populations disproportionately affected by the targeted diseases.

An organization that wishes to apply to participate in the demonstration should refer to the specific submission requirements at our Web site (listed in the **SUPPLEMENTARY INFORMATION** section of this notice).

E. Submission of Applications

Applications (an unbound original and 10 copies) must be received by us as indicated in the **DATES** and **ADDRESSES** sections of this notice. Only proposals that are considered ''on time'' will be reviewed and considered by the technical review panel. Applications must be typed for clarity and should not exceed 40 double-spaced pages, exclusive of the cover letter, executive summary, resumes, forms, and documentation supporting the cost proposal. That is, sections 4, 5, 6, 7, 8, and 9 below must be presented in 40 double-spaced typewritten pages. These sections make up the body of the proposal and must fully describe the proposed project.

Application Contents Outline

To facilitate the review process, the application should include the following contents in the following order:

1. Cover Letter

Must include a brief description of the proposed project and indicate the target population, and urban site or rural site, and identify any and all CMS provider numbers assigned to the applicant, a contact person, and contact information.

2. ''Application for Federal Assistance''—Standard Form 424

Must include SF–424a ''Budget Information'' and SF–424b ''Assurances'' available on our Web site (*www.hcfa.gov/research/dmdemo.htm*).

3. Executive Summary

Must include a summary of the project, disease management experience, existence of adequate information systems, and willingness to share protocols for disease management.

4. Statement of the Problem

5. Targeting the Appropriate Population

6. Description of Disease Management Intervention Services

7. Organizational Capabilities

8. Effectiveness of Intervention(s): Quality

9. Payment for Disease Management Services, Reduction of Medicare Expenditures, and Reinsurance

10. Related Supplemental Materials

III. Evaluation Process and Criteria

A panel of experts will conduct a review of responsive proposals. This technical review panel will convene in the months following the due date for submission of proposals. The panelists' recommendations will contain numerical ratings based on the evaluation criteria, the ranking of all responsive proposals, and a written assessment of each applicant. In addition, we will conduct a financial analysis of the recommended proposals and evaluate the proposed projects to ensure that aggregate Medicare program expenditures are reduced.

Our Administrator will make the final selection of projects for the demonstration from among the most highly qualified applicants, taking into consideration a number of factors, including operational feasibility, geographic location, and program priorities (for example, testing a variety of approaches for delivering services, targeting beneficiaries, and payment). Applicants should be aware that proposals may be accepted in whole or in part. In evaluating applications, we rely on our past experience with successful and unsuccessful demonstrations. We reserve the right to conduct one or more site visits before making awards. We expect to make the awards in 2002.

IV. Collection of Information Requirements

As this demonstration requires existing disease management organizations to (1) supplement their offerings with full prescription drug coverage, (2) provide reinsurance to guarantee reduced aggregate Medicare program expenditures, and (3) recruit and serve at least 5,000 appropriately-targeted Medicare beneficiaries, it is unlikely that many disease management organizations would be eligible to participate in this project. We expect fewer than 10 organizations to submit proposals. Therefore, the collection requirements referenced in this notice are not subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), as defined under 5 CFR 1320.3(c).

Authority: Section 121 of the Medicare, Medicaid, and State Child Health Insurance Program Benefits Improvement and Protection Act of 2000 (BIPA).

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

Dated: February 5, 2002.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 02–4355 Filed 2–21–02; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3061–FN]

RIN: 0938–AH15

Medicare Program; Disapproval of Alcon Laboratories' Request for an Adjustment in Payment Amounts for New Technology Intraocular Lenses Furnished by Ambulatory Surgical Centers

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

ACTION: Final notice.

SUMMARY: This final notice announces our disapproval of Alcon Laboratories' request for a $50 adjustment in payment amount for lenses reviewed for determination as a new technology intraocular lens (NTIOL).

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

SUPPLEMENTARY INFORMATION: *Copies:* To order copies of the **Federal Register** containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512–1800 (or toll-free at 1–888–293–6498) or by faxing to (202) 512–2250. The cost for each copy is $9. As an alternative, you can view and photocopy the **Federal Register** document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**. This **Federal Register** document is also available from the **Federal Register** online database through *GPO Access,* a service of the U.S. Government Printing Office. The Web site address is: *http://www.access.gpo.gov/nara/index.html.*

I. Background

In our regulations at 42 CFR part 416, subpart F, we describe the process an interested party must use to request that

we review the appropriateness of the payment amount for a new technology intraocular lens (NTIOL) furnished by ambulatory surgical centers (ASCs). On October 26, 2001, we published a notice with comment period in the **Federal Register** (66 FR 54261) listing the lenses for which we had received requests for a review for payment adjustment. We received only one request, on May 16, 2001 from Alcon Laboratories for its Acrysof lenses MA30BA, MA60BM, MA50BM, MA60MA, MA30AC, and MA60AC. Alcon Laboratories claimed these lenses provide a reduction in the rate of Nd:YAG capsulotomy and posterior capsule opacification (PCO). MA30BA and MA60BM were previously submitted in 1999 and we subsequently determined that these lenses did not demonstrate clinical advantages over existing lenses with respect to reduction in Nd:YAG capsulotomy and reduced posterior capsule opacification by reduction in lens epithelial cells (LECs) (65 FR 25738, 25739).

