and efficient administration of the Medicare program.

(3) Voluntary termination. If an ASC ceases to furnish services to the community, that shall be deemed to be a voluntary termination of the agreement by the ASC, effective on the last day of business with Medicare beneficiaries.

(b) Termination by CMS—(1) Cause for termination. CMS may terminate an agreement if it determines that the ASC—

(i) No longer meets the conditions for coverage as specified under §416.26; or

(ii) Is not in substantial compliance with the provisions of the agreement, the requirements of this subpart, and other applicable regulations of subchapter B of this chapter, or any applicable provisions of title XVIII of the Act.

(2) Notice of termination. CMS sends notice of termination to the ASC at least 15 days before the effective date stated in the notice.

(3) Appeal by the ASC. An ASC may appeal the termination of its agreement in accordance with the provisions set forth in part 498 of this chapter.

(c) Effect of termination. Payment is not available for ASC services furnished on or after the effective date of termination.

(d) Notice to the public. Prompt notice of the date and effect of termination is given to the public, through publication in local newspapers by—

(1) The ASC, after CMS has approved or set a termination date; or

(2) CMS, when it has terminated the agreement.

(e) Conditions for reinstatement after termination of agreement by CMS. When an agreement with an ASC is terminated by CMS, the ASC may not file another agreement to participate in the Medicare program unless CMS—

(1) Finds that the reason for the termination of the prior agreement has been removed; and

(2) Is assured that the reason for the termination will not recur.

other unexpected events or circumstances that are likely to threaten the health and safety of those in the ASC.

(2) The ASC coordinates the plan with State and local authorities, as appropriate.

(3) The ASC conducts drills, at least annually, to test the plan’s effectiveness. The ASC must complete a written evaluation of each drill and promptly implement any corrections to the plan.

[73 FR 68811, Nov. 18, 2008]

§ 416.42 Condition for coverage—Surgical services.

Surgical procedures must be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the ASC in accordance with approved policies and procedures of the ASC.

(a) Standard: Anesthetic risk and evaluation. (1) A physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed.

(2) Before discharge from the ASC, each patient must be evaluated by a physician or by an anesthetist as defined at §410.69(b) of this chapter, in accordance with applicable State health and safety laws, standards of practice, and ASC policy, for proper anesthesia recovery.

(b) Standard: Administration of anesthesia. Anesthetics must be administered by only—

(1) A qualified anesthesiologist; or

(2) A physician qualified to administer anesthesia, a certified registered nurse anesthetist (CRNA) or an anesthesiologist’s assistant as defined in §410.69(b) of this chapter, or a supervised trainee in an approved educational program. In those cases in 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: 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.


§ 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.