

organization, procedure, or practice are excepted from the requirements of notice and comment rulemaking.

We considered publishing a proposed notice to provide a period for public comment. However, we may waive that procedure if we find, for good cause, that prior notice and comment are impracticable, unnecessary, or contrary to the public interest. We find that the procedure for notice and comment is unnecessary because the formula used to calculate the SMI premium is statutorily directed, and we can exercise no discretion in applying that formula. Moreover, the statute establishes the time period for which the premium rates will apply, and delaying publication of the SMI premium rate such that it would not be published before that time would be contrary to the public interest. Therefore, we find good cause to waive publication of a proposed notice and solicitation of public comments.

(Section 1839 of the Social Security Act; 42 U.S.C. 1395r)

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance)

Dated: September 17, 2001.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Dated: September 27, 2001.

Tommy G. Thompson,

Secretary.

[FR Doc. 01-26700 Filed 10-19-01; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3061-NC]

RIN 0938-AH15

Medicare Program; Adjustment in Payment Amounts for New Technology Intraocular Lenses Furnished by Ambulatory Surgical Centers

AGENCY: Centers for Medicare & Medicaid Services (CMS), formerly the Health Care Financing Administration (HCFA), HHS.

ACTION: Notice with comment period.

SUMMARY: This notice announces the request we received from Alcon Laboratories seeking review of the appropriateness of the Medicare payment amount for new technology intraocular lenses furnished by an ambulatory surgical center. This

document also announces the 30-day period for the public to comment on the appropriateness or the payment amount of the IOL for which a review was requested.

DATES: We will consider comments regarding the lenses listed in this notice if we receive them at the appropriate address, as provided below, no later than 5 p.m. on November 26, 2001.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Centers for Medicare & Medicaid Services, Department of Health and Human Services (HHS), Attention: CMS-3061-NC, P.O. Box 8017, Baltimore, MD 21244-8017.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses: Room 443-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC, 20201, or Mailstop S3-02-01, 7500 Security Boulevard, Baltimore, Maryland 21244.

Because of the staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code CMS-3061-NC. For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Betty Shaw, (410) 786-6100.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments:

Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room C5-14-03 of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (Phone (410) 786-7195 or (410) 786-7201.)

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I. Background

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.

In accordance with the June 16, 1999 final rule, we published a notice in the **Federal Register**, titled "Annual Review of the Appropriateness of Payment Amounts for New Technology Intraocular Lenses Furnished by Ambulatory Surgical" (66 FR 18959) on April 12, 2001. In this notice, we solicited interested parties to submit requests for review of the appropriateness of the payment amount with regard to a particular intraocular lens.

II. Provisions of this Notice

On May 16, 2001, the following request was submitted to the Centers for Medicare & Medicaid Services for review:

Manufacturer: Alcon Laboratories.

Model Numbers: ACRYSOFT® Acrylic Foldable Sterile UV-Absorbing Multipiece Posterior Chamber Lenses, Models MA30BA, MA60BM, MA50BM, MA60MA, MA30AC, MA60AC.

Reason for Requesting Review: The manufacturer states that these lenses provide the following:

- Reduced risk of intra- or post-operative complications or trauma by a reduction in the area of lens epithelial cells (LEC), a major contributor to posterior capsule opacification (PCO) when compared with silicone and PMMA lenses, as evidenced by reduced Sommering's Ring scores.
- Ability to fold smaller, requiring a smaller incision than required for PMMA lenses, inducing less astigmatism thereby promoting accelerated postoperative recovery. Smaller size allows the lens to be easily explanted through the original incision.
- Reduced induced astigmatism because the lens can be inserted into the anterior ocular chamber with an average incision size of 3.5mm.
- Improved postoperative visual acuity due to their findings that the loss of visual acuity associated with

biocompatibility and inflammatory response was statistically significantly greater in patients with polymethylmethacrylate (PMMA) as compared to silicone or ACRYSOFT[®] lenses.

- More stable postoperative vision by reducing need for Nd:YAG capsulotomy. There is a difference in ND:YAG capsulotomy rates between ACRYSOFT[®] and a similar designed PMMA lens but not between ACRYSOFT[®] and a silicone lens.
- A high refractive index material that allows the thinner ACRYSOFT[®] lens to impart the same optical correction as a comparable diopter silicone or PMMA IOL.
- A clinical advantage for diabetic patients requiring posterior segment surgery to manage visual problems related to condensation and silicone oil. ACRYSOFT[®] Lens allows removal of silicone oil with relative ease.
- A clinical advantage for pediatric and uveitic patients due to the combination of foldability and size of the ACRYSOFT[®] lens.
- A decrease in anterior capsule movement when compared to similarly designed silicone PMMA lenses.

