAPI) program.

(a) *Standard: Program scope.* (1) The program must include, but not be limited to, an ongoing program that demonstrates measurable improvement in patient health outcomes, and improves patient safety by using quality indicators or performance measures associated with improved health outcomes and by the identification and reduction of medical errors.

(2) The ASC must measure, analyze, and track quality indicators, adverse patient events, infection control and other aspects of performance that includes care and services furnished in the ASC.

(b) *Standard: Program data.* (1) The program must incorporate quality indicator data, including patient care and other relevant data regarding services furnished in the ASC.

(2) The ASC must use the data collected to—

(i) Monitor the effectiveness and safety of its services, and quality of its care.

(ii) Identify opportunities that could lead to improvements and changes in its patient care.

(c) *Standard: Program activities.* (1) The ASC must set priorities for its performance improvement activities that—

(i) Focus on high risk, high volume, and problem-prone areas.

(ii) Consider incidence, prevalence, and severity of problems in those areas.

(iii) Affect health outcomes, patient safety, and quality of care.

(2) Performance improvement activities must track adverse patient events, examine their causes, implement improvements, and ensure that improvements are sustained over time.

(3) The ASC must implement preventive strategies throughout the facility targeting adverse patient events and ensure that all staff are familiar with these strategies.

(d) *Standard: Performance improvement projects.* (1) The number and scope of distinct improvement projects conducted annually must reflect the scope and complexity of the ASC's services and operations.

(2) The ASC must document the projects that are being conducted. The documentation, at a minimum, must include the reason(s) for implementing the project, and a description of the project's results.

(e) *Standard: Governing body responsibilities.* The governing body must ensure that the QAPI program—

(1) Is defined, implemented, and maintained by the ASC.

(2) Addresses the ASC's priorities and that all improvements are evaluated for effectiveness.

(3) Specifies data collection methods, frequency, and details.

(4) Clearly establishes its expectations for safety.

(5) Adequately allocates sufficient staff, time, information systems and training to implement the QAPI program.

[73 FR 68812, Nov. 18, 2008]

§ 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.

(b) *Standard: Safety from fire.* (1) Except as otherwise provided in this section, the ASC must meet the provisions applicable to Ambulatory Health Care Occupancies, regardless of the number of patients served, and must proceed in accordance with the Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4).

(2) In consideration of a recommendation by the State survey agency or Accrediting Organization or at the discretion of the Secretary, may waive, for periods deemed appropriate, specific provisions of the Life Safety Code, which 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) The provisions of the Life Safety Code do not apply in a State if CMS finds that a fire and safety code imposed by State law adequately protects patients in an ASC.

(4) An ASC may place alcohol-based hand rub dispensers in its facility if the dispensers are installed in a manner that adequately protects 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, or

(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 hazardous areas.

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

Facilities Code (NFPA 99, and Tentative Interim 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 would result in unreasonable hardship for the ASC, CMS may waive specific provisions of the Health Care Facilities Code, but only 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 coordinates, develops, and revises ASC policies and procedures to specify the types of emergency equipment required for use in the ASC's operating 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 in cardiopulmonary 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 Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may inspect a copy at the CMS 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 Code are incorporated by reference, 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, 1.617.770.3000.

(i) NFPA 99, Standards for Health Care Facilities Code of the National

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Fire Protection Association 99, 2012 edition, issued 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 1385, Jan. 10, 2003; 69 FR 18803, Apr. 9, 2004; 70 FR 15237, Mar. 25, 2005; 71 FR 55339, Sept. 22, 2006; 77 FR 29030, May 16, 2012; 81 FR 26896, May 4, 2016; 81 FR 42548, June 30, 2016]

§ 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 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.

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§ 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 (as applicable).

(3) Pre-operative diagnostic studies (entered before surgery), if performed.

(4) Findings and techniques of the operation, including a pathologist's report on all tissues removed during surgery, except those exempted by the governing body.

(5) Any allergies and abnormal drug reactions.

(6) Entries related to anesthesia administration.

(7) Documentation of properly executed informed patient consent.

(8) Discharge diagnosis.

[47 FR 34094, Aug. 5, 1982, as amended at 84 FR 51814, Sept. 30, 2019]