

(4) No payment is made for services of a “teaching physician” associated with moonlighting services, and the time spent furnishing these services is not included in the teaching hospital’s full-time equivalency count for the indirect GME payment (§412.105 of this chapter) and for the direct GME payment (§413.86 of this chapter).

(c) *Other settings.* Moonlighting services of a licensed resident in an approved GME program furnished outside the scope of that program in a hospital or other setting that does not participate in the approved GME program are payable under the physician fee schedule as set forth in §415.206(b)(1).

PART 416—AMBULATORY SURGICAL SERVICES

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 47 FR 34094, Aug. 5, 1982, unless otherwise noted.

Subpart A—General Provisions and Definitions

§416.1 Basis and scope.

(a) *Statutory basis.* (1) Section 1832(a)(2)(F)(i) of the Act provides for Medicare Part B coverage of facility services furnished in connection with surgical procedures specified by the Secretary under section 1833(i)(1) of the Act.

(2) Section 1833(i)(1)(A) of the Act requires the Secretary to specify the surgical procedures that can be performed safely on an ambulatory basis in an ambulatory surgical center, or a hospital outpatient department.

(3) Section 1833(i)(2)(A) and (3) specify the amounts to be paid for facility services furnished in connection with the specified surgical procedures when they are performed, respectively, in an ASC, or in a hospital outpatient department.

(b) *Scope.* This part sets forth—

(1) The conditions that an ASC must meet in order to participate in the Medicare program;

(2) The scope of covered services; and

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(3) The conditions for Medicare payment for facility services.

[56 FR 8843, Mar. 1, 1991; 56 FR 23022, May 20, 1991]

§ 416.2 Definitions.

As used in this part:

Ambulatory surgical center or *ASC* means any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization, has an agreement with HCFA to participate in Medicare as an ASC, and meets the conditions set forth in subparts B and C of this part.

ASC services means facility services that are furnished in an ASC.

Covered surgical procedures means those surgical and other medical procedures that meet the criteria specified in § 416.65 and are published by HCFA in the FEDERAL REGISTER.

Facility services means services that are furnished in connection with covered surgical procedures performed in an ASC, or in a hospital on an out-patient basis.

[56 FR 8843, Mar. 1, 1991; 56 FR 23022, May 20, 1991]

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.* HCFA 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 HCFA 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

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(3) The ASC authorizes the release to HCFA, of the findings of the accreditation survey.

(b) *Survey of ASCs.* (1) Unless HCFA 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 HCFA.

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

(c) *Acceptance of the ASC as qualified to furnish ambulatory surgical services.* If HCFA 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 HCFA.

(e) *Acceptance by HCFA.* If HCFA 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 HCFA refuses to enter into an agreement or if HCFA 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 HCFA.

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 HCFA any failure to do so.

(b) *Limitation on charges to beneficiaries.*¹ The ASC agrees to charge the

¹For facility services furnished before July 1987, the ASC had to agree to make no charge to the beneficiary, since those services were

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.

(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 HCFA is in effect.

(d) *Furnishing information.* The ASC agrees to furnish to HCFA, if requested, information necessary to establish payment rates specified in §§ 416.120–416.130 in the form and manner that HCFA 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, without the option of converting to or being paid as a hospital outpatient department, unless

not subject to the part B deductible and coinsurance provisions.

HCFA determines there is good cause to do otherwise.

(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 HCFA 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]

§ 416.35 Termination of agreement.

(a) *Termination by the ASC—(1) Notice to HCFA.* An ASC that wishes to terminate its agreement must send HCFA 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 HCFA, HCFA may set a date that will not be more than 6 months from the date on the ASC's notice of intent.

(ii) HCFA 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 HCFA—(1) Cause for termination.* HCFA 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.* HCFA sends notice of termination to the ASC at

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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 HCFA has approved or set a termination date; or

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

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

(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]

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 and for ensuring that these policies are administered so as to provide quality health care in a safe environment. 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. *Standard: Hospitalization.* The ASC must have an effective procedure for the immediate transfer to a hospital, of patients requiring emergency medical care be-

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yond the capabilities of the ASC. This hospital must be a local, Medicare participating hospital or a local, non-participating hospital that meets the requirements for payment for emergency services under §482.2 of this chapter. The ASC must have a written transfer agreement with such a hospital, or all physicians performing surgery in the ASC must have admitting privileges at such a hospital.

[47 FR 34094, Aug. 5, 1982, as amended at 51 FR 22041, June 17, 1986]

§ 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.* A physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed. Before discharge from the ASC, each patient must be evaluated by a physician 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 or an anesthesiologist's assistant as defined in §410.68(b) of this chapter, or a supervised trainee in an approved educational program. In those cases in which a non-physician administers the anesthesia, 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: Discharge.* All patients are discharged in the company of a responsible adult, except those exempted by the attending physician.

[57 FR 33899, July 31, 1992]

§ 416.43 Condition for coverage—Evaluation of quality.

