

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](mailto: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 17, 2000.

**John P. Burke III,**

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

[FR Doc. 00-11036 Filed 5-2-00; 8:45 am]

BILLING CODE 4120-03-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

[Document Identifier: HCFA-R-246]

#### Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

**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.

We are, however, requesting an emergency review of the Information collections 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. Due to the unanticipated event of the settlement agreement for the Grijalva court case requiring HCFA to revise the current instrument, and because the collection of this information is needed prior to the expiration of the normal time limits under OMB's regulations at 5 CFR Part 1320, we are requesting emergency review. The Agency cannot reasonably comply with the normal clearance procedures because public harm is likely to result due to the possibility of the Medicare program being unable to provide the necessary mandated information on whether Medicare+Choice organizations are meeting their notice and appeal requirements. Additional questions have been added to the survey that address the following: enrollee knowledge about appeal rights and the appeals process; whether the enrollee ever was denied care; whether the enrollee was given written notice of the right to file a formal complaint; and whether the enrollee ever filed a complaint with his/her Medicare+Choice organization.

HCFA is requesting OMB review and approval of this collection by July 3, 2000, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individuals designated below by June 28, 2000. During this 180-day period, we will publish a separate **Federal Register** notice announcing the initiation of an extensive 60-day agency review and public comment period on these requirements. We will submit the requirements for OMB review and an extension of this emergency approval.

*Type of Information Collection Request:* Revision of a currently approved collection;

*Title of Information Collection:* The Medicare Managed Care CAHPS Survey and Supporting Regulations in 42 CFR 417.126 and 417.470;

*Form No.:* HCFA-R-246 (OMB #0938-0732);

*Use:* The CAHPS data is necessary to hold the Medicare managed care industry accountable for the quality of care they are delivering. It is critical to HCFA's mission that we collect and disseminate information that will help beneficiaries choose among plans, contribute to improved quality of care through identification of quality improvement opportunities, and assist

HCFA in carrying out its responsibilities;

*Frequency:* On occasion;  
*Affected Public:* Individuals or households, business or other for-profit, and not-for-profit institutions;

*Number of Respondents:* 204,000;  
*Total Annual Responses:* 204,000;  
*Total Annual Hours:* 67,320.

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, to [Paperwork@hcfa.gov](mailto:Paperwork@hcfa.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 28, 2000:

Health Care Financing Administration,  
Office of Information Services,  
Security and Standards Group,  
Division of HCFA Enterprise  
Standards, Attention: Dawn  
Willingham, Room N2-14-26, 7500  
Security Boulevard, Baltimore,  
Maryland 21244-1850  
and

Office of Information and Regulatory  
Affairs, Office of Management and  
Budget, Room 10235, New Executive  
Office Building, Washington, DC  
20503, Fax Number: (202) 395-6974  
or (202) 395-5167 Attn: Allison  
Herron Eydt, HCFA Desk Officer.

Dated: April 24, 2000.

**John P. Burke III,**

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

[FR Doc. 00-11038 Filed 5-2-00; 8:45 am]

BILLING CODE 4120-03-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

[HCFA-3030-N]

RIN 0938-AH15

#### Medicare Program; Lenses Eligible for an Adjustment in Payment Amount for New Technology Intraocular Lenses Furnished by Ambulatory Surgical Centers

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

**ACTION:** Notice.

**SUMMARY:** This notice announces the lenses that we have determined meet the criteria and definition of a new technology intraocular lens (NTIOL). These lenses are eligible for a payment adjustment of \$ 50 when furnished by an ambulatory surgical center (ASC).

**DATES:** *Effective date of this notice:* May 18, 2000.

*Expiration date of this notice:* May 18, 2005.

**FOR FURTHER INFORMATION CONTACT:** Mary Stojak, (410) 786-6939.

**SUPPLEMENTARY INFORMATION:****Background**

In our regulations at 42 CFR Part 416, Subpart F, we describe the process an interested party may use to request that we review the appropriateness of the payment amount for NTIOLs furnished by ASCs. On December 20, 1999, we published a notice with comment period (64 FR 71148) listing lenses for which we had received requests for a review for payment adjustment. In accordance with those regulations, we asked the FDA to review the requests to determine whether the claims of specific clinical advantage and superiority over existing intraocular lenses had been approved for labeling and advertising purposes. HCFA uses only FDA's labeling review to determine if lenses meet the NTIOL criteria. FDA conveyed their analysis of the lenses to HCFA in a December 22, 1999 memorandum. Based on that information, HCFA determined that two of the lenses met the NTIOL criteria, but four did not. The approved lenses and model numbers are listed in the "Lenses Eligible for the Payment Adjustment" section of this notice.

