

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 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:

(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).