VI. Regulatory Impact Statement

We have examined the impact of this final notice as required by Executive Order 12866 and the Regulatory Flexibility Act (RFA) (Pub. L. 98–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). The RFA requires agencies to analyze options for regulatory relief for small businesses. For purposes of the RFA, States and individuals are not considered small entities.

Also, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis for any notice that may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we consider a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds.

This final notice recognizes CHAP as a national accreditation organization for HHAs that request participation in the Medicare program. There are neither significant costs nor savings for the program and administrative budgets of Medicare. Therefore, this final notice is not a major rule as defined in Title 5, United States Code, section 804(2) and is not an economically significant rule under Executive Order 12866. We have determined, and the Secretary certifies, that this final notice will not result in a significant impact on a substantial number of small entities and will not have a significant effect on the operations of a substantial number of small rural hospitals. Therefore, we are not preparing analyses for either the RFA or section 1102(b) of the Act.

In an effort to better assure the health, safety, and services of beneficiaries in HHAs already certified as well as provide relief to State budgets in this time of tight fiscal restraints, we deem HHAs accredited by CHAP as meeting our Medicare requirements. Thus, we continue our focus on assuring the health and safety of services by providers and suppliers already certified for participation in a cost-effective manner.

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget. In accordance with Executive Order 13132, we have determined that this final notice will not significantly affect the rights of States, local or tribal governments.

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

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplemental Medical Insurance Program)

Dated: February 11, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 05–5034 Filed 3–24–05; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3112–FN; 0938–ZA49]

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

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

ACTION: Final notice.

SUMMARY: In this final notice, we summarize timely public comments received in response to our July 23, 2004 notice with public comment period and announce our decision concerning applications submitted by Alcon Laboratories, Incorporated (Alcon) and Advanced Medical Optics (AMO) (formerly Pharmacia & Upjohn Company) [1] to adjust the Medicare payment amounts for certain intraocular lenses (IOLs) on the basis that they are new technology intraocular lenses (NTIOLs).

This is the third of three statutorily required **Federal Register** documents. On February 27, 2004, we published a notice in the **Federal Register** that solicited interested parties to submit requests for review of the appropriateness of the payment amount for an IOL furnished by an ambulatory surgical center. On July 23, 2004, we published a notice with comment period entitled ''Adjustment in Payment Amounts for New Technology Intraocular Lenses Furnished by Ambulatory Surgical Centers'' acknowledging timely receipt of application materials from Alcon and AMO. In this final notice, we announce our decision to disapprove the NTIOL applications submitted by both Alcon and AMO.

[1] Advanced Medical Optics acquired Pharmacia & Upjohn Company's surgical product line on June 28, 2004 and is now the party of interest for purposes of this Final Notice.

FOR FURTHER INFORMATION CONTACT: Michael Lyman, (410) 786–6938.

SUPPLEMENTARY INFORMATION:

I. Background

On October 31, 1994, the Social Security Act Amendments of 1994 (SSAA 1994) (Pub. L. 103–432) were enacted. Section 141(b)(1) of SSAA 1994 required us to develop and implement a process under which interested parties may request a review of the appropriateness of the payment amount for intraocular lenses furnished by ASCs under section 1833(i)(2)(A)(iii) of the Social Security Act (the Act) on the basis that those lenses constitute a class of new technology intraocular lenses.

On June 16, 1999, we published a final rule in the **Federal Register** entitled ''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. The June 16, 1999 final rule established a 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 IOLs that we determine are NTIOLs. The payment adjustment applies for a 5-year period that begins when we recognize a payment adjustment for the first IOL in a new class of technology, as explained below. Any subsequent IOLs having the same characteristics as the first IOL recognized for a payment adjustment will receive the same adjustment for the remainder of the 5-year period established by the first recognized NTIOL. In accordance with the payment review process specified in § 416.185, after July 16, 2002, the $50 adjustment amount can be modified through proposed and final rulemaking in connection with ASC services. To date, we have made no changes to the payment amount and have opted not to change the adjustment for calendar year 2004 (CY 2004).

We have previously approved two classes of NTIOLs: Multifocal and Reduction in Preexisting Astigmatism. These IOLs were approved for NTIOL status during calendar year 2000.

II. NTIOL Applications Submitted for Calendar Year 2004

On February 27, 2004, we published a notice in the **Federal Register** entitled

''Medicare Program; Calendar Year 2004 Review of the Appropriateness of Payment Amounts for New Technology Intraocular Lenses (NTIOLs) Furnished by Ambulatory Surgical Centers (ASCs)'' (69 FR 9322). In response to the February 27, 2004 notice, we received the following timely requests for review:

1. Manufacturer: Alcon Laboratories, Inc. Model Numbers: ACRYSOF® Natural IOL; Models: SB30AL (5.5 mm optic) and SN60AT (6.0 mm optic). These two models are made out of the same material and differ only in optic size. Accordingly, we are treating the two lenses as the same lens.

