requirements; and ability to provide us with the necessary data for validation.

Section 1865(b)(3)(A) of the Act further requires that we publish, within 60 days of receipt of an organization's complete 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. We have 210 days from our receipt of a completed application to publish approval or denial of the application.

The purpose of this proposed notice is to inform the public of our consideration of the TÜV Healthcare Specialists' (TÜVHS') request to become a national accreditation organization for hospitals. This notice also solicits public comment on the ability of TÜVHS requirements to meet or exceed the Medicare CoPs for hospitals.

## III. Evaluation of Deeming Authority Request

On December 2, 2005, the TÜV Healthcare Specialists (TÜVHS) submitted all the necessary materials to enable us to make a determination concerning its request for approval as a deeming organization for hospitals. Under section 1865(b)(2) of the Act and our regulations at § 488.8 (Federal review of accreditation organizations), our review and evaluation of TÜVHS will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of TÜVHS' standards for hospitals as compared with our comparable hospital CoPs.
- TÜVHS' survey process to determine the following:

—The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training.

—The comparability of TÜVHS' processes to those of State agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

—TÜVHS' processes and procedures for monitoring providers or suppliers found out of compliance with TÜVHS' program requirements. These monitoring procedures are used only when TÜVHS identifies noncompliance. If noncompliance is identified through validation reviews, the survey agency monitors corrections as specified at § 488.7(d).

—TÜVHS' capacity to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

—TÜVHS' capacity to provide us with electronic data in ASCII comparable code, and reports necessary for effective validation and assessment of the organization's survey process.

—The adequacy of TÜVHS' staff and other resources, and its financial viability.

—TÜVHS' capacity to adequately fund required surveys.

—TÜVHS' policies with respect to whether surveys are announced or unannounced.

—TÜVHS' agreement to provide us with a copy of the most current ac creditation survey together with any other information related to the survey as we may require (including corrective action plans).

## IV. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

## V. Response to Public Comments and Notice Upon Completion of Evaluation

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 proposed notice.

Upon completion of our evaluation, including evaluation of comments received as a result of this proposed notice, we will publish a final notice in the **Federal Register** responding to the public comments and announcing the result of our evaluation.

## VI. Executive Order 12866 Statement

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

**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—Supplementary Medical Insurance Program)

Dated: January 20, 2006.

**Mark B. McClellan,**

*Administrator, Centers for Medicare and Medicaid Services.*

[FR Doc. 06–748 Filed 1–26–06; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare and Medicaid Services

**[CMS–3144–FN]**

**0938–ZA49**

# Medicare Program; Approval of 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:** In this final notice we respond to public comments on our September 30, 2005 notice with comment period and announce our decision concerning an application submitted by Advanced Medical Optics (AMO) 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 May 27, 2005, we published a notice in the **Federal Register** entitled ''Medicare Program; Calendar Year 2005 Review of the Appropriateness of Payment Amounts for New Technology Intraocular Lenses (NTIOLs) Furnished by Ambulatory Surgical Centers (ASCs)'' (70 FR 30731) 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 September 30, 2005, we published a notice with comment period entitled ''Medicare Program; Calendar Year 2005 Review of the Appropriateness of Payment Amounts for New Technology Intraocular Lenses (NTIOLs) Furnished by Ambulatory Surgical Centers (ASCs)'' (70 FR 57297) acknowledging timely receipt of one application. In this final notice, we announce our decision to approve the NTIOL application submitted by Advanced Medical Optics (AMO) for Tecnis® (model numbers Z9000, Z9001, and Z9003).

**EFFECTIVE DATE:** This notice is effective on February 27, 2006.

**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 an initial 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 2005 (CY 2005).

## II. NTIOL Applications Submitted for Calendar Year 2005

On May 27, 2005 we published a notice in the **Federal Register** entitled ''Medicare Program; Calendar Year 2005 Review of the Appropriateness of Payment Amounts for New Technology Intraocular Lenses (NTIOLs) Furnished by Ambulatory Surgical Centers (ASCs)'' (70 FR 30731) 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. In response to the May 27, 2005 notice, we received one timely request for review:

1. Manufacturer: Advanced Medical Optics (AMO); Model Numbers: Tecnis® (model numbers Z9000, Z9001, and Z9003). Tecnis® Models Z9000 and Z9001 are made from silicone material. The Tecnis® Model Z9003 is made from acrylic material. All three lenses provide the same functionality, differing only in material. Accordingly, we are treating these lenses as the same lens.

