

minimize the information collection burden. However, the collection requirements associated with this notice have been approved by OMB, under control number 0938-0880, with a current expiration date of 3/31/2003.

Authority: Section 402 of the Social Security Act Amendments of 1967 (42 U.S.C. 1395b-1)

(Catalog of Federal Domestic Assistance Program No. 93.779, Health Care Financing Research, Demonstrations and Evaluations)

Dated: September 9, 2002.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3099-N]

Medicaid Program; Annual Review of the Appropriateness of Payment Amounts for New Technology Intraocular Lenses (NTIOLs) Furnished by Ambulatory Surgical Centers (ASCs)

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice solicits interested parties to submit requests for review of the appropriateness of the payment amount for a particular intraocular lens furnished by an ambulatory surgical center.

DATES: Requests for review must be received at the address provided no later than 5 p.m. E.S.T. on April 18, 2003.

ADDRESSES: Mail requests for review (one original and three copies) to the Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: Betty Shaw, Mailstop C1-09-06, 7500 Security Blvd., Baltimore, Maryland 21244-1850.

FOR FURTHER INFORMATION CONTACT: Betty Shaw, (410) 786-6100.

SUPPLEMENTARY INFORMATION: On October 31, 1994, the Social Security Act Amendments of 1994 (SSAA 1994) (Pub. L. 103-432) were enacted. Section 141(b) of SSAA 1994 requires us to develop and implement a process under which interested parties may request, for a class of new technology intraocular lens (NTIOLs), a review of the appropriateness of the payment amount

for IOLs furnished by ambulatory surgical centers (ASCs) under section 1833(i)(2)(A)(iii) of the Social Security Act (the Act).

On June 16, 1999, we published a final rule in the **Federal Register** titled "Adjustment in Payment Amounts for New Technology Intraocular Lenses Furnished by Ambulatory Surgical Centers" (64 FR 32198), which added subpart F to 42 CFR part 416. That rule set forth the process for adjusting payment amounts for NTIOLs furnished by ambulatory surgical centers (ASCs), defined the terms relevant to the process, and established a flat rate payment adjustment of \$50 for intraocular lenses (IOLs) that we determine are NTIOLs. This payment adjustment is good for a 5-year period that begins when we recognize a payment adjustment for the first intraocular lens in a new subset of an existing class of intraocular lens or a new class of technology, as explained below. Any subsequent IOL with the same characteristics as the first IOL recognized for a payment adjustment will receive the adjustment for the remainder of the 5-year period established by the first recognized IOL. After July 16, 2002, we may change the \$50 adjustment amount through a notice with comment period. There will be no adjustment change for calendar year 2003.

Review Process for Establishing Classes of New Technology Intraocular Lenses

We evaluate requests for the designation of an IOL as an NTIOL by doing the following:

(1) Publishing a notice in the **Federal Register** announcing the deadline and requirements for submitting a request for us to review payment for an IOL.

(2) Receiving requests to review the appropriateness of the payment amount for an IOL.

(3) Compiling a list of the requests we receive and identify 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.

(4) Publishing a notice in the **Federal Register** listing the requests, and giving the public 30 days to comment on the IOLs for which a review was requested.

(5) Reviewing the information submitted with the request to review, and requesting confirmation from the Food and Drug Administration (FDA) about labeling applications that have been approved on the model lens under review. We also request a

recommendation from the FDA about whether or not the lens model represents a new class of technology that sets it apart from other IOLs.

Using a baseline of the date of the last determination of new classes of intraocular lenses, the FDA states an opinion based on proof of superiority over existing lenses of the same type of material or over lenses that are classified by a predominant characteristic as reducing the risk of intraoperative or postoperative complications or trauma, or demonstrating accelerated postoperative recovery, reduced induced astigmatism, improved postoperative visual acuity, more stable postoperative vision, or other comparable clinical advantages.

(6) Determining which lenses meet the criteria to qualify for the payment adjustment based on clinical data and evidence submitted for review, the FDA's analysis, public comments on the lenses, and other available information.

(7) Designating a type of material or a predominant characteristic of an NTIOL that sets it apart from other IOLs to establish a new class.

(8) Publishing a notice in the **Federal Register** (within 120 days after we publish the notice identified in paragraph (4) of this section) announcing the IOLs that we have determined are "new technology" IOLs. These NTIOLs qualify for the following payment adjustment:

(a) Determinations made before July 16, 2002—\$50.

(b) Determinations made after July 16, 2002—\$50 or the amount announced through proposed and final rules in connection with ambulatory surgical center services.

(9) Adjusting payments effective 30 days after the publication of the notice announcing our determinations described in paragraph (8) of this section.

Who May Request a Review

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

Requests To Review

A request to review must include all of the following information:

- The name of the manufacturer, the model number, and the trade name of the IOL.
- A copy of the FDA's summary of the IOL's safety and effectiveness.