The following lenses that were considered for payment adjustment did not meet our criteria for NTIOLs:

(1) Alcon, manufacturer of Acrysof Models MA30BA and MA60BM, claimed these lenses provide a reduction in the rate of Nd:YAG capsulotomy and posterior capsule opacification. The FDA determined that these lenses did not demonstrate clinical advantages over existing lenses with respect to the claims made by the manufacturer.

(2) Allergan, manufacturer of AMO Silicone Posterior Chamber Models SI40NB and SI55NB, claimed the rate of Nd:YAG capsulotomy and posterior capsule opacification were lower after two years. The FDA determined that these lenses did not demonstrate clinical advantages over existing lenses for the claims made by the manufacturer.

(3) CIBA Vision Corporation, manufacturer of MemoryLens Models U940A and U940S, claimed that these lenses are the only small incision pre-rolled hydrophilic acrylic lenses in today's global market. They did not identify any specific clinical advantages. Based on their labeling claims, the FDA has determined that these lenses did not demonstrate any specific clinical advantages over existing lenses.

(4) Pharmacia and Upjohn, manufacturer of CeeOn Heparin Surface Modified Models 720C, 722C, 726C, 727C, 730C, 734C, 777C, 809C through 815C, and 820C, claimed that the amount of cellular deposits and the number of giant cells are reduced with their lenses. The FDA determined that these lenses did not demonstrate a clinical advantage over other approved IOLs.

We received 110 comments in response to the notice listing the lenses requesting a review. Of these, the majority were from ophthalmologists. The remainder of the comments were from professional organizations, ambulatory surgical centers, and one manufacturer of intraocular lenses.

**Analysis of, and Responses to, Public Comments on Lenses Requesting Review for an Adjustment in Payment Amount**

*Comment:* Over 100 of the comments received were testimonials in support of one or more of the lenses announced in the notice. The support was based on experience the commenters have had with a lens or lenses. A summary of these comments follow: 80 commenters supported the Alcon Acrysof lens, 29 commenters supported the Allergan Array Multifocal lens, 3 commenters supported the Pharmacia & Upjohn CeeOn lens, 3 commenters supported the STAAR Surgical Toric Optic lens, 1 commenter supported the Allergan AMO Silicone Posterior Chamber lens, and 3 commenters supported all of the lenses. These commenters suggested that these lenses be classified as new technology intraocular lenses, and, therefore, be eligible for the payment adjustment.

*Response:* We appreciate the commenters' interests in these lenses, and are pleased that these lenses have improved the quality of life of Medicare beneficiaries. Regulations at 42 CFR 416.180 require the FDA to determine whether the lens has specific clinical advantages and superiority over existing intraocular lenses. Testimonials that support the claims of an intraocular lens to be considered an NTIOL cannot substitute for the FDA's approval. The

FDA must rely on published clinical data to decide that a lens has specific clinical advantages and superiority over existing lenses in order to be considered an NTIOL.

*Comment:* Two commenters made reference to the payment adjustment for intraocular lenses and the need to implement the payment process in a timely manner.

*Response:* Payment issues are outlined in our regulations at 42 CFR 416.185. This section codifies the payment amount, and describes the time frame for implementation of the payment adjustment. The effective date of the payment adjustment is 30 days after the publication of this notice, which must be published within 90 days of the end of the comment period of the notice listing the lenses requesting review. Since the **Federal Register** notice listing the requests was published on December 20, 1999 (64 FR 71148), the effective date of the payment adjustments can be no later than May 18, 2000. Retroactive payment adjustments will be made, if necessary.

*Comment:* One commenter suggested that the manufacturers of the Alcon Acrysof lens and the Allergan AMO Posterior Chamber lens should not be able to claim that their lenses are superior to existing intraocular lenses in the rate of Nd:YAG capsulotomy. The commenter claims that the studies performed by these manufacturers showed only that their lenses were superior to one particular model.