On September 30, 2005 we published in the **Federal Register** a notice with comment period entitled ''Medicare Program; Calendar Year 2005 Review of the Appropriateness of Payment Amounts for New Technology Intraocular Lenses Furnished by Ambulatory Surgical Centers (ASCs)'' (70 FR 57297) acknowledging timely receipt of one application.

## 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 September 30, 2005 **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 a $50 payment adjustment (or other amount announced through notice and comment rulemaking); and
- Adjusting payments effective 30 days after the publication of the final notice announcing our determinations described in the preceding paragraph of this section.

In accordance with our NTIOL application review procedures, we asked the FDA to review the AMO application to determine whether the manufacturer's 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 12 timely public comments in response to the September 30, 2005 notice with comment period on the NTIOLs under review. Eleven were from ophthalmologists in support of NTIOL status for the Tecnis® lenses. One comment was received from another manufacturer who makes an IOL with similar aspheric optic design characteristics. The comments we received and our responses are as follows:

*Comments:* The commenting ophthalmologists strongly supported NTIOL designation for the Tecnis® lenses. Most of these commenters reported positive experiences from patients in whom they implanted the Tecnis® lenses during cataract surgery. The commenters reported improved contrast vision, reduced overall ocular spherical aberration, improved

functional vision, and significantly better contrast sensitivity and contrast acuity. One stated that surgeons should not use substandard lenses when better lenses are available. Another commenter provided a research article concluding the Tecnis® lens provided improved visual acuity and functional acuity contrast testing compared to conventional spherical silicone and acrylic IOLs. This article had been previously submitted by AMO in its 2004 and 2005 calendar year NTIOL submissions.

We also received a comment supporting NTIOL status for the Tecnis® lenses that suggested they be classified as ''Aspheric Optic'' NTIOLs. The commenter also requested that one of its IOL products having aspheric optic design characteristics, as well as an IOL of another manufacturer, be placed in this newly created ''Aspheric Optic'' NTIOL class.

We agree with the commenters in their support of the Tecnis® lenses. We do not agree with the comment that the Tecnis® lenses be classified as ''Aspheric Optic'' NTIOLs. NTIOL classes are defined by clinical outcomes which provide benefits to Medicare beneficiaries. The two previously created NTIOL classes are ''Multifocal'' and ''Reduction in Preexisting Astigmatism.'' We disagree with the commenter's suggestion to create a new ''Aspheric Optic'' NTIOL class as this class would not be based upon clinical outcome. We recommend that the commenter who claimed that one of its IOLs has aspheric optic design characteristics submit an application with evidence showing clinical benefits of its lenses during the 2006 NTIOL application period. We appreciate all commenters' interest in the NTIOL process.

## V. NTIOL Decision—Approval of Advanced Medical Optics Application

*AMO Tecnis® Lenses; Models Z9000, Z9001, and Z9003*

In CY 2004, AMO applied for NTIOL designation for the Tecnis® lenses. As part of the 2004 NTIOL review, CMS requested FDA review of AMO's NTIOL application. FDA's review confirmed that the clinical trial performed by AMO demonstrated that results under several conditions tested were statistically significantly better with the Tecnis® lens than with the control acrylic IOL. However, we denied AMO's CY 2004 NTIOL application for the Tecnis® lenses due to the lack of evidence that the Tecnis® design improvements provided clinical benefits to patients.

AMO resubmitted its NTIOL request in CY 2005 and provided additional information on the clinical relevance of reduced postoperative spherical aberration and increased contrast sensitivity. In the CY 2005 application, AMO provided additional peer-reviewed published studies, a meta-analysis, and a justification of the choice of comparator lens, none of which were included in the CY 2004 application. To demonstrate clinical superiority, AMO submitted journal articles and AMO-sponsored research reporting improved functional vision resulting from compensation for corneal spherical aberration. We reviewed the additional literature submitted by AMO in its CY 2005 application and found it to be acceptable and supportive of our requirements.

AMO claims the Tecnis® IOLs create a new class of IOLs compensating for corneal spherical aberration. AMO states this improves contrast sensitivity, functional performance, and especially safer night driving. Based on the additional information from AMO, CMS approves AMO's claims of clinical advantages and superiority of the Tecnis® IOL for ocular spherical aberrations and simulated night driving.

We find the AMO Tecnis® Lenses Models Z9000, Z9001, and Z9003 meet the NTIOL definition and are to be given the new NTIOL classification of Reduced Spherical Aberration.

## 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 $6 million to $29 million in any 1 year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined that this final notice will not have a significant economic impact on a substantial number of small entities.

