and respond to the facility's plan of correction in a timely manner.
—AAAASF's 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 AAAASF's staff and other resources, and its financial viability.
—AAAASF's capacity to adequately fund required surveys.
—AAAASF's policies with respect to whether surveys are announced or unannounced.
—AAAASF's agreement to provide us with a copy of the most current accreditation 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.

V. Response to Comments and Notice Upon Completion of Evaluation

[If you choose to comment on issues in this section, please include the caption ''Response to Comments and Notice Upon Completion of Evaluation'' at the beginning of your comments.]

Because of the large number of items of correspondence 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 public comments we receive by the date and time specified in the **DATES** section of this preamble, and when we proceed with a final notice, we will respond to the public comments in the preamble to the document.

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

In accordance with the provisions of Executive Order 12866, the Office of Management and Budget did not review this proposed notice.

In accordance with Executive Order 13132, we have determined that this proposed notice would not have a significant effect 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—Supplementary Medical Insurance Program)

Dated: July 1, 2004.

Mark B. McClellan,

Administrator, Centers for Medicare and Medicaid Services.

[FR Doc. 04–16431 Filed 7–22–04; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3112–NC2]

RIN 0938–ZA49

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

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

ACTION: Notice with public comment period.

SUMMARY: This notice with public comment period acknowledges receipt of materials submitted by entities requesting review of the appropriateness of the Medicare payment amount for new technology lenses furnished by Ambulatory Surgical Centers (ASCs). In response to the February 27, 2004 **Federal Register** notice entitled ''Medicare Program; Calendar Year 2004 Review of the Appropriateness of Payment Amounts for New Technology Intraocular Lenses (NTIOLs) Furnished by Ambulatory Surgical Centers'' we received a total of three timely applications for review by the March 29, 2004 public comment due date. Of the three received, one application was withdrawn by the requester. In this notice we summarize timely applications received and solicit public comments on the two intraocular lenses (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 August 23, 2004.

ADDRESSES: In commenting, please refer to file code CMS–3112–NC2. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.cms.hhs.gov/regulations/ecomments* (attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word).

2. *By 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, Attention: CMS–3112–NC2, P.O. Box 8010, Baltimore, MD 21244–8010.

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

3. *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: Gay W. Burton, (410) 786–4564.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on the appropriateness of the Medicare payment amount for new technology intraocular lenses furnished by an ambulatory surgical center (ASC) listed in section II of this notice. You can assist us by referencing the file code CMS–3112–NC2.

Inspection of Public Comments: All public 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, we post all electronic comments received before the close of the comment period on our 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 of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, please telephone (410) 786–9994.

This **Federal Register** document is 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.gpoaccess.gov/fr/index.html*.

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) of SSAA 1994 requires us to develop and implement a process under which interested parties may request, for 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; 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 subset of an existing class of IOLs or 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 IOL. In accordance with the payment review process specified in § 416.185(f)(2), after July 16, 2002, the $50 adjustment amount can be modified through proposed and final rulemaking in connection with ambulatory surgical center services. To date however, we made no changes to the payment amount and have opted not to change the adjustment for calendar year 2004 (CY 2004).

II. Applications for New Technology Intraocular Lens (NTIOLs) 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) to solicit requests for review of NTIOL applications.

Three requests for review were submitted to us by the March 29, 2004 public comment due date. Of the three timely applications submitted, one requester withdrew the application. We declined to accept an additional request for review, which was received after the March 29, 2004 comment due date, and lacked the required supporting documentation. We received the following timely review requests:

1. Manufacturer: Alcon Laboratories, Inc. Model Numbers: ACRYSOF® Natural IOL; Models: SB30AL and SN60AT.

Reason for Requesting Review: The manufacturer, Alcon Laboratories, Inc. indicates that the specified lenses are the first FDA-approved IOLs that filter light in a manner that approximates the human crystalline lens in the 400 to 475 blue light wavelength range, thereby, mitigating the risk of blue light-mediated damage to the retina and may be considered as providing more stable postoperative vision.

2. Manufacturer: Pharmacia & Upjohn Co. (A Subsidiary of Pfizer Inc.) Model Numbers: Tecnis®, with Z-Sharp Optic Technology, Foldable Posterior Chamber IOL; Models Z9000 and Z9001.

Reason for Requesting Review: The manufacturer, Pharmacia & Upjohn Co. indicates that these lenses are the first FDA-approved IOLs to use a modified prolate anterior optic surface in place of a conventional spherical optic. The manufacturer has also indicated that the Technis® lens has demonstrated a significant reduction of ocular spherical aberration resulting in improved functional vision, particularly in low light conditions such as night driving, compared to conventional spherical optic IOLs.

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 record keeping requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

IV. 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 of that document.

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

(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: July 13, 2004.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 04–16659 Filed 7–22–04; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3142–NC]

Medicare Program; Evaluation Criteria and Standards for Quality Improvement Program Contracts

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

ACTION: Notice with comment period.

SUMMARY: This notice describes the evaluation criteria we intend to use to evaluate the Quality Improvement Organizations (QIOs) under their contracts with CMS, for efficiency and effectiveness in accordance with the Social Security Act. These evaluation criteria are based on the tasks and related subtasks set forth in the QIO's Scope of Work (SOW). The current 7th SOW includes Tasks 1 through 4, with subtasks included under all tasks, excluding Task 4. QIOs were awarded contracts for the 7th SOW, or 7th Round, for three years, with staggered starting dates beginning August 2002, November 2002, and February 2003.

DATES: To be assured of consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on August 23, 2004.

ADDRESSES: In commenting, please refer to file code CMS–3142–NC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

1. *Electronically.* You may submit electronic comments to *http://www.cms.hhs.gov/regulations/ecomments or to www.regulations.gov* (attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word).

2. *By 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, Attention: CMS–3142–NC, P.O. Box 8016, Baltimore, MD 21244–8016.

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

3. *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) 786–7195 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: Maria Hammel, (410) 786–1775.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this notice with comment period to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS–3142–NC and the specific ''issue identifier'' that precedes the section on which you choose to comment.

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 website. 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 of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (410) 786–7195.

I. Background

[If you choose to comment on issues in this section, please include the caption ''BACKGROUND'' at the beginning of your comments.]

The Peer Review Improvement Act of 1982 (Title I, Subtitle C of Pub. L. 97–