2. Manufacturer: Advanced Medical Optics. Model Numbers: Tecnis®, with Z-Sharp Optic Technology, Foldable Posterior Chamber IOL; Models Z9000 (12 mm diameter) and Z9001 (13 mm diameter). These two models are also made out of the same material and differ only in diameter. Accordingly, we are also treating these lenses as the same lens.

On July 23, 2004, we published in the **Federal Register** a notice with comment period entitled ''Medicare Program; Adjustment in Payment Amounts for New Technology Intraocular Lenses Furnished by Ambulatory Surgical Centers'' (69 FR 44029) that summarized these timely applications and solicited public comments on the IOLs submitted by Alcon and AMO.

III. Criteria and Process for NTIOL Determination

We will classify an IOL as an NTIOL if the lens meets the definition of a ''new technology IOL'' in § 416.180, which incorporates section 141(b)(2) of SSAA 1994. Under that section, a ''new technology IOL'' is defined as ''an IOL that CMS determines has been approved by the FDA for use in labeling and advertising the IOL's claims of specific clinical advantages and superiority over existing IOLs with regard to reduced risk of intraoperative or postoperative complication or trauma, accelerated postoperative recovery, reduced induced astigmatism, improved postoperative visual acuity, more stable postoperative vision, or other comparable clinical advantages.''

The process we use for evaluating requests for NTIOL designation and reviewing the appropriateness of the payment amount for a NTIOL furnished by ASCs is described in our regulations at part 416, subpart F and in the February 27, 2004 **Federal Register** notice.

This process includes—

- Publishing a public notice in the **Federal Register** identifying requirements and the deadline for submitting a request;
- Processing requests to review the appropriateness of the payment amount for an IOL;
- Compiling a list of the requests we receive that identify the IOL manufacturer, IOL model number under review, name of the requester, and a summary of the request for review of the appropriateness of the IOL payment amount;
- Publishing an annual public notice in the **Federal Register** that lists the requests and provides for a public comment period;
- Reviewing the information submitted with the applicant's request for review, and requesting confirmation from the FDA about labeling applications that have been approved on the IOL model under review. We also request the FDA's recommendations as to whether or not the IOL model submitted represents a new class of technology that sets it apart from other IOLs. Using a baseline of the date of the last determination of a new class of IOLs, the FDA states an opinion based on proof of superiority over existing lenses of the same type of material or over lenses providing specific clinical advantages and superiority over existing IOLs as described in the preceding paragraph;
- 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;
- Designating a type of material or a predominant characteristic of an NTIOL that sets it apart from other IOLs to establish a new class;
- Publishing a notice in the **Federal Register** 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 ASC services; and
- Adjusting payments effective 30 days after the publication of the final notice announcing our determinations described in paragraph (8) of this section.

In accordance with our NTIOL application review procedures, we asked the FDA to review the Alcon and AMO NTIOL applications to determine whether the manufacturers' claims of specific clinical advantages and superiority over existing IOLs had been approved for labeling and advertising purposes. Our regulations require the FDA's approval of a requestor's claims for advertising and labeling in order for an IOL to be classified as a NTIOL.

IV. Analysis of and Responses to Public Comments

We received 14 timely public comments in response to the July 23, 2004 notice with comment period on the NTIOLs under review. Of these, 11 were from ophthalmologists, two were from IOL manufacturers, and one was from a private citizen. The comments we received and our responses are as follows:

Comment: Five commenters supported the Alcon Laboratories, Inc. Acrysof® lenses without distinguishing between the two models presented, and five commenters supported the AMO Tecnis® lenses without distinguishing between the two models presented. Based on their positive experiences with the IOLs, these commenters requested that the IOLs under review be classified as NTIOLs, and therefore, eligible for the payment adjustment.

Response: We appreciate the commenters' interests in these lenses and are pleased that these lenses have improved the quality of life of Medicare beneficiaries. However, anecdotal evidence supporting NTIOL status is not sufficient to characterize an IOL as a NTIOL. Our regulations at § 416.180 prohibit us from characterizing an IOL as a NTIOL unless the FDA has approved for use in labeling and advertising the IOL's claims of specific clinical advantages and superiority over existing IOLs. The FDA must rely on published clinical data to make this determination. Testimonials in support of an IOL being reclassified as a NTIOL cannot substitute for the FDA's approval. We present the FDA review in section V.

Comment: Two comments from ophthalmologists opposed NTIOL status for the Alcon Laboratories, Inc. Acrysof® lenses, contending that the relationship between blue light and macular degeneration is speculative. The comments did not distinguish between the two models presented.