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 Core-Based Statistical Area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined that this final notice will 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 whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately $120 million. This final notice will have no consequential effect on State, local, or tribal governments 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. Since this final notice does not impose any costs on State or local governments, the requirements of E.O. 13132 are not applicable.

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: January 9, 2006.

**Mark B. McClellan,**

*Administrator, Centers for Medicare and Medicaid Services.*

[FR Doc. E6–1049 Filed 1–25–06; 4:00 pm]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

**[CMS–3162–N]**

### Medicare Program; Meeting of the Medicare Coverage Advisory Committee—March 30, 2006

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

**ACTION:** Notice.

**SUMMARY:** This notice announces a public meeting of the Medicare Coverage Advisory Committee (MCAC). The Committee generally provides advice and recommendations about whether scientific evidence is adequate to determine whether certain medical items and services are reasonable and necessary under the Medicare statute. The charter also permits the MCAC to develop recommendations about other specific issues of Medicare coverage. This meeting concerns authoritative drug compendia that may be used in determining the medically accepted indications of drugs and biologicals used in an anti-cancer chemotherapeutic regimen under Part B of the Medicare program. Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)).

**DATES:** The public meeting will be held on Thursday, March 30, 2006 from 7:30 a.m. until 4:30 p.m. e.s.t.

*Deadlines: Deadline for Presentations and Comments:* Written comments and presentations must be received by February 27, 2006, 5 p.m., e.s.t.

*Deadline for Registration To Attend Meeting:* For security reasons, individuals wishing to attend this meeting must register by close of business on March 23, 2006.

*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 23, 2006 (see **FOR FURTHER INFORMATION CONTACT**).

**ADDRESSES:** The meeting will be held in the main auditorium of the Centers for Medicare & Medicaid Services, 7500 Security Blvd, Baltimore, MD 21244.

**FOR FURTHER INFORMATION CONTACT:** Michelle Atkinson, Executive Secretary, by telephone at 410–786–2881 or by e-mail at *Michelle.Atkinson@cms.hhs.gov.*

*Web site:* You may access up-to-date information on this meeting at *http://www.cms.hhs.gov/FACA/02_MCAC.asp#TopOfPage.*

*Presentations and Comments:* Interested persons may present data, information, or views orally or in writing on issues pending before the Committee. Please submit written comments to Michelle Atkinson, by e-mail at *Michelle.Atkinson@cms.hhs.gov* or by mail to the Executive Secretary for MCAC, Coverage and Analysis Group, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail Stop C1–09–06, Baltimore, MD 21244.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

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 a public meeting of the Committee.

*Meeting Topic:* The Committee will discuss evidence and hear presentations and public comments regarding the desired characteristics of published authoritative compendia that may be used by CMS to determine the medically accepted indications of drugs and biologicals employed in an anti-cancer chemotherapeutic regimen under Part B of the Medicare program, section 1861(t)(2) of the Social Security Act.

Background information about this topic, including panel materials, is available on the Internet at *http://www.cms.hhs.gov/coverage/.*

#### II. Procedure

This meeting is open to the public. The Committee will hear oral presentations from the public for approximately 45 minutes. The Committee may limit the number and duration of oral presentations to the time available. If you wish to make formal presentations, you must notify the Executive Secretary named in the **FOR FURTHER INFORMATION CONTACT** section 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, the names and addresses of proposed participants, and a written copy of your presentation. Your presentation should consider the questions we have posed to the Committee and focus on the issues specific to the topic. The questions will be available on our Web site at *http://www.cms.hhs.gov/FACA/02_MCAC.asp#TopOfPage.* We require 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 a 15 minute unscheduled 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.

#### III. Registration Instructions

The Coverage and Analysis Group is coordinating meeting registration. While there is no registration fee, individuals must register to attend. You may register by contacting Maria Ellis at 410–786–0309, mailing address: Coverage and Analysis Group, OCSQ; Centers for Medicare & Medicaid Services; 7500 Security Blvd, Mailstop: C1–09–06; Baltimore, MD 21244, or by e-mail at *Maria.Ellis@cms.hhs.gov.* Please provide your name, address, organization, telephone and fax number, and e-mail address.

You will receive a registration confirmation with instructions for your arrival at the CMS complex. You will be notified if the seating capacity has been reached.

This meeting is located on Federal property; therefore, for security reasons, any individuals wishing to attend this meeting must register by close of business on March 23, 2006.

#### IV. Security, Building, and Parking Guidelines

This meeting will be held in a Federal Government building; therefore, Federal security measures are applicable. In planning your arrival time, we