

government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$6 to \$29 million or less annually. For purposes of the RFA, all hospices are considered to be small entities. Individuals and States are not included in the definition of a small entity. This notice is the result of a statutory formula that does not involve any agency discretion or policy. Therefore, we do not believe further regulatory analysis is necessary because there are no regulatory options to be considered.

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.

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 expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. Because participation in the SCHIP program on the part of States is voluntary, any payments and expenditures States make or incur on behalf of the program that are not reimbursed by the Federal Government are made voluntarily. This notice will not create an unfunded mandate on States, tribal, or local governments. Therefore, we are not required to perform an assessment of the costs and benefits of these regulations.

Executive Order 13132 establishes certain requirements that an agency must meet when it publishes a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have reviewed this notice and have determined that it does not significantly affect States' rights, roles, and responsibilities.

Low-income children will benefit from payments under this program through increased opportunities for health insurance coverage. We believe this notice will have an overall positive impact by informing States, the District of Columbia, and Commonwealths and Territories of the extent to which they are permitted to expend funds under their child health plans using the FY

2000 and FY 2001 allotment's redistribution and retained amounts.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

(Section 1102 of the Social Security Act (42 U.S.C. 1302))

(Catalog of Federal Domestic Assistance Program No. 93.767, State Children's Health Insurance Program)

Dated: March 5, 2004.

**Dennis G. Smith,**

*Acting Administrator, Centers for Medicare & Medicaid Services.*

Dated: March 25, 2004.

**Tommy G. Thompson,**

*Secretary.*

[FR Doc. 04-14580 Filed 7-22-04; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare and Medicaid Services

**[CMS-2202-PN]**

**RIN 0938-ZA52**

#### Medicare and Medicaid Programs; Application by the American Association for Accreditation of Ambulatory Surgery Facilities, Inc., for Continued Deeming Authority for Ambulatory Surgical Centers

**AGENCY:** Centers for Medicare and Medicaid Services, HHS.

**ACTION:** Proposed notice.

**SUMMARY:** This proposed notice acknowledges the receipt of a renewal application by the American Association for Accreditation of Ambulatory Surgery Facilities, Inc. for approval as a national accreditation program for ambulatory surgical centers that wish to participate in the Medicare or Medicaid programs. The statute requires that within 60 days of receipt of an organization's written request, CMS publish a proposed notice that identifies the national accrediting body making the request, describing the nature of the request, and providing at least a 30-day public comment period. **DATES:** To be assured of consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on August 23, 2004.

**ADDRESSES:** In commenting, please refer to file code CMS-2202-PN. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on the issues in this notice to <http://www.cms.hhs.gov/regulations/ecomments>. (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-2202-PN, P.O. Box 8018, Baltimore, MD 21244-8018.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-7195 in advance to schedule your arrival with one of our staff members. Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244-1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

**FOR FURTHER INFORMATION CONTACT:** Milonda H. Mitchell, (410) 786-3511.

#### **SUPPLEMENTARY INFORMATION:**

*Submitting Comments:* We welcome comments from the public on all issues set forth in this proposed notice to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS-2202-PN and the specific "issue identifier" that precedes the section on which you choose to comment.

*Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. After the close of the comment period, CMS posts all

electronic comments received before the close of the comment period on its public web site. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, Yolanda Hayes, (410) 786-7195.

This **Federal Register** document is available from the **Federal Register** online database through *GPO Access*, a service of the U.S. Government Printing Office. The web site address is: <http://www.gpoaccess.gov/fr/index.html>.

### I. Background

[If you choose to comment on issues in this section, please include the caption "BACKGROUND" at the beginning of your comments.]

Under the Medicare program, eligible beneficiaries may receive covered services in an ambulatory surgical center (ASC), provided the ASC meets certain requirements. Section 1832(a)(2)(F)(i) of the Social Security Act (the Act) establishes the authority for the Secretary to establish distinct criteria for a facility seeking designation as an ASC. Under this authority, the Secretary has set forth in regulations minimum requirements that an ASC must meet to participate in Medicare. The regulations at 42 CFR part 416 (Ambulatory Surgical Services) specify the conditions under which Medicare makes payments for covered services provided by an ASC. Types of Medicare payment for ASC services can be found at § 416.120. Applicable regulations concerning provider agreements are at part 489 (Provider Agreements and Supplier Approval) and those pertaining to the survey and certification of facilities are at part 488 (Survey Certification and Enforcement Procedures), subpart A (General Provisions) and subpart B (Special Requirements).

In order for ASC services to be covered under the Medicare program, the ASC must be licensed by a State agency as an ASC. The licensure must be in place at the time the ASC is certified by a State survey agency as complying with the conditions or requirements set forth in part 416 of our regulations. Then, the ASC is subject to regular surveys by a State survey agency to determine whether it continues to meet these requirements (currently approved under OMB's #0938-0690 and

0938-0266). There is an alternative, however, to surveys by State agencies.

As it applies to ASCs, section 1865(b)(1) of the Act permits "accredited" provider entities to be exempt from routine surveys by State survey agencies to determine compliance with Medicare conditions for coverage. Accreditation by an accreditation organization is voluntary and is not required for Medicare participation. This section of the Act provides that, if a provider entity demonstrates through accreditation that all applicable Medicare conditions are met or exceeded, CMS shall "deem" it as having met the requirements.

If an accreditation organization is recognized in this manner with respect to a specific facility type (such as an ASC), any facility accredited by a national accrediting body's approved program is deemed to meet the Medicare conditions. A national accreditation organization applying for approval of "deeming authority" under part 488, subpart A must provide us with reasonable assurance that the accreditation organization requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning renewal of an accreditation organizations' deeming authority are set forth at § 488.4 and § 488.8(d)(3). The regulations at § 488.8(d)(3) require accreditation organizations to reapply for continued approval of deeming authority every 6 years, or sooner if we so determine. Our recognition of the American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF's) accreditation program for ASCs will terminate on December 2, 2004.

