

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

- More stable postoperative vision by reducing need for Nd:YAG capsulotomy. There is a difference in ND:YAG capsulotomy rates between ACRYSOFT<sup>®</sup> and a similar designed PMMA lens but not between ACRYSOFT<sup>®</sup> and a silicone lens.
- A high refractive index material that allows the thinner ACRYSOFT<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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

that the Secretary's findings consider the applying accreditation organization's requirements for accreditation, its survey procedures, its ability to provide adequate resources for conducting required surveys and supplying information for use in enforcement activities, its monitoring procedures for entities found out of compliance with the conditions or requirements, and its ability to provide the Secretary with necessary data for validation. The Secretary then examines the national accreditation organization's accreditation requirements to determine if they meet or exceed the Medicare conditions as we would have applied them.

Section 1865(b)(3)(A) of the Act requires that the Secretary publish within 60 days of receipt of a completed application, 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. In addition, the Secretary has 210 days from receipt of the request to publish a finding of approval or denial of the application. If the Secretary recognizes an accreditation organization in this manner, any entity accredited by the national accreditation body's CMS-approved program for that service will be "deemed" to meet the Medicare conditions of coverage.

## II. Purpose

The purpose of this notice is to notify the public of the Indian Health Service's (IHS) request for the Secretary's approval as a national accreditation organization for accrediting American Indian and Alaska Native entities to furnish outpatient diabetes self-management training services. The IHS proposes to endorse the NSDSMEP as its quality standards. This notice also solicits public comments on the ability of the IHS to develop and apply its standards to entities furnishing outpatient diabetes self-management training services that meet or exceed the Medicare conditions for coverage.

We understand the current template for the proposed notice includes only the identity of the organization seeking to become an accrediting body, but no other information on its proposed program to inform those proposing to comment in response to the notice. Since our regulation highlights the quality standards as a key factor in our determination of whether or not to accept an entity as an accrediting body, some basic information on this subject would make comments we receive more useful and relevant to our decision, both in the IHS case and in other cases.

## III. Outpatient Diabetes Self-Management Training Services Conditions for Coverage and Requirements

The regulations specifying the Medicare conditions for coverage for outpatient diabetes self-management training services are located in 42 CFR part 410, subpart H. These conditions implement section 1861(qq) of the Act, which provides for Medicare Part B coverage of outpatient diabetes self-management training services specified by the Secretary.

Under section 1865(b)(2) of the Act and our regulations at §§ 410.142 (CMS process for approving national accreditation organizations) and 410.143 (Requirements for approved accreditation organizations), we evaluate a national accreditation organization based on (but not necessarily limited to) the criteria set forth in § 410.142(b), and we review the ongoing responsibilities of an approved accreditation organization.

We may visit the prospective organization's offices to verify information in the organization's application, including, but not limited to, review of documents, and interviews with the organization's staff. For oversight activities, we may conduct an onsite visit to inspect the approved accreditation organization's operations and office in order to assess its compliance with its own policies and procedures. The onsite inspection may include, but is not limited to, reviewing documents, auditing documentation of meetings concerning the accreditation process, evaluating accreditation results or the accreditation status decision making process, and interviewing the organization's staff.

## IV. Notices Upon Completion of Evaluation

The process for becoming an accrediting body, as outlined in the regulation, includes two **Federal Register** notices. The first notice would solicit comments on the accreditation organization's proposed accreditation program. Upon completion of our evaluation, including evaluation of comments received as a result of this notice, we will publish the second notice announcing CMS's approval or disapproval of the organization as an accrediting body.

## V. Responses to Public Comments

Because of the large number of comments we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them

individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this notice and will respond to them in a forthcoming notice document.

In accordance with the provisions of Executive Order 12866, the Office of Management and Budget did not review this notice.

**Authority:** Section 1865 of the Social Security Act (42 U.S.C. 1395bb).

(Catalog of Federal Domestic Assistance Program No. 93.773 Medicare-Hospital Insurance Program; and No. 93.774, Medicare-Supplementary Medical Insurance Program)

Dated: October 1, 2001.

**Thomas A. Scully,**

*Administrator, Centers for Medicare & Medicaid Services.*

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**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-3072-FN]

### Medicare Program; Approval of Application by the American Diabetes Association (ADA) for Recognition as a National Accreditation Program for Accrediting Entities to Furnish Outpatient Diabetes Self-Management Training

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

**ACTION:** Final notice.

**SUMMARY:** This final notice announces the approval of the American Diabetes Association (ADA) as a national accreditation organization for purposes of determining that an entity meets the necessary quality standards to furnish outpatient diabetes self-management and training services under Part B of the Medicare program. Therefore, diabetes self-management training (DSMT) programs accredited by the ADA will receive deemed status under the Medicare program.

**EFFECTIVE DATE:** This accreditation is effective on October 26, 2001.

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

### SUPPLEMENTARY INFORMATION:

#### I. Background

To participate in the Medicare program, diabetes self-management training (DSMT) programs must meet conditions for coverage specified in our