The ASC, with the active participation of the medical staff, must conduct

an ongoing, comprehensive self-assessment of the quality of care provided, including medical necessity of procedures performed and appropriateness of care, and use findings, when appropriate, in the revision of center policies and consideration of clinical privileges.

§ 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.

(3) The ASC must establish a program for identifying and preventing infections, maintaining a sanitary environment, and reporting the results to appropriate authorities.

(b) *Standard: Safety from fire.* (1) Except as provided in paragraphs (b) (2) and (3) of this section, the ASC must meet the provisions of the 1985 edition of the Life Safety Code of the National Fire Protection Association (which is incorporated by reference)¹ that are applicable to ambulatory surgical centers.

(2) In consideration of a recommendation by the State survey agency, HCFA may waive, for periods deemed appropriate, specific provisions of the Life Safety Code which, if rigidly applied, 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) Any ASC that, on May 9, 1988, complies with the requirements of the 1981 edition of the Life Safety Code, with or without waivers, will be considered to be in compliance with this standard, so long as the ASC continues

to remain in compliance with that edition of the Life Safety Code.

(c) *Standard: Emergency equipment.* Emergency equipment available to the operating rooms must include at least the following:

(1) Emergency call system.

(2) Oxygen.

(3) Mechanical ventilatory assistance equipment including airways, manual breathing bag, and ventilator.

(4) Cardiac defibrillator.

(5) Cardiac monitoring equipment.

(6) Tracheostomy set.

(7) Laryngoscopes and endotracheal tubes.

(8) Suction equipment.

(9) Emergency medical equipment and supplies specified by the medical staff.

(d) *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.

[47 FR 34094, Aug. 5, 1982, amended at 53 FR 11508, Apr. 7, 1988; 54 FR 4026, Jan. 27, 1989]

§ 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.

¹See footnote to § 405.1134(a) of this chapter.

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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.

(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.

§ 416.48 Condition for coverage—Pharmaceutical services.

The ASC must provide drugs and biologicals in a safe and effective manner, in accordance with accepted professional practice, and under the direction of an individual designated responsible for pharmaceutical services.

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(a) *Standard: Administration of drugs.* Drugs must be prepared and administered according to established policies and acceptable standards of practice.

(1) Adverse reactions must be reported to the physician responsible for the patient and must be documented in the record.

(2) Blood and blood products must be administered by only physicians or registered nurses.

(3) Orders given orally for drugs and biologicals must be followed by a written order, signed by the prescribing physician.

(b) [Reserved]

§ 416.49 Condition for coverage—Laboratory and radiologic services.

If the ASC performs laboratory services, it must meet the requirements of part 493 of this chapter. If the ASC does not provide its own laboratory services, it must have procedures for obtaining routine and emergency laboratory services from a certified laboratory in accordance with part 493 of this chapter. The referral laboratory must be certified in the appropriate specialties and subspecialties of service to perform the referred tests in accordance with the requirements of part 493 of this chapter. The ASC must have procedures for obtaining radiologic services from a Medicare approved facility to meet the needs of patients.

[57 FR 7135, Feb. 28, 1992]

Subpart D—Scope of Benefits

§ 416.60 General rules.

(a) The services payable under this part are facility services furnished to Medicare beneficiaries, by a participating facility, in connection with covered surgical procedures specified in § 416.65.

(b) The surgical procedures, including all preoperative and post-operative services that are performed by a physician, are covered as physician services under part 410 of this chapter.

[56 FR 8844, Mar. 1, 1991]

§ 416.61 Scope of facility services.

(a) *Included services.* Facility services include, but are not limited to—

(1) Nursing, technician, and related services;

(2) Use of the facilities where the surgical procedures are performed;

(3) Drugs, biologicals, surgical dressings, supplies, splints, casts, and appliances and equipment directly related to the provision of surgical procedures;

(4) Diagnostic or therapeutic services or items directly related to the provision of a surgical procedure;

(5) Administrative, recordkeeping and housekeeping items and services; and

(6) Materials for anesthesia.

(7) Intra-ocular lenses (IOLs).

(8) Supervision of the services of an anesthetist by the operating surgeon.

(b) *Excluded services.* Facility services do not include items and services for which payment may be made under other provisions of part 405 of this chapter, such as physicians' services, laboratory, X-ray or diagnostic procedures (other than those directly related to performance of the surgical procedure), prosthetic devices (except IOLs), ambulance services, leg, arm, back and neck braces, artificial limbs, and durable medical equipment for use in the patient's home. In addition, they do not include anesthetist services furnished on or after January 1, 1989.

[56 FR 8844, Mar. 1, 1991, as amended at 57 FR 33899, July 31, 1992]

§ 416.65 Covered surgical procedures.

Covered surgical procedures are those procedures that meet the standards described in paragraphs (a) and (b) of this section and are included in the list published in accordance with paragraph (c) of this section.

