its decision-making documentation and processes met our standards. We also observed a survey in real time to see that it met or exceeded our standards. As a result of our review of the documents and observations, we requested certain clarifications to AOA's survey and communications processes. These clarifications were provided as indicated above, and changes were made to the documentation in the application. Therefore, we recognize AOA as a national accreditation organization for hospitals that request participation in the Medicare program, effective March 25, 2005 through September 25, 2009.

VII. Collection of Information Requirements

This document does not impose any information collection and record keeping requirements subject to the Paperwork Reduction Act (PRA). Consequently, it does not need to be reviewed by the Office of Management and Budget (OMB) under the authority of the PRA. The requirements associated with granting and withdrawal of deeming authority to national accreditation, codified in part 488, ''Survey, Certification, and Enforcement Procedures,'' are currently approved by OMB under OMB approval number 0938–0690, with an expiration date of October 31, 2005.

VIII. Regulatory Impact Statement

We have examined the impacts of this notice as required by Executive Order 12866 and the Regulatory Flexibility Act (RFA) (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). The RFA requires agencies to analyze options for regulatory relief for small businesses. For purposes of the RFA, States and individuals are not considered small entities.

Also, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis for any notice that may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we consider a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds.

This notice merely recognizes AOA as a national accreditation organization for hospitals that request participation in the Medicare program. As evidenced by the following data for the cost of surveys, there are neither significant costs nor savings for the program and administrative budgets of the Medicare program. This notice is not a major rule as defined in Title 5, United States Code, section 804(2) and is not an economically significant rule under Executive Order 12866.

Therefore, we have determined, and the Secretary certifies, that this notice will not result in a significant impact on a substantial number of small entities and will not have a significant effect on the operations of a substantial number of small rural hospitals. Therefore, we are not preparing analyses for either the RFA or section 1102(b) of the Act.

In an effort to better ensure the health, safety, and services of beneficiaries in hospitals already certified, and to provide relief to State budgets in this time of tight fiscal constraints, we deem hospitals accredited by the AOA as meeting our Medicare hospital conditions of participation.

In accordance with Executive Order 13122, Federalism, we have included various provisions throughout this regulation that demonstrate cooperation with the States. For example, while the provisions of this notice may reduce the number of surveys a State Agency performs for Medicare certification of hospital, it may engender additional validation surveys to assess the performance of the AOA survey process and standards as the validation process expands with the growth of deemed status facilities. State officials will remain responsible for any survey and certification requirements that are allegedly not being enforced.

IX. Executive Order 12866 Statement

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by OMB.

Authority: Sec. 1865(b)(3)(A) of the Social Security Act (42 U.S.C. 1395bb(b)(3)(A)).

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.778, Medical Assistance Program)

Dated: February 18, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 05–5550 Filed 3–24–05; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–2256–FN]

Medicare and Medicaid Programs; Reapproval of the Deeming Authority of the Community Health Accreditation Program (CHAP) for Home Health Agencies

AGENCY: Centers for Medicare and Medicaid Services, HHS.

ACTION: Final notice.

SUMMARY: This notice announces our decision to approve the Community Health Accreditation Program for continued recognition as a national accreditation program for home health agencies seeking to participate in the Medicare or Medicaid programs.

DATES: *Effective Date:* This final notice is effective March 31, 2005 through March 31, 2008.

FOR FURTHER INFORMATION CONTACT: Cindy Melanson, (410) 786–0310.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in a Home Health Agency (HHA) provided certain requirements are met. Sections 1861(o) and 1891 of the Social Security Act (the Act) establish distinct criteria for facilities seeking designation as an HHA program. The regulations at 42 CFR part 484 specify the conditions that an HHA must meet in order to participate in the Medicare program, the scope of covered services, and the conditions for Medicare payment for home health care. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488.

Generally, to enter into an agreement, an HHA must first be certified by a state survey agency as complying with the conditions or requirements set forth in part 484 of our regulations. Then, the HHA is subject to regular surveys by a state survey agency to determine whether it continues to meet those requirements. There is an alternative, however, to surveys by state agencies.

Section 1865(b)(1) of the Act provides that, if a provider entity demonstrates through accreditation by an approved national accreditation organization that all applicable Medicare conditions are met or exceeded, we would ''deem'' those provider entities as having met the

requirements. Accreditation by an accreditation organization is voluntary and is not required for Medicare participation.

