

January 1, 2008, that meet the criteria specified in § 416.166.

*Facility services* means for the period before January 1, 2008, services that are furnished in connection with covered surgical procedures performed in an ASC, and beginning January 1, 2008, means services that are furnished in connection with covered surgical procedures performed in an ASC as provided in § 416.164(a) for which payment is included in the ASC payment established under § 416.171 for the covered surgical procedure.

[56 FR 8843, Mar. 1, 1991; 56 FR 23022, May 20, 1991, as amended at 71 FR 68226, Nov. 24, 2006; 72 FR 42544, Aug. 2, 2007; 73 FR 68811, Nov. 18, 2008]

### Subpart B—General Conditions and Requirements

#### § 416.25 Basic requirements.

Participation as an ASC is limited to facilities that—

- (a) Meet the definition in § 416.2; and
- (b) Have in effect an agreement obtained in accordance with this subpart.

[56 FR 8843, Mar. 1, 1991]

#### § 416.26 Qualifying for an agreement.

(a) *Deemed compliance.* CMS may deem an ASC to be in compliance with any or all of the conditions set forth in subpart C of this part if—

- (1) The ASC is accredited by a national accrediting body, or licensed by a State agency, that CMS determines provides reasonable assurance that the conditions are met;
- (2) In the case of deemed status through accreditation by a national accrediting body, where State law requires licensure, the ASC complies with State licensure requirements; and
- (3) The ASC authorizes the release to CMS, of the findings of the accreditation survey.

(b) *Survey of ASCs.* (1) Unless CMS deems the ASC to be in compliance with the conditions set forth in subpart C of this part, the State survey agency must survey the facility to ascertain compliance with those conditions, and report its findings to CMS.

(2) CMS surveys deemed ASCs on a sample basis as part of CMS's validation process.

(c) *Acceptance of the ASC as qualified to furnish ambulatory surgical services.* If CMS determines, after reviewing the survey agency recommendation and other evidence relating to the qualification of the ASC, that the facility meets the requirements of this part, it sends to the ASC—

(1) Written notice of the determination; and

(2) Two copies of the ASC agreement.

(d) *Filing of agreement by the ASC.* If the ASC wishes to participate in the program, it must—

(1) Have both copies of the ASC agreement signed by its authorized representative; and

(2) File them with CMS.

(e) *Acceptance by CMS.* If CMS accepts the agreement filed by the ASC, returns to the ASC one copy of the agreement, with a notice of acceptance specifying the effective date.

(f) *Appeal rights.* If CMS refuses to enter into an agreement or if CMS terminates an agreement, the ASC is entitled to a hearing in accordance with part 498 of this chapter.

[56 FR 8843, Mar. 1, 1991]

#### § 416.30 Terms of agreement with CMS.

As part of the agreement under § 416.26 the ASC must agree to the following:

(a) *Compliance with coverage conditions.* The ASC agrees to meet the conditions for coverage specified in subpart C of this part and to report promptly to CMS any failure to do so.

(b) *Limitation on charges to beneficiaries.*<sup>1</sup> The ASC agrees to charge the beneficiary or any other person only the applicable deductible and coinsurance amounts for facility services for which the beneficiary—

(1) Is entitled to have payment made on his or her behalf under this part; or

(2) Would have been so entitled if the ASC had filed a request for payment in accordance with § 410.165 of this chapter.

<sup>1</sup> For facility services furnished before July 1987, the ASC had to agree to make no charge to the beneficiary, since those services were not subject to the part B deductible and coinsurance provisions.

(c) *Refunds to beneficiaries.* (1) The ASC agrees to refund as promptly as possible any money incorrectly collected from beneficiaries or from someone on their behalf.

(2) As used in this section, *money incorrectly collected* means sums collected in excess of those specified in paragraph (b) of this section. It includes amounts collected for a period of time when the beneficiary was believed not to be entitled to Medicare benefits if—

(i) The beneficiary is later determined to have been entitled to Medicare benefits; and

(ii) The beneficiary's entitlement period falls within the time the ASC's agreement with CMS is in effect.

(d) *Furnishing information.* The ASC agrees to furnish to CMS, if requested, information necessary to establish payment rates specified in §§ 416.120–416.130 in the form and manner that CMS requires.

(e) *Acceptance of assignment.* The ASC agrees to accept assignment for all facility services furnished in connection with covered surgical procedures. For purposes of this section, assignment means an assignment under § 424.55 of this chapter of the right to receive payment under Medicare Part B and payment under § 424.64 of this chapter (when an individual dies before assigning the claim).

(f) *ASCs operated by a hospital.* In an ASC operated by a hospital—

(1) The agreement is made effective on the first day of the next Medicare cost reporting period of the hospital that operates the ASC; and

(2) The ASC participates and is paid only as an ASC.

(3) Costs for the ASC are treated as a non-reimbursable cost center on the hospital's cost report.

(g) *Additional provisions.* The agreement may contain any additional provisions that CMS finds necessary or desirable for the efficient and effective administration of the Medicare program.

[47 FR 34094, Aug. 5, 1982, as amended at 51 FR 41351, Nov. 14, 1986; 56 FR 8844, Mar. 1, 1991; 74 FR 60680, Nov. 20, 2009]

**§ 416.35 Termination of agreement.**

(a) *Termination by the ASC—(1) Notice to CMS.* An ASC that wishes to termi-

nate its agreement must send CMS written notice of its intent.

(2) *Date of termination.* The notice may state the intended date of termination which must be the first day of a calendar month.

(i) If the notice does not specify a date, or the date is not acceptable to CMS, CMS may set a date that will not be more than 6 months from the date on the ASC's notice of intent.

(ii) CMS may accept a termination date that is less than 6 months after the date on the ASC's notice if it determines that to do so would not unduly disrupt services to the community or otherwise interfere with the effective 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 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.

[47 FR 34094, Aug. 5, 1982, as amended at 52 FR 22454, June 12, 1987; 56 FR 8844, Mar. 1, 1991; 61 FR 40347, Aug. 2, 1996; 82 FR 38515, Aug. 14, 2017]

### Subpart C—Specific Conditions for Coverage

#### § 416.40 Condition for coverage—Compliance with State licensure law.

The ASC must comply with State licensure requirements.

#### § 416.41 Condition for coverage—Governing body and management.

The ASC must have a governing body that assumes full legal responsibility for determining, implementing, and monitoring policies governing the ASC's total operation. The governing body has oversight and accountability for the quality assessment and performance improvement program, ensures that facility policies and programs are administered so as to provide quality health care in a safe environment, and develops and maintains a disaster preparedness plan.

(a) *Standard: Contract services.* When services are provided through a contract with an outside resource, the ASC must assure that these services are provided in a safe and effective manner.

(b) *Standard: Hospitalization.* (1) The ASC must have an effective procedure for the immediate transfer, to a hospital, of patients requiring emergency medical care beyond the capabilities of the ASC.

(2) This hospital must be a local, Medicare-participating hospital or a local, nonparticipating hospital that meets the requirements for payment for emergency services under § 482.2 of this chapter.

(3) The ASC must periodically provide the local hospital with written no-

tice of its operations and patient population served.

[73 FR 68811, Nov. 18, 2008, as amended at 81 FR 64022, Sept. 16, 2016; 84 FR 51814, Sep. 30, 2019]

#### § 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) Immediately before surgery—

(i) A physician must examine the patient to evaluate the risk of the procedure to be performed; and

(ii) A physician or anesthetist as defined at § 410.69(b) of this chapter must examine the patient to evaluate the risk of anesthesia.

(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 (c) 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