estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

We are, however, requesting an emergency review of the information collection referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR part 1320. This is necessary to ensure compliance with an initiative of the Administration. We cannot reasonably comply with the normal clearance procedures. The use of normal clearance procedures is reasonably likely to cause a statutory deadline to be missed.

This survey will support the required evaluation of the Medicare Home Health Independence Demonstration mandated under Section 702 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). Section 702 of the MMA requires the Secretary to collect data on effects of the demonstration on quality of care, patient outcomes, and any additional costs to Medicare. One year after the project's termination (currently projected to be October, 2006), the Secretary is to submit a report including recommendations to exempt permanently and severely disabled homebound beneficiaries from the traditional homebound restrictions. The purpose of this survey is to develop the information Congress seeks, and to provide CMS with a sound basis for making the mandated recommendations. This survey is designed to study the health and quality of life impacts of changing the eligibility requirement, and to provide descriptive information about the demonstration's target population.

CMS is requesting OMB review and approval of this collection by June 27, 2005, with a 180-day approval period. Written comments and recommendation will be accepted from the public if received by the individuals designated below by June 27, 2005.

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/regulations/pra* or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, comments on these information collection and recordkeeping requirements must be mailed and/or faxed to the designees referenced below by June 27, 2005:

Centers for Medicare and Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Room C5–13–27, 7500 Security Boulevard, Baltimore, MD 21244–1850. Fax Number: (410) 786–0262, Attn: William N. Parham, III, CMS–10158; and,

OMB Human Resources and Housing Branch, Attention: Christopher Martin, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: May 23, 2005.

Michelle Shortt,

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

[FR Doc. 05–10706 Filed 5–25–05; 9:15 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3144–N]

RIN 0938–ZA49

Medicare Program; Calendar Year 2005 Review of the Appropriateness of Payment Amounts for New Technology Intraocular Lenses (NTIOLs) Furnished by Ambulatory Surgical Centers (ASCs)

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.

DATES: Requests for review must be received at the address provided no later than 5 pm E.S.T. on June 27, 2005.

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: 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 (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, 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 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 in connection with ambulatory surgical center services. We have opted not to change the adjustment amount for calendar year 2005 (CY 05).

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.''

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 public 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 requesting confirmation from the FDA about labeling applications that have been approved on the IOL model under review. We also request 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.

(6) 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. NTIOL applicants should provide good evidence-based studies supporting the claimed clinical benefits. We are interested in receiving data showing functional clinical improvements, as opposed to improvements that have statistical significance without functional clinical significance.

(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.

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 § 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.

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 labeling claims of specific clinical advantages approved by the FDA 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.).

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.

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.

I. Provisions of This Notice

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.

II. 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 record keeping 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.*).

III. 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 affect 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 21, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 05–10760 Filed 5–26–05; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–4095–N]

Medicare Program; Meeting of the Advisory Panel on Medicare Education, June 21, 2005

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 June 21, 2005. 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 June 21, 2005, from 9 a.m. to 3:30 p.m., e.d.t.

Deadline for Presentations and Comments: June 14, 2005, 12 noon, e.d.t.

ADDRESSES: The meeting will be held at the Marriot at Metro Center, 775 12th Street, NW., Washington, DC 20005, (202) 737–2200.

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/apme/default.asp*) for additional information and updates on committee activities, or contact Ms. Johnson via e-mail at *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 panel for the purpose of advising the Secretary 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.
- To expand outreach to vulnerable and underserved communities, including racial and ethnic minorities, in the context of a national Medicare education program.
- To assemble an information base of best practices for helping consumers evaluate health plan options and build a community infrastructure for information, counseling, and assistance.

The current members of the Panel are: Dr. Drew E. Altman, President and Chief Executive Officer, Henry J. Kaiser Family Foundation; Dr. Jane Delgado, Chief Executive Officer, National Alliance for Hispanic Health; Clayton Fong, President and Chief Executive Officer, National Asian Pacific Center on Aging; Thomas Hall, Chairman and Chief Executive Officer, Cardio-Kinetics, Inc.; The Honorable Bobby Jindal, United States Congress; David Knutson, Director, Health System Studies, Park