

- (i) Generally result in extensive blood loss;
- (ii) Require major or prolonged invasion of body cavities;
- (iii) Directly involve major blood vessels; or
- (iv) Are generally emergency or life-threatening in nature.

(c) *Publication of covered procedures.* CMS will publish in the FEDERAL REGISTER a list of covered surgical procedures and revisions as appropriate.

**§ 416.75 Performance of listed surgical procedures on an inpatient hospital basis.**

The inclusion of any procedure as a covered surgical procedure under § 416.65 does not preclude its coverage in an inpatient hospital setting under Medicare.

**Subpart E—Payment for Facility Services**

**§ 416.120 Basis for payment.**

The basis for payment depends on where the services are furnished.

(a) *Hospital outpatient department.* Payment is in accordance with part 413 of this chapter.

(b) [Reserved]

(c) *ASC—(1) General rule.* Payment is based on a prospectively determined rate. This rate covers the cost of services such as supplies, nursing services, equipment, etc., as specified in § 416.61. The rate does not cover physician services or other medical services covered under part 410 of this chapter (for example, X-ray services or laboratory services) which are not directly related to the performance of the surgical procedures. Those services may be billed separately and paid on a reasonable charge basis.

(2) *Single and multiple surgical procedures.* (i) If one covered surgical procedure is furnished to a beneficiary in an operative session, payment is based on the prospectively determined rate for that procedure.

(ii) If more than one surgical procedure is furnished in a single operative session, payment is based on—

(A) The full rate for the procedure with the highest prospectively determined rate; and

(B) One half of the prospectively determined rate for each of the other procedures.

(3) *Deductibles and coinsurance.* Part B deductible and coinsurance amounts apply as specified in § 410.152 (a) and (i) of this chapter.

[56 FR 8844, Mar. 1, 1991; 56 FR 23022, May 20, 1991]

**§ 416.125 ASC facility services payment rate.**

(a) The payment rate is based on a prospectively determined standard overhead amount per procedure derived from an estimate of the costs incurred by ambulatory surgical centers generally in providing services furnished in connection with the performance of that procedure.

(b) The payment must be substantially less than would have been paid under the program if the procedure had been performed on an inpatient basis in a hospital.

[56 FR 8844, Mar. 1, 1991]

**§ 416.130 Publication of revised payment methodologies.**

Whenever CMS proposes to revise the payment rate for ASCs, CMS publishes a notice in the FEDERAL REGISTER describing the revision. The notice also explains the basis on which the rates were established. After reviewing public comments, CMS publishes a notice establishing the rates authorized by this section. In setting these rates, CMS may adopt reasonable classifications of facilities and may establish different rates for different types of surgical procedures.

[47 FR 34094, Aug. 5, 1982, as amended at 56 FR 8844, Mar. 1, 1991]

**§ 416.140 Surveys.**

(a) *Timing, purpose, and procedures.* (1) No more often than once a year, CMS conducts a survey of a randomly selected sample of participating ASCs to collect data for analysis or reevaluation of payment rates.

(2) CMS notifies the selected ASCs by mail of their selection and of the form and content of the report the ASCs are required to submit within 60 days of the notice.

(3) If the facility does not submit an adequate report in response to CMS's survey request, CMS may terminate the agreement to participate in the Medicare program as an ASC.

(4) CMS may grant a 30-day postponement of the due date for the survey report if it determines that the facility has demonstrated good cause for the delay.

(b) *Requirements for ASCs.* ASCs must—

(1) Maintain adequate financial records, in the form and containing the data required by CMS, to allow determination of the payment rates for covered surgical procedures furnished to Medicare beneficiaries under this subpart.

(2) Within 60 days of a request from CMS submit, in the form and detail as may be required by CMS, a report of—

(i) Their operations, including the allowable costs actually incurred for the period and the actual number and kinds of surgical procedures furnished during the period; and

(ii) Their customary charges for each surgical procedure furnished for the period.

[47 FR 34094, Aug. 5, 1982, as amended at 56 FR 8845, Mar. 1, 1991]

**§ 416.150 Beneficiary appeals.**

A beneficiary (or ASC as his or her assignee) may request a hearing by a carrier (subject to the limitations and conditions set forth in part 405, subpart H of this chapter) if the beneficiary or the ASC—

(a) Is dissatisfied with a carrier's denial of a request for payment made on his or her behalf by an ASC;

(b) Is dissatisfied with the amount of payment; or

(c) Believes the request for payment is not being acted upon with reasonable promptness.

**Subpart F—Adjustment in Payment Amounts for New Technology Intraocular Lenses Furnished by Ambulatory Surgical Centers**

SOURCE: 64 FR 32205, June 16, 1999, unless otherwise noted.

**§ 416.180 Definitions.**

As used in this subpart, the following definitions apply:

*Class of new technology intraocular lenses (IOLs)* means all of the IOLs, collectively, that CMS determines meet the definition of "new technology IOL" under the provisions of this subpart.

*Interested party* means any individual, partnership, corporation, association, society, scientific or academic establishment, professional or trade organization, or any other legal entity.

*New technology IOL* means an IOL that CMS determines has been approved by the FDA for use in labeling and advertising the IOL's claims of specific clinical advantages and superiority over existing IOLs with regard to reduced risk of intraoperative or postoperative complication or trauma, accelerated postoperative recovery, reduced induced astigmatism, improved postoperative visual acuity, more stable postoperative vision, or other comparable clinical advantages.

*New technology subset* means a group of IOLs that CMS determines meet the criterion for being treated as new technology IOLs and that share a common feature or features that distinguish them from other IOLs. For example, all new technology IOLs that are made of a particular bioengineered material could comprise one subset, while all that rely on a particular optical innovation could comprise another.

**§ 416.185 Payment review process.**

(a) CMS publishes a FEDERAL REGISTER notice announcing the deadline and requirements for submitting a request for CMS to review payment for an IOL.

(b) CMS receives a request to review the appropriateness of the payment amount for an IOL.

(c) CMS compiles a list of the requests it receives and identifies the IOL manufacturer's name, the model number of the IOL to be reviewed, the interested party or parties that submit requests, and a summary of the interested party's grounds for requesting review of the appropriateness of the IOL payment amount.

(d) CMS publishes the list of requests in a FEDERAL REGISTER notice with comment period, giving the public 30