(a) *General standards.* Covered surgical procedures are those surgical and other medical procedures that—

(1) Are commonly performed on an inpatient basis in hospitals, but may be safely performed in an ASC;

(2) Are not of a type that are commonly performed, or that may be safely performed, in physicians' offices;

(3) Are limited to those requiring a dedicated operating room (or suite), and generally requiring a post-operative recovery room or short-term (not overnight) convalescent room; and

(4) Are not otherwise excluded under § 405.310 of this chapter.

(b) *Specific standards.* (1) Covered surgical procedures are limited to those that do not generally exceed—

(i) A total of 90 minutes operating time; and

(ii) A total of 4 hours recovery or convalescent time.

(2) If the covered surgical procedures require anesthesia, the anesthesia must be—

(i) Local or regional anesthesia; or

(ii) General anesthesia of 90 minutes or less duration.

(3) Covered surgical procedures may not be of a type that—

(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.* HCFA 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

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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 HCFA proposes to revise the payment rate for ASCs, HCFA 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, HCFA publishes a notice establishing the rates authorized by this section. In setting these rates, HCFA may adopt reasonable classifications of facilities and

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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, HCFA conducts a survey of a randomly selected sample of participating ASCs to collect data for analysis or reevaluation of payment rates.

(2) HCFA 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 HCFA's survey request, HCFA may terminate the agreement to participate in the Medicare program as an ASC.

(4) HCFA 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 HCFA, 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 HCFA submit, in the form and detail as may be required by HCFA, 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 HCFA 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 HCFA 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 HCFA 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) HCFA publishes a FEDERAL REGISTER notice announcing the deadline and requirements for submitting a request for HCFA to review payment for an IOL.

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

(c) HCFA 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) HCFA publishes the list of requests in a FEDERAL REGISTER notice with comment period, giving the public 30 days to comment on the IOLs for which review was requested.

(e) HCFA reviews the information submitted with the request to review, any timely public comments that are submitted regarding the list of IOLs published in the FEDERAL REGISTER, and any other timely information that HCFA deems relevant to decide whether to provide a payment adjustment as specified in § 416.200. HCFA makes a determination of whether the IOL meets the definition of a new technology IOL in § 416.180.

(f) If HCFA determines that a lens is a new technology IOL, HCFA establishes a payment adjustment as follows:

(1) Before July 16, 2002—\$50.

(2) After July 16, 2002—\$50 or the amount announced through proposed and final rulemaking in connection with ambulatory surgical center services.

(g) HCFA designates a predominant characteristic of a new technology IOL that both sets it apart from other IOLs and links it with other similar IOLs with the same characteristic to establish a specific subset of new technology within the "class of new technology IOLs."

(h) Within 90 days of the end of the comment period following the FEDERAL REGISTER notice identified in paragraph (d) of this section, HCFA publishes in the FEDERAL REGISTER its determinations with regard to IOLs that

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it has determined are “new technology” lenses that qualify for a payment adjustment.

(i) Payment adjustments are effective beginning 30 days after the publication of HCFA’s determinations in the FEDERAL REGISTER.

§416.190 Who may request a review.

Any party who is able to furnish the information required in §416.195 may request that HCFA review the appropriateness of the payment amount provided under section 1833(i)(2)(A)(iii) of the Act with respect to an IOL that meets the definition of a new technology IOL in §416.180.

§416.195 A request to review.

(a) *Content of a request.* The request must include all of the following information:

(1) The name of the manufacturer, the model number, and the trade name of the IOL.

(2) A copy of the FDA’s summary of the IOL’s safety and effectiveness.

(3) A copy of the labeling claims of specific clinical advantages approved by the FDA for the IOL.

(4) A copy of the IOL’s original FDA approval notification.

(5) Reports of modifications made after the original FDA approval.

(6) Other information that HCFA finds necessary for identification of the IOL.

(b) *Confidential information.* To the extent that information received from an IOL manufacturer can reasonably be characterized as a trade secret or as privileged or confidential commercial or financial information, HCFA maintains the confidentiality of the information and protects it from disclosure not otherwise authorized or required by Federal law as allowed under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552(b)(4)) and, with respect to trade secrets, the Trade Secrets Act (18 U.S.C. 1905).

§416.200 Application of the payment adjustment.

(a) HCFA recognizes the IOL(s) that define a new technology subset for purposes of this subpart as belonging to the class of new technology IOLs for a period of 5 years effective from the

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date that HCFA recognizes the first new technology IOL for a payment adjustment.

(b) Any IOL that HCFA subsequently recognizes as belonging to a new technology subset receives the new technology payment adjustment for the remainder of the 5-year period established with HCFA’s recognition of the first IOL in the subset.

(c) Beginning 5 years after the effective date of HCFA’s initial recognition of a new technology subset, payment adjustments cease for all IOLs that HCFA designates as belonging to that subset and payment reverts to the standard payment rate set under section 1833(i)(2)(A)(iii) of the Act for IOL insertion procedures performed in ASCs.

(d) ASCs that furnish an IOL designated by HCFA as belonging to the class of new technology IOLs must submit claims using specific billing codes to receive the new technology IOL payment adjustment.

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

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