

for-profit institutions, and State, Local or Tribal governments; *Number of Respondents*: 100,000; *Total Annual Responses*: 100,000; *Total Annual Hours*: 100,000.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov), or call the Reports Clearance Office on (410) 786-1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received at the address below, no later than 5 p.m. on June 27, 2006.

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development—B, Attention: William N. Parham, III, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: April 24, 2006.

**Michelle Shortt,**

*Acting Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. E6-6385 Filed 4-27-06; 8:45 am]

BILLING CODE 4120-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-3171-N; and 0938-ZA91]

#### Medicare Program; Calendar Year 2006 Review of the Appropriateness of Payment Amounts for New Technology Intraocular Lenses (NTIOLs) Furnished by Ambulatory Surgical Centers (ASCs) and Correction

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

**ACTION:** Notice.

**SUMMARY:** This notice solicits interested parties to submit requests for review of the appropriateness of the payment amount for a particular intraocular lens furnished by an ambulatory surgical center. Also, this notice corrects typographical errors in the notice with public comment period that appeared in the September 30, 2005 **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 57297), and in the final notice that appeared in the January 27, 2006 **Federal Register** entitled "Medicare Program; Approval of Adjustment in Payment Amounts for New Technology Intraocular Lenses Furnished by Ambulatory Surgical Centers" (71 FR 4586).

**DATES:** Requests for review must be received at the address provided no later than 5 p.m. on May 30, 2006.

**ADDRESSES:** Mail requests for review (one original and three copies) to the Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: Michael Lyman, Mailstop C1-09-06, 7500 Security Blvd., Baltimore, Maryland 21244-1850.

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

#### SUPPLEMENTARY INFORMATION:

##### I. Background

###### A. Statutory Requirements

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 the Secretary of the Department of Health and Human Services to develop and implement a process under which interested parties may request a review of the appropriateness of the payment amount for intraocular lenses (IOLs) furnished by ambulatory surgical centers (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 (NTIOLs).

On June 16, 1999, the Centers for Medicare & Medicaid Services (CMS) (then known as the Health Care Financing Administration), 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 IOL request that we review and approve with the same characteristics as the first IOL

recognized for a payment adjustment will receive the adjustment for the remainder of the 5-year period established by the first recognized NTIOL. After July 16, 2002, we have the option of changing the \$50 adjustment amount through proposed and final rulemaking. We have opted not to change the adjustment amount for calendar year 2006 (CY 06).

#### B. CMS Review Process for Establishing Classes of New Technology Intraocular Lenses (NTIOLs)

We will classify an IOL as a NTIOL if the lens meets the definition of a "new technology IOL" in 42 CFR 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 Food and Drug Administration (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." Thus, an IOL must first be an FDA approved IOL before we can designate that IOL as an NTIOL.

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

(1) Publishing a public notice in the **Federal Register** that identifies the requirements and deadline for submitting a request for a review of the appropriateness of the payment amount for an IOL.

(2) Processing requests to review the appropriateness of the payment amount for an IOL.

(3) 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.

(4) Publishing an annual notice in the **Federal Register** that lists the requests and provides the public with 30 days to submit comments on the IOLs for which a review was requested.

(5) Reviewing the information submitted with the applicant's request for review, and confirming the FDA labeling for the IOL model under review. We also review the available evidence relevant to FDA's labeling approval as to whether or not the IOL model submitted represents a new class

of technology that sets it apart from other IOLs.

(6) Determining which lenses meet the criteria to qualify for the payment adjustment based on clinical data and evidence submitted for review, the FDA approved label, public comments on the lenses, and other available information. NTIOL applicants should provide good evidence-based studies supporting the claimed clinical benefits. We are interested in receiving data showing functional clinical improvements.

(7) Designating a type of material or a predominant characteristic of an NTIOL that sets it apart from other IOLs to establish a new class.

(8) Publishing a notice in the **Federal Register** (within 90 days after we publish the notice identified in paragraph (4) of this section) that announces the IOLs that we have determined are “new technology” IOLs. These NTIOLs qualify for a \$50 (or other amount that we may adopt through notice and comment rulemaking) payment adjustment for a 5-year period.

(9) Adjusting payments effective 30 days after the publication of the final notice announcing our determinations described in paragraph (8) of this section.