In accordance with our NTIOL procedures, we asked the Food and Drug Administration (FDA) to review Alcon's new request to determine whether the claims of specific clinical advantage and superiority over existing intraocular lenses (IOLs) had been approved for labeling and advertising purposes. Our regulations require FDA's approval of its claims for advertising and labeling in order for an IOL to be classified as an NTIOL. The FDA conveyed its analysis of the lenses to CMS in an August 16, 2001 memorandum.

The FDA determined that the Acrysof lenses did not demonstrate clinical superiority over a representative sample of lenses outside the new class with respect to a reduced rate of Nd:YAG capsulotomy and PCO. Alcon Laboratories provided articles that could arguably support clinical advantages over a particular silicone IOL. However, Alcon Laboratories' FDA approved labeling states that there were no differences in Nd:YAG rate between the Acrysof lens and the silicone IOL studied.

II. Analysis of and Responses to Public Comments

We also received 20 comments in response to the notice listing the lenses requesting a review. Of these, 17 were from ophthalmologists. The other three comments were from one public interest group and two competing manufacturers of IOLs.

Comment: Seventeen of the commenters supported the Alcon Laboratories Acrysof lenses announced in the notice. All of these commenters were practicing ophthalmologists. The comments received were testimonials of support based on the commenters' experiences with the Acrysof lenses. Commenters stated that the lenses reduced formation and migration of lens epithelial cells (LECs), and that there is a lower incidence of PCO, thus reducing Nd:YAG laser capsulotomy rates. The commenters also stated that the Acrysof lens unfolded more predictably, and with less force, thereby reducing the risk of inadvertent malpositioning of the lens.

Response: We appreciate the commenters' testimonials with regard to intra-operative and post-operative experiences with the Acrysof lenses. However, testimonials are substantially less reliable than published clinical data in deciding whether a lens has specific clinical advantages and superiority over existing lenses in order to be considered an NTIOL.

Comment: One commenter stated that claims that Acrysof lenses are superior to polyacrylic or second-generation silicone IOLs are not supported by published data.

Response: We agree with the commenter.

Comment: One commenter indicated that more recent studies report lower incidences of PCO with silicone IOLs than earlier reports, leading to a recent decrease in Nd:YAG laser capsulotomy rates. The commenter noted that the decrease was attributed to improvements in surgical technique rather than improvements in lens material or design.

Response: The manufacturer of these lenses has not demonstrated clinical advantages and superiority over existing lenses, as the regulations require.

III. Criteria for Determination

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

(1) Has the requestor identified the new class of IOLs to which its lens belongs based on a type of material and/or predominant characteristic that it does not share with lenses outside of the new class?

(2) Has the requestor demonstrated that its lens is clinically superior to a representative sample of lenses outside of the new class? Clinical superiority includes reducing the risk of intraoperative or postoperative complication or trauma, or demonstrating accelerated postoperative recovery, reduced induced astigmatism, improved postoperative visual acuity, more stable postoperative vision, or other comparable clinical advantages.

(3) Has the requestor demonstrated that the clinical superiority is produced by the material and/or predominant characteristic that defines the new class?

(4) Has the FDA approved the claim of clinical superiority for labeling and advertising?

IV. Decision

In determining which lenses meet the criteria and definition of an NTIOL, we relied on the clinical data and evidence submitted to us by Alcon Laboratories, public comments, and the FDA's approval of Alcon's claims. We independently reached the same decision as the FDA.

In regard to the first criterion, it is appears that Alcon is claiming that the Acrysof lenses are a new class because of outcomes resulting in reduced LEC migration and reduced incidence of Nd:YAG posterior capsulotomy. However, the criterion specifically states that a new class must be based on a material and/or predominant characteristic. CMS asserts that ''predominant characteristic,'' like material characteristic, would be some physical property of the lens, and that it would be this material or predominant characteristic that would lead to the outcome benefit. Alcon did not define the material and/or predominant characteristic of the Acrysof lenses that would constitute a new technology class.

The second criterion in Section III of this notice states that the lens must be shown superior to a representative sample of lenses outside of this new class. Not only did Alcon fail to define what the new class is for Acrysof, it also did not provide a systematic comparison of the lens to other IOLs. For example, if Alcon identified Acrysof as a new class of foldables, then a comparison of Acrysof to all foldables would be an example of one systematic comparison.

The third criterion states that the clinical superiority seen is produced by the new material and/or predominant characteristic that defined the new class. As stated above, there was no definitive demonstration that a new class was achieved, nor was there a thorough, systematic comparison of said new class lens to other lenses outside the class. Thus, Alcon failed to meet this third criterion.

The fourth criterion states that the lens in question must have received FDA approval for the claimed superiority. The FDA did approve Acrysof's claims of superiority in reduced LEC migration and reduced incidence of Nd:YAG posterior

capsulotomy as compared to one similarly designed PMMA IOL (PMMA is the only type of non-foldable IOL currently being distributed). However, the FDA has not approved a claim that Acrysof is superior to all non-foldable lenses or to any other type of foldable lens. Therefore, Alcon has not met criterion four. We conclude that the Acrysof lenses described in this notice are not NTIOLs, and, therefore, not eligible for the additional $50 payment.

