

## §416.190

days to comment on the IOLs for which review was requested.

(e) CMS 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 CMS deems relevant to decide whether to provide a payment adjustment as specified in §416.200. CMS makes a determination of whether the IOL meets the definition of a new technology IOL in §416.180.

(f) If CMS determines that a lens is a new technology IOL, CMS 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) CMS 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, CMS publishes in the FEDERAL REGISTER its determinations with regard to IOLs that 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 CMS’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 CMS 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:

## 42 CFR Ch. IV (10–1–03 Edition)

(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 CMS 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, CMS 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) CMS 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 date that CMS recognizes the first new technology IOL for a payment adjustment.

(b) Any IOL that CMS 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 CMS’s recognition of the first IOL in the subset.

(c) Beginning 5 years after the effective date of CMS’s initial recognition of a new technology subset, payment adjustments cease for all IOLs that CMS 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 CMS 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**

### **Subpart A—General Provisions**

Sec.

- 417.1 Definitions.
- 417.2 Basis and scope.

### **Subpart B—Qualified Health Maintenance Organizations: Services**

- 417.101 Health benefits plan: Basic health services.
- 417.102 Health benefits plan: Supplemental health services.
- 417.103 Providers of basic and supplemental health services.
- 417.104 Payment for basic health services.
- 417.105 Payment for supplemental health services.
- 417.106 Quality assurance program; Availability, accessibility, and continuity of basic and supplemental health services.

### **Subpart C—Qualified Health Maintenance Organizations: Organization and Operation**

- 417.120 Fiscally sound operation and assumption of financial risk.
- 417.122 Protection of enrollees.
- 417.124 Administration and management.
- 417.126 Recordkeeping and reporting requirements.

### **Subpart D—Application for Federal Qualification**

- 417.140 Scope.
- 417.142 Requirements for qualification.
- 417.143 Application requirements.
- 417.144 Evaluation and determination procedures.

### **Subpart E—Inclusion of Qualified Health Maintenance Organizations in Employee Health Benefits Plans**

- 417.150 Definitions.
- 417.151 Applicability.
- 417.153 Offer of HMO alternative.
- 417.155 How the HMO option must be included in the health benefits plan.
- 417.156 When the HMO must be offered to employees.
- 417.157 Contributions for the HMO alternative.
- 417.158 Payroll deductions.

- 417.159 Relationship of section 1310 of the Public Health Service Act to the National Labor Relations Act and the Railway Labor Act.

### **Subpart F—Continued Regulation of Federally Qualified Health Maintenance Organizations**

- 417.160 Applicability.
- 417.161 Compliance with assurances.
- 417.162 Reporting requirements.
- 417.163 Enforcement procedures.
- 417.164 Effect of revocation of qualification on inclusion in employee's health benefit plans.
- 417.165 Reapplication for qualification.
- 417.166 Waiver of assurances.

### **Subparts G–I [Reserved]**

### **Subpart J—Qualifying Conditions for Medicare Contracts**

- 417.400 Basis and scope.
- 417.401 Definitions.
- 417.402 Effective date of initial regulations.
- 417.404 General requirements.
- 417.406 Application and determination.
- 417.407 Requirements for a Competitive Medical Plan (CMP).
- 417.408 Contract application process.
- 417.410 Qualifying conditions: General rules.
- 417.412 Qualifying condition: Administration and management.
- 417.413 Qualifying condition: Operating experience and enrollment.
- 417.414 Qualifying condition: Range of services.
- 417.416 Qualifying condition: Furnishing of services.
- 417.418 Qualifying condition: Quality assurance program.

### **Subpart K—Enrollment, Entitlement, and Disenrollment Under Medicare Contract**

- 417.420 Basic rules on enrollment and entitlement.
- 417.422 Eligibility to enroll in an HMO or CMP.
- 417.423 Special rules: ESRD and hospice patients.
- 417.424 Denial of enrollment.
- 417.426 Open enrollment requirements.
- 417.428 Marketing activities.
- 417.430 Application procedures.
- 417.432 Conversion of enrollment.
- 417.434 Reenrollment.
- 417.436 Rules for enrollees.
- 417.440 Entitlement to health care services from an HMO or CMP.
- 417.442 Risk HMO's and CMP's: Conditions for provision of additional benefits.
- 417.444 Special rules for certain enrollees of risk HMOs and CMPs.
- 417.446 [Reserved]