#### C. Who May Request a Review

As specified in § 416.190, any party who is able to furnish the information required in § 416.195 may request that we review the appropriateness of the payment amount provided under section 1833(i)(2)(A)(iii) of the Act for an IOL that, as claimed by the party, meets the definition of a new technology IOL in § 416.180.

#### D. Requests to Review

As specified in § 416.195(a), a request to review must include all of the following information:

- The name of the manufacturer, the model number, and the trade name of the IOL.
- A copy of the FDA’s summary of the IOL’s safety and effectiveness.
- A copy of the current FDA approved label supporting claims of specific clinical advantages for the IOL.
- A copy of the IOL’s original FDA approval notification.
- Reports of modifications made after the original FDA approval.
- Other information that supports the requestor’s claim (including clinical trials, case studies, journal articles, etc.).

#### E. Privileged or Confidential Information

To the extent that information received from an IOL manufacturer can reasonably be characterized as a trade

secret or as privileged or confidential commercial or financial information, § 416.195(b) requires that we maintain the confidentiality of the information and protect it from disclosure not otherwise authorized or required by Federal law as allowed under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552(b)(4)) and, with respect to trade secrets, the Trade Secrets Act (18 U.S.C. 1905). We recommend that the requestor clearly identify all information that is to be characterized as confidential.

#### F. Application of the Payment Adjustment

As provided in § 416.200, we recognize all IOL(s) that meet the definition of a new technology IOL for purposes of subpart F of part 416 as belonging to a class of NTIOLs for a period of 5 years effective from the date that we recognize the first NTIOL in that subset. Any IOL that we subsequently recognize as belonging to a new technology subset receives the new technology payment adjustment for the remainder of the 5-year period established with our recognition of the first NTIOL in the subset. Beginning 5 years after the effective date of our initial recognition of a new technology subset, the payment adjustment ceases for all IOLs that we have designated as belonging to that subset. The process to apply for inclusion in an existing NTIOL subset is described at: <http://www.cms.hhs.gov/CoverageGenInfo/downloads/AppforcurrentNTIOLsubset.pdf>.

## II. Provisions of This Notice

#### A. Calendar Year 2006 Review of the Appropriateness of Payment Amounts for New Technology Intraocular Lenses (NTIOLs) Furnished by Ambulatory Surgical Centers (ASCs)

Under our rules at 42 CFR part 416, subpart F, we are soliciting requests for review of the appropriateness of the payment amount for IOLs furnished by an ASC. Requests for review must comply with our regulations at § 416.195 and be received at the address provided by the date specified in the **DATES** section of this notice. We will announce timely requests for review in a subsequent notice that will allow for public comment. Currently, if we determine that an intraocular lens meets the definition of a new technology intraocular lens, the lens will be eligible for a payment adjustment of \$50.

#### B. Summary of Corrections to the September 30, 2005 and January 27, 2006 **Federal Register** Notices

In this notice, we also correct a typographical error that appeared in the September 30, 2005 **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 57297) and in the final notice that published in the **Federal Register** on January 27, 2006 entitled “Medicare Program; Approval of Adjustment in Payment Amounts for New Technology Intraocular Lenses Furnished by Ambulatory Surgical Centers” (71 FR 4586). We approved the NTIOL application submitted by AMO for Tecnis® IOL model numbers Z9000, Z9001, and ZA9003. However, we made a typographical error and listed the Tecnis® IOL model as “Z9003” instead of “ZA9003” in both the September 30, 2005 notice with public comment period and the January 27, 2006 final notice. In this notice, we correct the Tecnis® IOL model number Z9003 and replace it with Tecnis® IOL model number ZA9003.

#### C. Corrections to September 30, 2005 and January 27, 2006 **Federal Register** Notices

In FR Doc. 05–19483, published on September 30, 2005, (70 FR 57297), we are making the following correction:

1. On page 57299, in the first column, in the 16th line, “Z9003” is corrected to read “ZA9003”.

In FR Doc. E6–1049, published on January 27, 2006 (71 FR 4586), we are making the following corrections:

1. On page 4586, in the third column, in the second paragraph, in the last line, “Z9003” is corrected to read “ZA9003”.

2. On page 4587, in the first column, in the last paragraph, lines 4 and 6, “Z9003” is corrected to read “ZA9003”.

3. On page 4588, in the first column, in the 16th line from the bottom, “Z9003” is corrected to read “ZA9003”.

4. On page 4588, in the second column, in the third paragraph, in the second line, “Z9003” is corrected to read “ZA9003”.

