

- 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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1225-GNC]

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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.