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 (including, clinical trials, case studies, and 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 (FOIA), 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 IOLs 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 merely solicits interested parties to submit requests for review of the appropriateness of the payment amount with regard to a particular IOL furnished by an ASC.

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 million 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 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 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.

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

Dated: February 5, 2004.

Dennis G. Smith,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 04–4274 Filed 2–26–04; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–4090–N]

Medicare Program; Town Hall Meeting on Proposed Collection—Comment Request for Skilled Nursing Facility Advance Beneficiary Notice (SNFABN)

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

ACTION: Notice of meeting.

SUMMARY: This notice announces a Town Hall meeting to solicit input from the public on the proposed use of a Skilled Nursing Facility Advance Beneficiary Notice (SNFABN). Interested persons are invited to comment on the SNFABN Notice (CMS–10055 form) collection instrument, the associated burden 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 associated time 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. The meeting is open to the public, but attendance is limited to space available.

DATES: The Town Hall meeting will be held on Wednesday, March 16, 2004, from 1 p.m. to 4 p.m., e.s.t.

ADDRESSES: The Town Hall meeting will be held in the Multi-Purpose Room at the Centers for Medicare & Medicaid Services (CMS), 7500 Security Boulevard, Baltimore, Maryland 21244.

FOR FURTHER INFORMATION CONTACT: E. Joan Collins by phone at (410) 786–4618, via e-mail at *ecollins1@cms.hhs.gov,* or by fax at (410) 786–9963.

SUPPLEMENTARY INFORMATION:

I. Background

The Skilled Nursing Facility Advance Beneficiary Notice (SNFABN) replaces the Skilled Nursing Facility (SNF) Notices Of Non-Coverage previously used for notification purposes. SNFs must also meet the advance beneficiary notice (ABN) Standards in § 40.3 of chapter 30, Financial Liability Protections, of the IOM Pub. 100–4 at *http://www.cms.hhs.gov/manuals/104_claims/clm104c30.pdf* in completing and delivering SNFABNs.

A SNFABN is a CMS-approved written notice that the SNF gives to a Medicare beneficiary, or to their authorized representative, before extended care services or items are furnished, reduced, or terminated when the SNF, the Utilization Review entity, the Quality Improvement Organization, or the Medicare contractor believes that Medicare will not pay for, or will not continue to pay for, extended care services that the SNF furnishes and that a physician ordered on the basis of one of the following statutory exclusions:

- Not reasonable and necessary ("medical necessity") for the diagnosis or treatment of illness, injury, or to improve the functioning of a malformed body member—section 1862(a)(1) of the Social Security Act (the Act); or
- Custodial care ("not a covered level of care")—section 1862(a)(9) of the Act.

These exclusions provide the only statutory authority for application of the limitation on liability (LOL) provision at section 1879 of the Act to denied SNF claims.

The SNFABN (CMS–10055 form) is for use with SNF Prospective Payment System services. This form satisfies the requirements under LOL for advance beneficiary notice and the beneficiary's agreement to pay. The use of any other notices or of modified SNFABNs may be ineffective in protecting users from liability. The SNFABN must be prepared with an original and at least one patient copy, a SNF copy containing the signature of the patient or authorized representative, an attending physician copy, and (when necessary) a Medicare contractor copy. SNFs may produce SNFABNs using self-carboning paper and other methods of producing copies, including photocopying, printing, and electronic generation, but they must conform to the Form CMS–10055 design.

This Town Hall meeting is intended to provide a forum for all interested individuals to comment on and discuss the SNFABN. The SNFABN form and instructions may be reviewed prior to the public meeting by accessing *http://www.cms.hhs.gov/medicare/bni* on the Internet. This information is available for immediate review.

II. Meeting Format

Registered persons from the public may discuss and make individual recommendations concerning the Skilled Nursing Facility Advance Beneficiary Notice. Individuals who wish to make formal presentations must include that information when registering. Presentations must be brief, and three written copies must be submitted to accompany the oral presentation. Presenters may also make copies available for approximately 70 meeting participants.

III. Registration Instructions

Representatives of providers and suppliers furnishing skilled nursing facility services, health care consumer advocacy groups, and other members of the public who wish to participate in the public meeting are asked to notify us, in advance, of their interest in attending. Interested persons may register by providing notification to E. Joan Collins either by telephone at (410) 786–4618, fax at (410) 786–9963, or by e-mail at *ecollins1@cms.hhs.gov.* Please submit the following information when registering: name, company name, address, telephone number, and e-mail address and an indication of whether you wish to make a formal presentation.

Because this meeting will be located on Federal property, for security reasons, any persons wishing to attend this meeting must register by close of business on March 10, 2004. In order to gain access to the building and grounds, participants must show to the Federal Protective Service or guard service personnel government-issued photo identification and a copy of their registration confirmation. Individuals who have not registered in advance will not be allowed to enter the building to attend the meeting. Seating capacity is limited to the first 250 registrants.

The on-site check-in for visitors will be held from 12 noon until 1 p.m., followed by opening remarks. Please allow sufficient time to arrive to go through the security checkpoints. It is suggested that you arrive at 7500 Security Boulevard no later than 12 noon so that you will be able to arrive promptly at the meeting by 1 p.m. All items brought to us, whether personal or for the purpose of demonstration or to support a presentation, are subject to inspection.

Individuals requiring sign language interpretation or other special accommodations must provide that information upon registering for the meeting.

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

Dated: February 12, 2004.

Dennis G. Smith,

Acting Administrator, Centers for Medicare and Medicaid Services.

[FR Doc. 04–4275 Filed 2–26–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1268–N]

Medicare Program; Town Hall Meeting on the Fiscal Year 2005 Applications for New Medical Services and Technologies Add-On Payments Under the Hospital Inpatient Prospective Payment System

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

ACTION: Notice of meeting.