Response: Based upon our review of the literature, we agree with the commenters that the relationship between blue light and macular degeneration is speculative and not proven by available evidence. We present our review of the literature in section V.

Comment: We received one comment from an IOL manufacturer opposing NTIOL status for the Alcon Laboratories, Inc. Acrysof® IOLs, contending that the FDA failed to approve Alcon's claims of

specific clinical advantages. The comment did not distinguish between the two models presented.

Response: While the manufacturer claims clinical advantages for blue light filtering in its application for NTIOL status, the manufacturer does not make this claim in its FDA-approved labeling. As previously stated, claims of clinical superiority must be approved by the FDA for use in labeling and advertising for an IOL to qualify as a NTIOL under § 416.180. We believe that the relationship between blue light and macular degeneration is not adequately substantiated by the literature.

Comment: We received one comment from an IOL manufacturer opposing NTIOL status for the AMO Tecnis® lenses, claiming they provide no useful improvements over existing IOLs.

Response: The literature submitted by the manufacturer validates AMO's claims of increased contrast sensitivity for the Tecnis® IOLs only when the lenses are compared to one other IOL. However, both the literature submitted by AMO and our independent review of the literature did not show that the Tecnis® lenses demonstrate increased contrast sensitivity over the spectrum of available IOLs. We believe that for a lens to be approved as an NTIOL, it must offer benefits superior to those offered by more than one other available lens.

V. NTIOL Decision—Disapproval of July 23, 2004 Applications by Alcon and AMO

A. Alcon Acrysof® Natural Lenses; Model Numbers SB30AL and SN60AT

Alcon claims to have created a class of IOL that reduces chronic blue light exposure to the retina and reduces long-term retinal damage (macular degeneration). However, these claims are absent from the IOLs' FDA-approved labeling and advertising. In addition, a July 12, 2004 FDA letter to CMS concerning Alcon's NTIOL application states, in part, as follows: ''* * * At this point, it appears as though there is no definitive explanation in regards to the extent blue light plays in retinal damage. Retinal damage is a multi-factorial issue, because so many things (*e.g.*, environment, nutrition, etc.) may also impact the degree of damage, if any.''

The same FDA letter also states that Alcon did not receive FDA approval to make the claim in its labeling that ''the blue light filtering quality of the ACRYSOF® Natural IOL provides a specific clinical advantage over existing IOLs in mitigating the risk of blue light-mediated damage to the retina.'' In contrast, the FDA approved labeling states only that blue light transmittal is reduced ''without negatively affecting color vision.'' No claims of clinical superiority for reducing blue light transmission are made in the labeling. Accordingly, because the FDA has not approved labeling supporting Alcon's claim that these lenses, independent of the other influencing factors, reduce long-term retinal damage, we cannot approve Alcon's application to adjust the Medicare payment amounts for these lenses. Additionally, we reviewed the literature submitted by Alcon and performed our own literature search. There is insufficient published peer-reviewed evidence addressing the cause and effect relationship between the blue light filtering effects of an IOL and retinal damage.

B. AMO Tecnis® Lenses with Z-Sharp Optic Technology, Foldable Posterior Chamber IOL; Models Z9000 and Z9001

In a July 12, 2004 letter to CMS regarding AMO's NTIOL application, the FDA states that ''* * * significantly less with the Tecnis® lens than with the acrylic lens. The simulated night driving results (functional vision) under several of the conditions tested and the visual acuity results were statistically significantly better in [the] eye implanted with the Technis® lens. However, another objective [of] the study was to demonstrate the mesopic (6 cd/m^2) intra-individual difference in the postoperative quality of vision using sine-wave contrast sensitivity testing between the Tecnis® lens (Z9000) and a lens with a spherical optic. In this clinical investigation, the contrast sensitivity results were not significantly different as stated in the labeling.''

We interpret this FDA statement, as well as our own literature review, to mean that while there may be a difference in contrast sensitivity between the Tecnis® lens and two other IOLs tested, that difference is not statistically significant. We also reviewed the literature submitted by AMO and performed our own literature search. We believe there is insufficient published peer-reviewed evidence addressing the cause and effect relationship between the implanted Tecnis® lens and a reduction in contrast sensitivity. However, we encourage AMO to resubmit this application with additional data from published peer-reviewed evidence.

VI. Collection of Information Requirements

Because the requirements referenced in this final notice will not affect 10 or more persons on an annual basis, this notice does not impose any information collection and record keeping requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

VII. Regulatory Impact Statement

We have examined the impacts of this notice as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) and Executive Order 13132.

Executive Order 12866, (as amended by Executive Order 13258, which merely reassigns responsibility of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We have determined that this final notice is not a major rule. The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $8.5 million or less in any 1 year. We have determined that this final notice will not affect small businesses.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a regulation may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We have determined that this final notice does not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the

private sector, of $110 million. We have determined that this final notice will not have a consequential effect on the governments mentioned or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it publishes a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State, local, or tribal governments, preempts State law, or otherwise has Federalism implications. We have determined that this final notice does not have an economic impact on State, local, or tribal governments.