If an accreditation organization is recognized by the Secretary as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program would be 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 reapproval of accrediting organizations 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 as we determine. The Community Health Accreditation Program's (CHAP's) term of approval as a recognized accreditation program for HHAs expires March 31, 2005.

II. Deeming Applications Approval Process

Section 1865(b)(3)(A) of the Act provides a statutory timetable to ensure that our review of deeming applications is conducted in a timely manner. The Act provides us with 210 calendar days after the date of receipt of an application to complete our survey activities and application review process. Within 60 days of receiving a completed application, we must publish a notice in the **Federal Register** that identifies the national accreditation body making the request, describes the request, and provides no less than a 30-day public comment period. At the end of the 210-day period, we must publish an approval or denial of the application.

III. Proposed Notice

On September 24, 2004, we published a proposed notice (69 FR 57307) announcing the CHAP's request for reapproval as a deeming organization for HHAs. In the proposed notice, we detailed our evaluation criteria. Under section 1865(b)(2) of the Act and our regulations at § 488.4 (Application and reapplication procedures for accreditation organizations), we conducted a review of the CHAP application in accordance with the criteria specified by our regulation, which include, but are not limited to the following:

- An onsite administrative review of CHAP's (1) corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its surveyors; (4) ability to investigate and respond appropriately to complaints against accredited facilities; and (5) survey review and decision-making process for accreditation.
- A comparison of CHAP's HHA accreditation standards to our current Medicare HHA conditions for participation.
- A documentation review of CHAP's survey processes to:
  + Determine the composition of the survey team, surveyor qualifications, and the ability of CHAP to provide continuing surveyor training.
  + Compare CHAP's processes to those of State survey agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.
  + Evaluate CHAP's procedures for monitoring providers or suppliers found to be out of compliance with CHAP program requirements. The monitoring procedures are used only when the CHAP identifies noncompliance. If noncompliance is identified through validation reviews, the survey agency monitors corrections as specified at § 488.7(d).
  + Assess CHAP's ability to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.
  + Establish CHAP's ability to provide us with electronic data in ASCII–comparable code and reports necessary for effective validation and assessment of CHAP's survey process.
  + Determine the adequacy of staff and other resources.
  + Review CHAP's ability to provide adequate funding for performing required surveys.
  + Confirm CHAP's policies with respect to whether surveys are announced or unannounced.
  + Obtain CHAP'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.

In accordance with section 1865(b)(3)(A) of the Act, the September 24, 2004 proposed notice (69 FR 57307) also solicited public comments regarding whether CHAP's requirements met or exceeded the Medicare conditions of participation for HHAs. In response to our proposed notice, we did receive a comment of support for CHAP to remain a deeming authority for home health agencies.

IV. Provisions of the Final Notice

A. Differences Between the Community Health Accreditation Program's and Medicare's Conditions and Survey Requirements

We compared the standards contained in CHAP's ''Standard of Excellence for HHAs'' and ''The Core Standards of Excellence'' and its survey process in the ''Reapplication for Deeming Authority for HHA Programs'' with the Medicare HHA conditions for participation and our State Operations Manual. Based on our review and evaluation as described in section III of this final notice, CHAP has made the following revisions and clarifications:

- CHAP included the assignment of the home health aide to a specific patient as its standard to meet the requirements at § 484.36(c)(1).
- CHAP stated in its element that the home health agency must comply with subpart I of 42 CFR part 489 and each patient must receive written information on the HHA's policies on advance directives in order to comply with the requirements at § 484.10(c)(2)(ii).
- CHAP addressed in its element the provisions of the drug regimen review at § 484.55(c).

B. Term of Approval

Based on the review and observations described in section III of this final notice, we have determined that CHAP's requirements for HHAs meet or exceed our requirements. Therefore, we recognize the CHAP as a national accreditation organization for HHAs that request participation in the Medicare program. Because we are planning to revise the conditions of participation for HHAs over the next 3 years, we believe it is most appropriate to renew the current deeming authority for a similar period. As a result, we are approving CHAP's program effective March 31, 2005 through March 31, 2008.

V. Collection of Information Requirements

This final notice does not impose any information collection and record keeping requirements subject to the Paperwork Reduction Act (PRA). Consequently, it does not need to be reviewed by the Office of Management and Budget (OMB) under the authority of the PRA. The requirements associated with granting and withdrawal of deeming authority to national accreditation organizations, codified in 42 CFR part 488, ''Survey, Certification, and Enforcement Procedures,'' are currently approved by OMB under OMB approval number 0938–0690.

