minimize the information collection burden. However, the collection requirements associated with this notice have been approved by OMB, under control number 0938–0880, with a current expiration date of 3/31/2003.

Authority: Section 402 of the Social Security Act Amendments of 1967 (42 U.S.C. 1395b–1)

(Catalog of Federal Domestic Assistance Program No. 93.779, Health Care Financing Research, Demonstrations and Evaluations)

Dated: September 9, 2002.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 03–3879 Filed 2–24–03; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3099–N]

Medicaid Program; Annual 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 p.m. E.S.T. on April 18, 2003.

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

FOR FURTHER INFORMATION CONTACT: Betty Shaw, (410) 786–6100.

SUPPLEMENTARY INFORMATION: 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 IOLs furnished by ambulatory surgical centers (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** titled ''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. That rule set forth the process for adjusting payment amounts for NTIOLs furnished by ambulatory surgical centers (ASCs), defined the terms relevant to the process, and established a flat rate payment adjustment of $50 for intraocular lenses (IOLs) that we determine are NTIOLs. This payment adjustment is good for a 5-year period that begins when we recognize a payment adjustment for the first intraocular lens in a new subset of an existing class of intraocular lens or a new class of technology, as explained below. Any subsequent IOL 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. After July 16, 2002, we may change the $50 adjustment amount through a notice with comment period. There will be no adjustment change for calendar year 2003.

Review Process for Establishing Classes of New Technology Intraocular Lenses

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

(1) Publishing a notice in the **Federal Register** announcing the deadline and requirements for submitting a request for us to review payment for an IOL.

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

(3) Compiling a list of the requests we receive and identify the IOL manufacturer's name, the model number of the IOL to be reviewed, the interested party or parties that submit requests, and a summary of the interested party's grounds for requesting review of the appropriateness of the IOL payment amount.

(4) Publishing a notice in the **Federal Register** listing the requests, and giving the public 30 days to comment on the IOLs for which a review was requested.

(5) Reviewing the information submitted with the request to review, and requesting confirmation from the Food and Drug Administration (FDA) about labeling applications that have been approved on the model lens under review. We also request a recommendation from the FDA about whether or not the lens model represents a new class of technology that sets it apart from other IOLs.

Using a baseline of the date of the last determination of new classes of intraocular lenses, the FDA states an opinion based on proof of superiority over existing lenses of the same type of material or over lenses that are classified by a predominant characteristic as reducing the risk of intraoperative or postoperative complications or trauma, or demonstrating accelerated postoperative recovery, reduced induced astigmatism, improved postoperative visual acuity, more stable postoperative vision, or other comparable clinical advantages.

(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** (within 120 days after we publish the notice identified in paragraph (4) of this section) announcing the IOLs that we have determined are ''new technology'' IOLs. These NTIOLs qualify for the following payment adjustment:

(a) Determinations made before July 16, 2002—$50.

(b) Determinations made after July 16, 2002—$50 or the amount announced through proposed and final rules in connection with ambulatory surgical center services.

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

Who May Request a Review

Any party who is able to furnish the information required in § 416.195 (A request to review) 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 meets the definition of a new technology IOL in § 416.180 (Definitions).

Requests To Review

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 (that is, 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, 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, for 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. Under the Freedom of Information Act, we may not withhold publication of information based on the type of information contained, but rather on an identifiable harm that release of that information would present.

Application of the Payment Adjustment

We recognize the IOL(s) that define a new technology subset for purposes of subpart F of part 416 as belonging to the class of NTIOLs for a period of 5 years effective from the date that we recognize the first new technology IOL within the subset for a payment adjustment. 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.

II. 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 intraocular lenses 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 a lens as an NTIOL, the lens will be eligible for a payment adjustment of $50 or a different amount implemented through proposed and final rules.

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 (44 U.S.C. 3501 *et seq.*).

IV. Regulatory Impact Statement

We have examined the impacts of this rule 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 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 is merely soliciting interested parties to submit requests for review of the appropriateness of the payment amount with regard to a particular intraocular lens furnished by an ambulatory surgical center.

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 $26 to $29 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 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 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 one 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: Section 1832(a)(2)(F)(i) and 1833(i)(2)(a) of the Social Security Act (42 U.S.C. 1395k(a)(2)(F)(i) and 1395l(i)(2)(A)).

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

Dated: February 24, 2003.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 03–4734 Filed 2–27–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1225–GNC]

RIN 0938–ZA22

Medicare Program; Criteria and Standards for Evaluating Intermediary, Carrier, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Regional Carrier Performance During Fiscal Year 2003

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

ACTION: General notice with comment period.