## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

**[Document Identifier: HCFA–576]**

### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden 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.

*Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Organ Procurement Organization (OPO) Request for Designation and Supporting Regulations in 42 CFR 486.301–486.325; *Form No.:* HCFA–576 (OMB# 0938–0512); *Use:* The information provided on this form serves as a basis for certifying OPOs for participation in the Medicare and Medicaid programs and will indicate whether the OPO is meeting the specified performance standards for reimbursement of service; *Frequency:* Annually; *Affected Public:* Business or other for-profit, and Not-for-profit institutions; *Number of Respondents:* 69; *Total Annual Responses:* 69; *Total Annual Hours:* 138.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards, Attention: Julie Brown Attn.: HCFA 576, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: April 4, 2001.

**John P. Burke III,**

*HCFA Reports Clearance Officer, HCFA Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards.*

[FR Doc. 01–9090 Filed 4–11–01; 8:45 am]

**BILLING CODE 4120–03–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

**[Document Identifier: HCFA–485]**

### Agency Information Collection Activities: Submission For OMB Review; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the burden 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.

*Type of Information Collection Request:* Reinstatement, without change, of a previously approved collection; *Title of Information Collection:* Home Health Services Under Hospital Insurance, Manual Instructions and Supporting Regulations in 42 CFR 409.40-.50, 410.36, 410.170, 411.4-.15, 421.100, 424.22, 484.18 and 489.21; *Form No.:* HCFA–485 (OMB# 0938–0357); *Use:* The ''Home Health Services Under Hospital Insurance'' is a certification and plan of care used by the Regional Home Health Intermediaries (RHHIs) to ensure reimbursement is made to Home Health agencies only for services that are covered and medically necessary under Part A and Part B. The attending physician must sign the HCFA–485 (OMB 0938–0357) authorizing the home services for a period not to exceed 62 days; *Frequency:* Other (every 60 days); *Affected Public:* Business or other for-profit; *Number of Respondents:* 7,322; *Total Annual Responses:* 5,580,000; *Total Annual Hours:* 1,395,000.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's web site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: April 4, 2001.

**John P. Burke III,**

*HCFA Reports Clearance Officer, HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.*

[FR Doc. 01–9087 Filed 4–11–01; 8:45 am]

**BILLING CODE 4120–03–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

**[HCFA–3057–N]**

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

**AGENCY:** Health Care Financing Administration (HCFA), HHS.

**ACTION:** Notice.

**SUMMARY:** This notice is 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.

**DATES:** Requests for review must be received at the address provided no

later than 5:00 p.m. E.S.T. on May 14, 2001.

**ADDRESSES:** Mail requests for review (one original and three copies) to the Health Care Financing Administration, Department of Health and Human Services, Attention Betty Shaw, Mailstop S3–02–01, 7500 Security Blvd. Baltimore, Maryland 21244–1850.

**FOR FURTHER INFORMATION CONTACT:** Betty Shaw, (410) 786–6100; or Mary Stojak, (410) 786–6939.

**SUPPLEMENTARY INFORMATION**

## I. 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, with respect to a class of new technology intraocular lens (IOLs), a review of the appropriateness of the payment amount for 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** 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 416. That rule set forth the process for adjusting payment amounts for new technology intraocular lenses (NTIOLs) furnished by ambulatory surgical centers (ASCs), defined the terms relevant to the process, and established a flat rate payment adjustment of $50 for IOLs that we determine (before July 16, 2002) to be 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 would receive the adjustment for the remainder of the 5-year period established by the first recognized IOL.

*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 FDA about labeling applications that have been approved on the model lens under review. We also request a recommendation from FDA about whether or not the lens model represents a new class of technology, or a new technology subset of an existing class of technology. (A new technology subset is a group of IOLs that we determine meets the criterion for being treated as new technology IOLs and that share a common feature or features that distinguish them from other IOLs. For example, all new technology IOLs that are made of a particular bioengineered material could comprise one subset, while all that rely on a particular optical innovation could comprise another.)

Using a baseline of the date of the last determinations 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 and/or over lenses that are classified by a predominant characteristic as reducing the risk of intraoperative or postoperative complication 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 the FDA review, public comments on the lenses submitted for review, and other available information. (We send results of the reviews to the requestors by mail.)

(7) Designating a predominant characteristic of an NTIOL that both sets it apart from other IOLs and links it with other similar IOLs with the same characteristic to establish a specific subset of new technology within the ''class of NTIOLs.''

(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 rulemaking 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 may request that we review the appropriateness of the payment amount provided under section 1833(i)(2)(A)(iii) of the Act with respect to an IOL that meets the definition of a new technology IOL in § 416.180.

*Requests to Review*

A request for 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. (Note: The supplemental that approves for certain claims will not have a summary on safety and effectiveness, but the original will have it.)
- 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, with respect to trade secrets, the Trade Secrets Act (18 U.S.C. 1905). We recommend the requestor clearly identify all information that is to be characterized as confidential. The Freedom of Information Act does not prohibit the disclosure of any information; rather it allows us to withhold certain information based on identifiable harms as described above.

*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 416 subpart F, we are soliciting requests for review of the appropriateness of the payment amount with respect to 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 to be an NTIOL, the lens will be eligible for a payment adjustment of $50.

**III. Collection of Information Requirements**

Given that the requirements referenced in this notice will not effect 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**

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

We have reviewed this notice under the threshold criteria of Executive Order 13132 of August 4, 1999, Federalism. We have determined that the notice does not significantly affect the rights, roles, and responsibilities of States.

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million in any one year. This notice will not have an effect on the governments mentioned, and the private sector costs will not be greater than the $100 million threshold.

**Authority:** Sections 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. 93.778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: February 2, 2001.

**Michael McMullan,**

*Acting Deputy Administrator, Health Care Financing Administration.*

[FR Doc. 01–9041 Filed 4–11–01; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources And Services Administration

### Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

**Proposed Project: State-by-State Self Assessment of Trauma Care Systems—(NEW)**

The Health Resources and Services Administration (HRSA) proposes to collect baseline data from the 56 States and Territories on their current trauma care systems and self-identified unmet needs to achieve minimum standards for a comprehensive statewide trauma care program. This information will be used to establish a national strategy to assist in future grant opportunities to the States to improve or enhance their basic systems infrastructure in trauma care. The HRSA's Maternal and Child Health Bureau (MCHB) and the Office of Rural Health Policy and the Department of Transportation's Emergency Medical Services Division are jointly administering this project. HRSA has included national performance measures for Trauma/EMS for this project in accordance with the requirements of the ''Government Performance and Results Act (GPRA) of 1993'' (Pub. L. 103–62). This act requires the establishment of measurable goals for Federal programs that can be reported as part of the budgetary process, thus linking funding decisions with performance.

The estimated response burden is as follows:

| Type of form | Number of respondents | Responses per respondent | Burden hours per response | Total burden hours |
|---|---|---|---|---|
| Self Assessment questionnaire | 56 | 1 | 10 | 560 |