VI. Regulatory Impact Statement

We have examined the impact of this final notice as required by Executive Order 12866 and the Regulatory Flexibility Act (RFA) (Pub. L. 98–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). The RFA requires agencies to analyze options for regulatory relief for small businesses. For purposes of the RFA, States and individuals are not considered small entities.

Also, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis for any notice that may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we consider a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds.

This final notice recognizes CHAP as a national accreditation organization for HHAs that request participation in the Medicare program. There are neither significant costs nor savings for the program and administrative budgets of Medicare. Therefore, this final notice is not a major rule as defined in Title 5, United States Code, section 804(2) and is not an economically significant rule under Executive Order 12866. We have determined, and the Secretary certifies, that this final notice will not result in a significant impact on a substantial number of small entities and will not have a significant effect on the operations of a substantial number of small rural hospitals. Therefore, we are not preparing analyses for either the RFA or section 1102(b) of the Act.

In an effort to better assure the health, safety, and services of beneficiaries in HHAs already certified as well as provide relief to State budgets in this time of tight fiscal restraints, we deem HHAs accredited by CHAP as meeting our Medicare requirements. Thus, we continue our focus on assuring the health and safety of services by providers and suppliers already certified for participation in a cost-effective manner.

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget. In accordance with Executive Order 13132, we have determined that this final notice will not significantly affect 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—Supplemental Medical Insurance Program)

Dated: February 11, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 05–5034 Filed 3–24–05; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3112–FN; 0938–ZA49]

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

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

ACTION: Final notice.

SUMMARY: In this final notice, we summarize timely public comments received in response to our July 23, 2004 notice with public comment period and announce our decision concerning applications submitted by Alcon Laboratories, Incorporated (Alcon) and Advanced Medical Optics (AMO) (formerly Pharmacia & Upjohn Company) [1] to adjust the Medicare payment amounts for certain intraocular lenses (IOLs) on the basis that they are new technology intraocular lenses (NTIOLs).

This is the third of three statutorily required **Federal Register** documents. On February 27, 2004, we published a notice in the **Federal Register** that solicited interested parties to submit requests for review of the appropriateness of the payment amount for an IOL furnished by an ambulatory surgical center. On July 23, 2004, we published a notice with comment period entitled ''Adjustment in Payment Amounts for New Technology Intraocular Lenses Furnished by Ambulatory Surgical Centers'' acknowledging timely receipt of application materials from Alcon and AMO. In this final notice, we announce our decision to disapprove the NTIOL applications submitted by both Alcon and AMO.

[1] Advanced Medical Optics acquired Pharmacia & Upjohn Company's surgical product line on June 28, 2004 and is now the party of interest for purposes of this Final Notice.

FOR FURTHER INFORMATION CONTACT: Michael Lyman, (410) 786–6938.

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)(1) of SSAA 1994 required us to develop and implement a process under which interested parties may request a review of the appropriateness of the payment amount for intraocular lenses furnished by ASCs under section 1833(i)(2)(A)(iii) of the Social Security Act (the Act) on the basis that those lenses constitute a class of new technology intraocular lenses.

On June 16, 1999, we published a final rule in the **Federal Register** entitled ''Adjustment in Payment Amounts for New Technology Intraocular Lenses Furnished by Ambulatory Surgical Centers'' (64 FR 32198), which added subpart F to 42 CFR part 416. The June 16, 1999 final rule established a process for adjusting payment amounts for 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 are NTIOLs. The payment adjustment applies for a 5-year period that begins when we recognize a payment adjustment for the first IOL in a new class of technology, as explained below. Any subsequent IOLs having the same characteristics as the first IOL recognized for a payment adjustment will receive the same adjustment for the remainder of the 5-year period established by the first recognized NTIOL. In accordance with the payment review process specified in § 416.185, after July 16, 2002, the $50 adjustment amount can be modified through proposed and final rulemaking in connection with ASC services. To date, we have made no changes to the payment amount and have opted not to change the adjustment for calendar year 2004 (CY 2004).

We have previously approved two classes of NTIOLs: Multifocal and Reduction in Preexisting Astigmatism. These IOLs were approved for NTIOL status during calendar year 2000.

II. NTIOL Applications Submitted for Calendar Year 2004

On February 27, 2004, we published a notice in the **Federal Register** entitled