

(b) *Who may submit a request.* Any individual, partnership, corporation, association, society, scientific or academic establishment, or professional or trade organization able to furnish the information required in paragraph (c) of this section 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 criteria of a new technology IOL under § 416.195.

(c) *Content of a request.* In order to be accepted by CMS for review, a request for review of the ASC payment amount for insertion of an IOL must include all the information as specified by CMS.

(d) *Confidential information.* In order for CMS to invoke the protection 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), the requestor must clearly identify all information that is to be characterized as confidential.

§ 416.195 Determination of membership in new classes of new technology IOLs.

(a) *Factors to be considered.* CMS uses the following criteria to determine whether an IOL qualifies for a payment adjustment as a member of a new class of new technology IOLs when inserted at an ASC:

(1) The IOL is considered new. CMS will evaluate an application for a new technology IOL only if the IOL type has received initial FDA premarket approval within the 3 years prior to the new technology IOL application submission date.

(2) The IOL shall have a new lens characteristic in comparison to currently available IOLs. The labeling, which must be approved by FDA, shall contain a claim of a specific clinical benefit imparted by the new lens characteristic.

(3) The IOL is not described by an active or expired class of new technology IOLs; that is, it does not share a predominant, class-defining characteristic associated with improved clinical outcomes with members of an active or expired class.

(4) Any specific clinical benefit referred to in paragraph (a)(2) of this sec-

tion must be supported by evidence that demonstrates that the IOL results in a measurable, clinically meaningful, improved outcome. Improved outcomes include:

- (i) Reduced risk of intraoperative or postoperative complication or trauma;
- (ii) Accelerated postoperative recovery;
- (iii) Reduced induced astigmatism;
- (iv) Improved postoperative visual acuity;
- (v) More stable postoperative vision;
- (vi) Other comparable clinical advantages.

(b) *CMS determination of eligibility for payment adjustment.* CMS reviews the information submitted with a completed request for review, public comments submitted timely, and other pertinent information and makes a determination as follows:

(1) The IOL is eligible for a payment adjustment as a member of a new class of new technology IOLs.

(2) The IOL is a member of an active class of new technology IOLs and is eligible for a payment adjustment for the remainder of the period established for that class.

(3) The IOL does not meet the criteria for designation as a new technology IOL and a payment adjustment is not appropriate.

[71 FR 68226, Nov. 24, 2006, as amended at 77 FR 68558, Nov. 15, 2012; 80 FR 70604, Nov. 13, 2015]

§ 416.200 Payment adjustment.

(a) CMS establishes the amount of the payment adjustment for classes of new technology IOLs through proposed and final rulemaking in connection with ASC facility services.

(b) CMS adjusts the payment for insertion of an IOL approved as belonging to a class of new technology IOLs for the 5-year period of time established for that class.

(c) Upon expiration of the 5-year period of the payment adjustment, payment reverts to the standard rate for IOL insertion procedures performed in ASCs.

(d) ASCs that furnish an IOL designated by CMS as belonging to a class of new technology IOLs must submit claims using billing codes specified by