

§ 416.25

Covered surgical procedures means those surgical procedures furnished before January 1, 2008, that meet the criteria specified in § 416.65 and those surgical procedures furnished on or after 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

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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.*¹ 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

¹For 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.