In accordance with the provisions of Executive Order 12866, this final notice was not reviewed by the Office of Management and Budget.

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh)

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

Dated: March 14, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 05–5593 Filed 3–24–05; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1297–N]

Medicare Program; Public Meetings in Calendar Year 2005 for All New Public Requests for Revisions to the Healthcare Common Procedure Coding System (HCPCS) Coding and Payment Determinations

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

ACTION: Notice.

SUMMARY: This notice announces the dates and location of the Healthcare Common Procedure Coding System (HCPCS) public meetings to be held in calendar year 2005 to discuss our preliminary coding and payment determinations for all new public requests for revisions to the HCPCS. These meetings provide a forum for interested parties to make oral presentations or to submit written comments in response to preliminary coding and payment determinations. Discussion will be directed toward responses to our specific preliminary recommendations and will include all items on the public meeting agenda.

DATES: *Meeting Dates:* Given the expansion of the public meeting process, we have scheduled 8 additional meeting times for 2005: Tuesday, June 7; Wednesday, June 8; Tuesday, June 14; Wednesday, June 15; Thursday, June 16; Tuesday, June 21; Wednesday, June 22; and Thursday, June 23. We may not need all 8 days. Once the review and coding recommendation process is underway, we will have a firmer idea of the exact number of days needed to schedule the public meetings. We will consider each meeting individually, and we may modify the meeting dates and times published in this notice.

Final confirmation of meeting dates, times, and agenda items will be posted 3 weeks in advance of each scheduled meeting on the official HCPCS Web site: *http://www.cms.hhs.gov/medicare/hcpcs*. Each meeting day will begin at 9 a.m. and end at 5 p.m., E.S.T.

ADDRESSES: The public meetings will be held in the auditorium at Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244.

FOR FURTHER INFORMATION CONTACT: Gloria Knight, (410) 786–4598, Jennifer Carver, (410) 786–6610.

Web Site: Additional details regarding the public meeting process for all new public requests for revisions to the HCPCS, along with information on how to register and guidelines for an effective presentation, will be posted at least 1 month before the first meeting date on the official HCPCS Web site: *http://www.cms.hhs.gov/medicare/hcpcs*.

Individuals who intend to provide a presentation at a public meeting need to familiarize themselves with this information. The HCPCS Web site will also include ''The Healthcare Common Procedures Coding System (HCPCS) Procedures,'' a description of the new HCPCS coding process, along with a detailed explanation of the procedures used to make coding and payment determinations for all the products, supplies, and services that are coded in the HCPCS. A summary of each public meeting will be posted on the HCPCS Web site by the end of July 2005.

SUPPLEMENTARY INFORMATION:

I. Background

On December 21, 2000, the Congress passed the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554). Section 531(b) of BIPA mandated that we establish procedures that permit public consultation for coding and payment determinations for new durable medical equipment (DME) under Medicare Part B of title XVIII of the Social Security Act (the Act). The procedures and public meetings announced in this notice for new DME are in response to the mandate of section 531(b) of BIPA.

We published a notice in the November 23, 2001 **Federal Register** (66 FR 58743) with information regarding the establishment of the public meeting process for DME.

The public meeting process previously limited to DME has been expanded to include all new public requests for revisions to the HCPCS. This change will provide more opportunities for the public to become aware of coding changes under consideration, as well as opportunities for CMS to gather public input.

II. Registration

Registration Procedures: Registration can be completed online at *http://www.cms.hhs.gov/medicare/hcpcs*. To register by telephone, contact Public Meeting Coordinators Gloria Knight at (410) 786–4598 or Jennifer Carver at (410) 786–6610. The following information must be provided when registering: name, company name and address, telephone and fax numbers, e-mail address, and special needs information. Registrants must also indicate whether they are the ''primary speaker'' for an agenda item. Primary speakers must be designated by the entity that submitted the HCPCS coding request. A CMS staff member will confirm your registration by mail, e-mail, or fax.

Registration Deadline: Individuals must register for each date they plan either to attend or to provide a presentation. The deadline for registration of all the meeting dates is Tuesday, May 17, 2005.

III. Presentations and Comment Format

A. Primary Speaker Presentations

The entity that requested revisions to the HCPCS coding system for a particular agenda item may designate one ''primary speaker'' to make a presentation for a maximum of 15 minutes. Fifteen minutes is the total time interval for the presentation, and must incorporate the demonstration, set-up, and distribution of material. In establishing the public meeting agenda, we may group multiple, related requests under the same agenda item. In that case, we will decide whether additional time will be allotted, and may opt to increase the amount of time allotted to