the EMTALA TAG is to review regulations affecting hospital and physician responsibilities under EMTALA to individuals who come to a hospital seeking examination or treatment for medical conditions.

FOR FURTHER INFORMATION CONTACT: Beverly J. Parker, (410) 786–5320. George Morey, (410) 786–4653. Press inquiries are handled through the CMS Press Office at (202) 690–6145.

SUPPLEMENTARY INFORMATION:

I. Background

Sections 1866(a)(1)(I), 1866(a)(1)(N), and 1867 of the Social Security Act (the Act) impose specific obligations on Medicare-participating hospitals that offer emergency services. These obligations concern individuals who come to a hospital emergency department and request or have a request made on their behalf for examination or treatment for a medical condition. EMTALA applies to all these individuals, regardless of whether or not they are beneficiaries of any program under the Act. Section 1867 of the Act sets forth requirements for medical screening examinations for emergency medical conditions, as well as necessary stabilizing treatment or appropriate transfer.

Regulations implementing the EMTALA legislation are set forth at 42 CFR 489.20(l), (m), (q) and (r)(1), (r)(2), (r)(3), and 489.24. Section 945 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), requires that the Secretary establish a Technical Advisory Group (TAG) for advice concerning issues related to EMTALA regulations and implementation.

Section 945 of the MMA specifies that the EMTALA TAG—

- Shall review the EMTALA regulations;
- May provide advice and recommendations to the Secretary concerning these regulations and their application to hospitals and physicians;
- Shall solicit comments and recommendations from hospitals, physicians, and the public regarding implementation of such regulations; and
- May disseminate information concerning the application of these regulations to hospitals, physicians, and the public.

The EMTALA TAG, as chartered under the legal authority of section 945 of the MMA, is also governed by the provisions of the Federal Advisory Committee Act (FACA) (5 U.S.C. Appendix 2) for the selection of members and the conduct of all meetings.

In the May 28, 2004 **Federal Register** (69 FR 30654), we specified the statutory requirements regarding the charter, general responsibilities, and structure of the EMTALA TAG. That notice also solicited nominations for members based on the statutory requirements for the EMTALA TAG. In the August 27, 2004 **Federal Register** (69 FR 52699), we solicited nominations again for members in two categories (patient representatives and a State survey agency representative) for which no nominations were received in response to the May 28, 2004 **Federal Register** notice. In the March 15, 2005 **Federal Register** (70 FR 12691), we announced the inaugural meeting of the EMTALA TAG and the membership selection. That meeting was held on March 30 and 31, 2005. On May 18, 2005 (70 FR 28541) we announced the second meeting of the EMTALA TAG with a purpose to hear public testimony and consider written responses from medical societies and other organizations on specific issues considered by the EMTALA TAG at its inaugural meeting. The second TAG meeting was held on June 15, 16, and 17, 2005.

On September 23, 2005, (70 FR 55903), we announced the third meeting of the EMTALA TAG, for the purpose of enabling the EMTALA TAG to hear additional testimony and further consider written responses from medical societies and other organizations on specific issues considered by the TAG at previous meetings. The third TAG meeting is scheduled for October 26, 27, and 28, 2005

II. Selection of New EMTALA TAG Member

In the March 15, 2005 **Federal Register** (70 FR 12691), we announced the EMTALA TAG membership. One of those original members, a hospital representative, has been unable to complete his term of service. To enable the TAG to continue to function as required by section 945 of the MMA and to ensure that the concerns of hospitals are appropriately considered during TAG deliberations, another member has been selected to serve as a hospital representative. The new member is Rory Jaffe, M.D., M.B.A., of the University of California/Davis Medical Center. Dr. Jaffe was selected from the original list of nominees for the EMTALA TAG.

Authority: Section 945 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

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

Dated: September 23, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 05–19484 Filed 9–29–05; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3144–NC; 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 with public comment period.

SUMMARY: In this notice with public comment period, we announce the requests we have received from entities seeking review of the appropriateness of the Medicare payment amount for new technology lenses furnished by ambulatory surgical centers (ASCs). Interested parties submitted these requests for review in response to our May 27, 2005 **Federal Register** notice 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).'' We received one timely application for review by the June 27, 2005 due date listed in that **Federal Register** notice. In this notice with comment period, we summarize the timely application received and solicit public comments on the one intraocular lens (IOL) under review.

DATES: To be assured consideration, comments regarding the intraocular lenses specified in this notice must be received at one of the addresses provided below, no later than 5 p.m. on October 31, 2005.

ADDRESSES: In commenting, please refer to file code CMS–3144–NC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this notice to *http://*

www.cms.hhs.gov/regulations/ecomments (attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word).