### II. Approval of Deeming Organizations

[If you choose to comment on issues in this section, please include the caption "Approval of Deeming Organizations" at the beginning of your comments.]

Section 1865 (b)(2) of the Act requires that our findings concerning review of national accrediting organization's requirements consider, among other factors, the reapplying accreditation organization's requirements for accreditation, survey procedures, resources for conducting required surveys, capacity to furnish information for use in enforcement activities, monitoring procedures for provider entities found not in compliance with the conditions or requirements, and ability to provide us with the necessary data for validation (currently approved under OMB's #0938-0690 and 0938-0266).

Section 1865(b)(3)(A) of the Act further requires that we publish, within 60 days of receipt of an organization's complete reapplication, a notice identifying the national accreditation body making the request, describing the nature of the request, and providing at least a 30-day public comment period. We have 210 days from our receipt of a completed application to publish approval or denial of the application.

The purpose of this proposed notice is to inform the public of our consideration of AAAASF's request to review its "deeming authority" for ASCs. This notice also solicits public comment on the ability of AAAASF's requirements to meet or exceed the Medicare conditions for coverage for ASCs.

### III. Evaluation of Deeming Authority Request

[If you choose to comment on issues in this section, please include the caption "Evaluation of Deeming Authority Request" at the beginning of your comments.]

On May 24, 2004, AAAASF submitted all the necessary materials concerning its request for renewal as a deeming organization for ASCs to enable us to make a determination. Under section 1865(b)(2) of the Act and regulations at § 488.8 (Federal review of accreditation organizations), our review and evaluation of AAAASF will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of AAAASF standards for an ASC as compared with our comparable ASC conditions for coverage.
- AAAASF's survey process to determine the following:
  - The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training.
  - The comparability of AAAASF's processes to that of State agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.
  - AAAASF's processes and procedures for monitoring providers or suppliers found out of compliance with AAAASF's program requirements. These monitoring procedures are used only when AAAASF identifies noncompliance. If noncompliance is identified through validation reviews, the survey agency monitors corrections as specified at § 488.7(d).
  - AAAASF's capacity to report deficiencies to the surveyed facilities

- and respond to the facility's plan of correction in a timely manner.
- AAAASF's capacity to provide us with electronic data in ASCII comparable code, and reports necessary for effective validation and assessment of the organization's survey process.
- The adequacy of AAAASF's staff and other resources, and its financial viability.
- AAAASF's capacity to adequately fund required surveys.
- AAAASF's policies with respect to whether surveys are announced or unannounced.
- AAAASF's agreement to provide us with a copy of the most current accreditation survey together with any other information related to the survey as we may require (including corrective action plans).

#### IV. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

#### V. Response to Comments and Notice Upon Completion of Evaluation

[If you choose to comment on issues in this section, please include the caption "Response to Comments and Notice Upon Completion of Evaluation" at the beginning of your comments.]

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all public comments we receive by the date and time specified in the **DATES** section of this preamble, and when we proceed with a final notice, we will respond to the public comments in the preamble to the document.

Upon completion of our evaluation, including evaluation of comments received as a result of this notice, we will publish a final notice in the **Federal Register** announcing the result of our evaluation.

In accordance with the provisions of Executive Order 12866, the Office of Management and Budget did not review this proposed notice.

In accordance with Executive Order 13132, we have determined that this proposed notice would not have a significant effect the rights of States, local, or tribal governments.

**Authority:** Section 1865 of the Social Security Act (42 U.S.C. 1395bb)

(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: July 1, 2004.

**Mark B. McClellan,**

*Administrator, Centers for Medicare and Medicaid Services.*

[FR Doc. 04-16431 Filed 7-22-04; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-3112-NC2]

**RIN 0938-ZA49**

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

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

**ACTION:** Notice with public comment period.

**SUMMARY:** This notice with public comment period acknowledges receipt of materials submitted by entities requesting review of the appropriateness of the Medicare payment amount for new technology lenses furnished by Ambulatory Surgical Centers (ASCs). In response to the February 27, 2004 **Federal Register** notice entitled "Medicare Program; Calendar Year 2004 Review of the Appropriateness of Payment Amounts for New Technology Intraocular Lenses (NTIOLs) Furnished by Ambulatory Surgical Centers" we received a total of three timely applications for review by the March 29, 2004 public comment due date. Of the three received, one application was withdrawn by the requester. In this notice we summarize timely applications received and solicit public comments on the two intraocular lenses (IOL) under review.

**DATES:** To be assured consideration, comments regarding the intraocular lenses specified in this notice must be received at one of the addresses provided below, no later than 5 p.m. on August 23, 2004.

**ADDRESSES:** In commenting, please refer to file code CMS-3112-NC2. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to <http://www.cms.hhs.gov/regulations/ecomments> (attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word).

2. *By mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-3112-NC2, P.O. Box 8010, Baltimore, MD 21244-8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members. Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244-1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

**FOR FURTHER INFORMATION CONTACT:** Gay W. Burton, (410) 786-4564.

#### **SUPPLEMENTARY INFORMATION:**

*Submitting Comments:* We welcome comments from the public on the appropriateness of the Medicare payment amount for new technology intraocular lenses furnished by an ambulatory surgical center (ASC) listed in section II of this notice. You can assist us by referencing the file code CMS-3112-NC2.

*Inspection of Public Comments:* All public comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or