## III. Collection of Information Requirements

Because the requirements referenced in this notice will not affect 10 or more persons on an annual basis, this notice does not impose any information collection and recordkeeping requirements that are subject to review by the Office of Management and

Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

#### IV. Regulatory Impact Statement

We have examined the impact 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 Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132.

Executive Order 12866 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 annually). We have determined that this notice is not a major rule because it merely solicits interested parties to submit requests for review of the appropriateness of the payment amount with regard to a particular IOL furnished by an ASC.

The RFA requires agencies to analyze options for small business regulatory relief. 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 or less in any 1 year period. Approximately 83 percent of ASCs generate revenues of \$18.5 million or less and are considered small business entities according to the Small Business Administration. Although a substantial number of ASCs may be affected, we do not believe there will be significant economic impact on small businesses for the reason stated above.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule 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 notice, which affects only ASCs, will have no effect on 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 one year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. Because this notice only affects ASCs, we have determined that it 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 promulgates 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. Because this notice merely solicits interested parties to submit requests for review of the appropriateness of the payment amount with regard to a particular IOL furnished by an ASC, we have determined that it does not have an economic impact on State, local, or tribal governments.

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

**Authority:** Sections 1832(a)(2)(F)(i) and 1833(i)(2)(a)(iii) of the Social Security Act (42 U.S.C. 1395k(a)(2)(F)(i) and 1395l(i)(2)(A)(iii)).

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

Dated: April 19, 2006.

**Mark B. McClellan,**

*Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. 06-3973 Filed 4-27-06; 8:45 am]

**BILLING CODE 4120-01-P**

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Centers for Medicare & Medicaid Services

[CMS-4113-N]

##### Medicare Program; Meeting of the Advisory Panel on Medicare Education, May 25, 2006

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

**ACTION:** Notice of meeting.

**SUMMARY:** In accordance with the Federal Advisory Committee Act, 5 U.S.C. Appendix 2, section 10(a) (Pub. L. 92-463), this notice announces a meeting of the Advisory Panel on Medicare Education (the Panel) on May

25, 2006. The Panel advises and makes recommendations to the Secretary of Health and Human Services and the Administrator of the Centers for Medicare & Medicaid Services on opportunities to enhance the effectiveness of consumer education strategies concerning the Medicare program. This meeting is open to the public.

**DATES:** The meeting is scheduled for May 25, 2006 from 9 a.m. to 3:30 p.m., e.d.t.

**Deadline for Presentations and Comments:** May 18, 2006, 12 noon, e.d.t.

**ADDRESSES:** The meeting will be held at the City Center Hotel, 1143 New Hampshire Avenue, NW., Washington, DC 20036, (202) 775-0800.

**FOR FURTHER INFORMATION CONTACT:** Lynne Johnson, Health Insurance Specialist, Division of Partnership Development, Center for Beneficiary Choices, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail stop S2-23-05, Baltimore, MD 21244-1850, (410) 786-0090. Please refer to the CMS Advisory Committees' Information Line (1-877-449-5659 toll free)/(410-786-9379 local) or the Internet ([http://www.cms.hhs.gov/FACA/04\\_APME.asp](http://www.cms.hhs.gov/FACA/04_APME.asp)) for additional information and updates on committee activities, or contact Ms. Johnson via e-mail at [Lynne.Johnson@cms.hhs.gov](mailto:Lynne.Johnson@cms.hhs.gov). Press inquiries are handled through the CMS Press Office at (202) 690-6145.

**SUPPLEMENTARY INFORMATION:** Section 222 of the Public Health Service Act (42 U.S.C. 217a), as amended, grants to the Secretary of Health and Human Services (the Secretary) the authority to establish an advisory council or committee for the purpose of advising him in connection with any of his functions. The Secretary signed the charter establishing this Panel on January 21, 1999 (64 FR 7849) and approved the renewal of the charter on January 14, 2005. The Panel advises and makes recommendations to the Secretary and the Administrator of the Centers for Medicare & Medicaid Services (CMS) on opportunities to enhance the effectiveness of consumer education strategies concerning the Medicare program.

The goals of the Panel are as follows:

- To develop and implement a national Medicare education program that describes the options for selecting a health plan under Medicare.
- To enhance the Federal government's effectiveness in informing the Medicare consumer, including the appropriate use of public-private partnerships.