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attn: CAPT Michael Lyman, CMS–3144–NC, Mail Stop C1–09–06, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address only:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3144–NC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or

7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

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

SUPPLEMENTARY INFORMATION:

I. Regulatory 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, with respect to a class of new technology intraocular lens (NTIOLs), a review of the appropriateness of the payment amount for intraocular lenses (IOLs) furnished by ASCs under section 1833(i)(2)(A)(iii) of the Social Security Act (the Act).

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 ASCs (§ 416.185); defined the terms relevant to the process (§ 416.180); and established an initial flat rate payment adjustment of $50 for IOLs that we determined were NTIOLs (§ 416.185(f)(1)). As provided in section 416.200, the payment adjustment applies for a 5-year period that begins when we recognize a payment adjustment for the first NTIOL. Any subsequent IOLs with the same characteristics as the first IOL recognized for a payment adjustment will receive the same payment adjustment for the remainder of the 5-year period established by the first recognized NTIOL (§ 416.200(b)). In accordance with the payment review process specified in § 416.185(f)(2), after July 16, 2002, we have authority to modify the $50 adjustment amount through proposed and final rulemaking in connection with ambulatory surgical center services. To date however, we have made no changes to the payment amount and have opted not to change the adjustment for calendar year 2005 (CY 2005).

We will classify an IOL as an 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 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 an NTIOL furnished by ASCs is described in our regulations at 42 CFR part 416, subpart F and in the February 27, 2004 **Federal Register** notice. This process includes: (1) Publishing a public notice in the **Federal Register** identifying requirements and the deadline for submitting a request; (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 for a 30-day public comment period; (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 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 proof of superiority over existing IOLs as described in the preceding paragraph; (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; (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** announcing the IOLs that we have determined are ''new technology'' IOLs. These NTIOLs qualify for a $50 payment adjustment or the amount announced through proposed and final rules in connection with ASC services; and (9) Adjusting payments effective 30 days after the publication of the final notice announcing our determinations described in paragraph (8) of this section.

II. Applications for New Technology Intraocular Lens (NTIOLs) for Calendar Year 2005

On May 27, 2005 we published the first 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)'' to solicit requests for review of applications for a payment adjustment with respect to a class of NTIOLs.

We received one request for the $50 payment adjustment by the June 27, 2005 due date specified in the notice:

Manufacturer and Requestor: Advanced Medical Optics (AMO); 1700 E. St. Andrew Place; P.O. Box 25162; Santa Ana, California 92799–5162.

Model Numbers: Tecnis® Models Z9000, Z9001 and Z9003.

Reason for Requesting Review: The requestor states that the Tecnis® IOLs were designed to improve contrast sensitivity, reduce ocular spherical aberration, and improve the functional vision of cataract surgery patients with implanted IOLs.

Tecnis® Models Z9000 and Z9001 were previously submitted for NTIOL designation in calendar year 2004 and were determined by CMS to be ineligible for NTIOL designation due to a lack of evidence that the design improvements provided a clinical benefit to patients. AMO has resubmitted its NTIOL request and provided additional information on the clinical relevance of increased contrast sensitivity. AMO provided FDA-approved product labeling claiming improved functional vision compared with another IOL. AMO also provided additional studies, a meta-analysis, and justification of the choice of comparator lens that were not included in the previous 2004 NTIOL application.

Submitting Comments: We welcome comments from the public on the appropriateness of the Medicare payment amount for the Tecnis' IOLs listed in this notice with public comment period. You can assist us by referencing the file code CMS–3144–NC.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. After the close of the comment period, CMS posts all electronic comments received before the close of the comment period on its public Web site. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday from 8:30 a.m. to 4 p.m. Please contact us by phone at (800) 743–3951 to schedule an appointment to view public comments associated with this notice.

Copies: You can view and photocopy this **Federal Register** document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**.

This **Federal Register** document is also available from the **Federal Register** online database through GPO Access, a service of the U.S. Government Printing Office. The web site address is: *http://www.access.gpo.gov/fr/index.html.*

Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, 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 preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

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 16, 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 notice is not a major rule because it merely summarizes the timely applications received and solicits comments on IOLs under review.

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 small governmental jurisdictions. 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 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 603 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 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 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 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. We have determined that this notice 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) (42 U.S.C. 1395k(a)(2)(F)(i)) and 1833(i)(2)(A)(iii) (42 U.S.C. 1395l(i)(2)(A)(iii)) of the Social Security Act, and Section 141(b) of the Social Security Act Amendments of 1994, Pub. L. 103–432).

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

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

Dated: September 23, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 05–19483 Filed 9–29–05; 8:45 am]

BILLING CODE 4120–01–P