This notice solicits comments on the appropriateness of the payment amount for the IOL for which a review was requested.

Authority: Sections 1832 (a)(2)(F)(i) and 1833(i)(2)(A) of the Social Security Act (42 U.S.C. 1395k(a)(2)(F)(i) and 13951(i)(2)(A)). (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: September 25, 2001.

Thomas A Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 01-26036 Filed 10-25-01; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Center for Medicare & Medicaid Services

[CMS-3076-PN]

Medicare Program: Application by the Indian Health Service for Recognition as a National Accreditation Organization for Accrediting American Indian and Alaska Native Entities To Furnish Outpatient Diabetes Self-Management Training

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

ACTION: Proposed notice.

SUMMARY: In this proposed notice, we announce the receipt of an application from the Indian Health Service (IHS) for CMS recognition as a national accreditation organization for accrediting American Indian and Alaska Native entities that wish to furnish outpatient diabetes self-management training to Medicare beneficiaries. Section 1865(b)(3) of the Social Security Act requires that the Secretary publish a notice identifying the national accreditation body making the request, describing the nature of the request, and providing at least a 30-day public comment period.

DATES: We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on November 26, 2001.

ADDRESSES: In commenting, please refer to file code CMS-3076-PN. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. Mail written comments (one original and three copies) to the following address ONLY: Center for Medicare and Medicaid Services, Department of Health and Human Services, Attention: HCFA-3076-PN, P.O. Box 8016, Baltimore, MD 21244-8016.

Please allow sufficient time for mailed comments to be timely received in the event of delivery delays.

If you prefer, you may deliver (by hand or courier) your written comments (one original and three copies) to one of the following addresses: Room 443-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5-14-03, 7500 Security Boulevard, Baltimore, MD 21244-1850.

Comments mailed to the above addresses may be delayed and received too late for us to consider them.

For information on viewing public comments, see the beginning of the SUPPLEMENTARY INFORMATION section.

FOR FURTHER INFORMATION CONTACT: Eva Fung, (410) 786-7539, or Joan A. Brooks, (410) 786-5526.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments:

Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Center for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments,

phone (410) 786-7195 or (410) 786-5241.

I. Background

Section 4105 of the Balanced Budget Act of 1997 authorized expanded Medicare coverage for outpatient diabetes self-management training when ordered by the physician (or qualified non-physician practitioner) treating the beneficiary's diabetes, provided certain requirements are met. We sometimes use national accrediting organizations to determine whether an entity meets some or all of the requirements that are necessary to provide a service for which Medicare payment can be made. Reliance on accreditation organizations is authorized by section 1865 of the Social Security Act (the Act) and our regulations in 42 CFR part 410, subpart H. A national accreditation organization must have an agreement in effect with the Secretary and must meet the standards and requirements specified in section 1865(b)(2) of the Act and 42 CFR part 410. The applicable regulations require a national organization applying to become a body accrediting entities that furnish such training to use one of three types of quality standards: CMS's own standards, the standard developed by a national advisory group (referred to as the NSDSMEP), or other standards that we determine meet or exceed our standards. The accreditation organization, after being approved and recognized by CMS, may accredit an entity to meet one of the sets of quality standards in § 410.144 (Quality standards for deemed entities).

The regulations pertaining to application procedures for national accreditation organizations for diabetes self-management training services are at § 410.142 (CMS process for approving national accreditation organizations). We may approve and recognize a nonprofit or not-for-profit organization with demonstrated experience in representing the interests of individuals with diabetes to accredit entities to furnish training.

A national accreditation organization applying for deeming authority must provide us with reasonable assurance that the accrediting organization requires accredited entities to meet requirements that are at least as stringent as CMS's. Section 1865(b)(1) of the Act provides that if the Secretary finds that accreditation of an entity by a national accreditation body demonstrates that all of the applicable conditions and requirements are met or exceeded, the Secretary will deem those entities as meeting the applicable Medicare requirements. Section 1865(b)(2) of the Act further requires