*Response:* The manufacturers of these lenses have not demonstrated clinical advantages and superiority over existing lenses, as the regulations require.

**Lenses Eligible for the Payment Adjustment**

In determining which lenses meet the criteria and definition of an NTIOL, we relied on the clinical data and evidence submitted to the FDA by the various manufacturers, demonstrating that these lenses have specific clinical advantages and superiority over existing lenses. These claims must be approved by the FDA for use in advertising and labeling. The lenses eligible for a payment adjustment are identified by a characteristic or subset of an NTIOL. The payment adjustment is effective for 5 years from the effective date of this notice. Any subsequent NTIOL with the same characteristic, and determined to be eligible for a payment adjustment, will receive the payment adjustment for the remainder of the 5 year period. Based on the FDA's approval process as required by our regulations, the following lenses are eligible for a payment adjustment of \$50 when

furnished by an ambulatory surgical center:

Manufacturer: Allergan

Lens and Model Number: AMO Array Multifocal Model SA40N

Characteristic: Multifocal

Procedure Code: Q1001—NTIOL Category 1

Manufacturer: STAAR Surgical Company

Lens and Model Numbers: Elastic Ultraviolet-Absorbing Silicone Posterior Chamber

Intraocular Lens with Toric Optic Models AA4203T, AA4203TF, and AA4203TL

Characteristic: Reduction in Preexisting Astigmatism

Procedure Code: Q1002—NTIOL Category 2

#### Payment Adjustments made to ASCs

Payment adjustments made to ASCs that provide these lenses will be effective on May 18, 2000 and continue until May 18, 2005.

**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: April 11, 2000.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

[FR Doc. 00-10970 Filed 5-2-00; 8:45 am]

BILLING CODE 4120-01-P

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Health Resources and Services Administration

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

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

#### Proposed Project: Application for the National Health Service Corps (NHSC) Scholarship Program (OMB No. 0915-0146); Extension

The National Health Service Corps (NHSC) Scholarship Program was established to help alleviate the geographic and specialty maldistribution of physicians and other health practitioners in the United States. Under this program, health professions students are offered scholarships in return for service in a federally designated Health Professional Shortage Area (HPSA). The Scholarship Program provides the NHSC with the health professionals it requires to carry out its mission of providing primary health care to HPSA populations in areas of greatest need. Students are supported who are well qualified to participate in the NHSC Scholarship Program and who want to assist the NHSC in its mission, both during and after their period of obligated service. Scholars are selected for these competitive awards based on the information provided in the application and during the semistructured personal interview that is conducted by a team of two interviewers who use a structured scoring procedure. Awards are made to applicants that demonstrate a high potential for providing quality primary health care services.

The estimated response burden is as follows:

| Form              | Number of respondents | Responses per respondent | Hours per response | Total burden hours |
|-------------------|-----------------------|--------------------------|--------------------|--------------------|
| Application ..... | 2,000                 | 1                        | 1                  | 2,000              |
| Interview .....   | 1,100                 | 1                        | 1                  | 1,100              |
| Total .....       | 3,100                 | .....                    | .....              | 3,100              |

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Wendy A. Taylor, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: April 26, 2000.

Jane Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 00-10930 Filed 5-2-00; 8:45 am]

BILLING CODE 4160-15-P

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Health Resources and Services Administration

##### Federal Set-Aside Program; Special Projects of Regional and National Significance; Data Utilization and Enhancement: Cooperative Agreements for State Information Systems

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice of availability of funds.

**SUMMARY:** The Health Resources and Services Administration (HRSA) announces that approximately \$428,000 in fiscal year (FY) 2000 funds is

available for 6 to 10 cooperative agreements to improve maternal and child health State information systems. All awards will be made under the program authority of section 502(a) of the Social Security Act, the Maternal and Child Health (MCH) Federal Set-Aside Program (42 U.S.C. 702(a)). This Data Utilization and Enhancement (DUE) Cooperative Agreement Program (CFDA #93.110 U) will be administered by the Maternal and Child Health Bureau (MCHB), HRSA. Projects will be approved for a 3-year period, with awards at average yearly amounts ranging from \$30,000 to \$80,000. Funds for DUE cooperative agreements are appropriated by Public Law 106-113.

The DUE competition announced in this notice is a successor to a similar