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 1395l(i)(2)(A).

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

Dated: January 20, 2002.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 02–4354 Filed 2–21–02; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3087–N]

Medicare Program; Meeting of the Executive Committee of the Medicare Coverage Advisory Committee—April 16, 2002

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

ACTION: Notice of meeting.

SUMMARY: This notice announces a public meeting of the Executive Committee (the Committee) of the Medicare Coverage Advisory Committee (MCAC). The Committee provides advice and recommendations to us about clinical issues. The Committee will act upon recommendations from the Diagnostic Imaging Panel of the MCAC regarding whether and when it is scientifically justified to use FDG Positron Emission Tomography or other neuroimaging devices for the diagnosis and patient management of those with Alzheimer's disease.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)(1) and (a)(2)).

DATES: *The Meeting:* April 16, 2002 from 8 a.m. until 4:30 p.m., E.D.T.

Deadline for Presentations and Comments: March 27, 2002, 5 p.m., E.D.T.

Special Accommodations: Persons attending the meeting who are hearing or visually impaired, or have a condition that requires special assistance or accommodations, are asked to notify the Executive Secretary by March 18, 2002 (see **FOR FURTHER INFORMATION CONTACT**).

ADDRESSES: *The Meeting:* The meeting will be held at the Baltimore Convention Center, Room 321–322, One West Pratt Street, Baltimore, MD 21201.

Presentations and Comments: Submit formal presentations and written comments to Janet A. Anderson, Executive Secretary; Office of Clinical Standards and Quality; Centers for Medicare & Medicaid Services; 7500 Security Boulevard; Mail Stop C1–09–06; Baltimore, MD 21244.

Website: You may access up-to-date information on this meeting at *www.hcfa.gov/coverage.*

Hotline: You may access up-to-date information on this meeting on the CMS Advisory Committee Information Hotline, 1–877–449–5659 (toll free) or in the Baltimore area (410) 786–9379.

FOR FURTHER INFORMATION CONTACT: Janet A. Anderson, Executive Secretary, 410–786–2700.

SUPPLEMENTARY INFORMATION: On December 14, 1998, we published a notice in the **Federal Register** (63 FR 68780) to describe the Medicare Coverage Advisory Committee (MCAC), which provides advice and recommendations to us about clinical issues. This notice announces the following April 16, 2002 public meeting of the Executive Committee (the Committee) of the MCAC.

Current Panel Members

Harold C. Sox, M.D.; Daisy Alford-Smith, Ph.D.; Wade Aubry, M.D.; Linda Bergthold, Ph.D.; Ronald M. Davis, M.D.; John H. Ferguson, M.D.; Leslie P. Francis, J.D., Ph.D.; Alan M. Garber, M.D., Ph.D.; Thomas V. Holohan, M.D., M.A.; Michael D. Maves, M.D., M.B.A.; Barbara J. McNeil, M.D., Ph.D.; Robert L. Murray, Ph.D.; Frank J. Papatheofanis, M.D., Ph.D.; Randel E. Richner, M.P.H.

Meeting Topic

The Committee will act on recommendations from the Diagnostic Imaging Panel of the MCAC regarding FDG Positron Emission Tomography imaging for Alzheimer's disease, mild cognitive impairment, and dementia.

Procedure and Agenda

This meeting is open to the public. The Committee will hear oral presentations from the public for approximately 90 minutes. The Committee may limit the number and duration of oral presentations to the time available. If you wish to make a formal presentation, you must notify the Executive Secretary named in the **FOR FURTHER INFORMATION CONTACT** section of this notice, and submit the following by the *Deadline for Presentations and Comments* date listed in the **DATES** section of this notice: a brief statement of the general nature of the evidence or arguments you wish to present, and the names and addresses of proposed participants. A written copy of your presentation must be provided to the Executive Secretary before offering your public comments. We will request that you declare at the meeting whether or not you have any financial involvement with manufacturers of any items or services being discussed (or with their competitors).

After the public and CMS presentations, the Committee will deliberate openly on the topic. Interested persons may observe the deliberations, but the Committee will not hear further comments during this time except at the request of the chairperson. The Committee will also allow approximately a 30-minute open public session for any attendee to address issues specific to the topic. At the conclusion of the day, the members will vote, and the Committee will make its recommendation.

Authority: 5 U.S.C. App. 2, section 10(a)(1) and (a)(2).

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

Dated: January 31, 2002.

Jeffrey L. Kang,

Director, Office of Clinical Standards and, Quality, Centers for Medicare & Medicaid Services.

[FR Doc. 02–3986 Filed 2–21–02; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1214–N]

Medicare Program; March 25–26, 2002, Meeting of the Practicing Physicians Advisory Council

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

ACTION: Notice of meeting.

SUMMARY: In accordance with section 10(a) of the Federal Advisory Committee Act, this notice announces a meeting of the Practicing Physicians Advisory