



Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-05-28

DATE: May 12, 2005

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Renewal of Deeming Authority for Hospitals Accredited by the American Osteopathic Association (AOA), and Home Health Agencies Accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the Community Health Accreditation Program (CHAP).

Letter Summary

This memorandum announces the Centers for Medicare & Medicaid Services' (CMS) decision to re-approve the following applications for deeming authority as national accrediting organizations for hospitals and home health agencies seeking to participate in Medicare:

- AOA for hospitals,
- JCAHO for home health agencies, and
- CHAP for home health agencies

Section 1865(b) of the Social Security Act (the Act) permits providers and suppliers accredited by an approved national accrediting body to be "*deemed*" to meet Medicare Conditions for Coverage or Participation. To receive approval, accreditation organizations must demonstrate to CMS that their requirements meet or exceed the Medicare conditions.

CMS reviewed three applications for renewal of deeming authority in accordance with 42 CFR 488.4 and 42 CFR 488.8: AOA's accreditation program for hospitals, and JCAHO's and CHAP's accreditation program for home health agencies. Our review included each accreditation organization's survey and accrediting process as well as its health and safety standards. CMS' review found AOA's accreditation program for hospitals, JCAHO's accreditation program for home health agencies and CHAP's accreditation program for home health agencies to meet or exceed the Medicare Conditions of Participation (CoP).

CMS announced the decision to re-approve these organizations in the March 25, 2005, *Federal Register* (see attached). This deeming authority under 1865(b) of the Act is limited to the Medicare CoPs and does not apply to other Medicare requirements such as enrollment and licensure. AOA's deeming authority for hospitals is for a period of four and one-half years from March 25, 2005 through Sept 25, 2009. JCAHO's deeming authority for home health agencies is for a period of three years from March 31, 2005 through March 31, 2008. CHAP's deeming authority is for a period of three years from March 31, 2005 through March 31, 2008.

If you have any questions regarding this memorandum, please contact Cindy Melanson at 410-786-0310 or via E-mail at cindy.melanson@cms.hhs.gov.

Effective date: Immediately. The state agency should disseminate this information within 30 days of the date of this memorandum.

Training: The information contained in this announcement should be shared with relevant survey and certification staff, their managers, and the state/RO training coordinator.

/s/

Thomas E. Hamilton

Attachments

cc: Survey and Certification Regional Office Management
George Reuther, Director AOA-HFAP
Maryanne Popovich, Director Home Care Accreditation Services, JCAHO
Terry Duncomb, President, CHAP

A covered entity may amend or supplement its response at any time and may propose voluntary compliance through a corrective action plan at any time. CMS may require modifications in the terms of a proposed corrective action plan as a prerequisite to accepting the corrective action plan. If a corrective action plan is accepted, CMS will actively monitor the plan, and the covered entity will be required to periodically report to CMS its progress towards compliance. If the covered entity comes into voluntary compliance, CMS will notify the complainant by mail or electronically. The parties to the complaint will be notified, as appropriate, when the complaint is closed.

CMS will make reasonable efforts to secure a timely response from the covered entity. If the covered entity fails or refuses to provide the information sought, an investigational subpoena may be issued in accordance with 45 CFR 160.504 to require the attendance and testimony of witnesses and/or the production of any other evidence sought in furtherance of the investigation.

After finding that a violation exists, the Secretary will pursue other options, such as, but not limited to, civil money penalties.

Collection of Information Requirements

The form associated with this complaint process entitled, "HIPAA Non-Privacy Complaint Form", is currently approved under OMB control number 0938-0948.

Authority: Sections 1102 and 1171 through 1179 of the Social Security Act (42 U.S.C. 1302a and 1320d through 1320d-8).

Dated: December 7, 2004.

Tommy G. Thompson,
Secretary.

[FR Doc. 05-5795 Filed 3-24-05; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-2204-FN]

Medicare and Medicaid Programs; Reapproval of the Deeming Authority of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) for Home Health Agencies

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Final notice.

SUMMARY: This notice announces our decision to approve the Joint Commission on Accreditation of Healthcare Organizations for continued recognition as a national accreditation program for home health agencies seeking to participate in the Medicare or Medicaid programs.

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 Joint Commission on Accreditation of Healthcare Organizations' (JCAHO'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 57305) announcing the JCAHO'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) and § 488.8 (Federal review of accreditation organization), we conducted a review of the JCAHO application in accordance with the criteria specified by our regulation, which include, but are not limited to the following:

- An onsite administrative review of JCAHO'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 JCAHO's HHA accreditation standards to our current Medicare HHA conditions for participation.

- A documentation review of JCAHO's survey processes to:
 - + Determine the composition of the survey team, surveyor qualifications, and the ability of JCAHO to provide continuing surveyor training.
 - + Compare JCAHO'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 JCAHO's procedures for monitoring providers or suppliers found to be out of compliance with JCAHO program requirements. The monitoring procedures are used only when the JCAHO identifies noncompliance. If noncompliance is identified through validation reviews, the survey agency monitors corrections as specified at § 488.7(d).
 - + Assess JCAHO's ability to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.
 - + Establish JCAHO's ability to provide us with electronic data in ASCII-comparable code and reports necessary for effective validation and assessment of JCAHO's survey process.
 - + Determine the adequacy of staff and other resources.
 - + Review JCAHO's ability to provide adequate funding for performing required surveys.
 - + Confirm JCAHO's policies with respect to whether surveys are announced or unannounced.
 - + Obtain JCAHO'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 57305) also solicited public comments regarding whether JCAHO's requirements met or exceeded the Medicare conditions of participation for HHA. We received no public comments in response to our proposed notice.

IV. Provisions of the Final Notice

A. Differences Between the Joint Commission on Accreditation of Healthcare Organizations' and Medicare's Conditions and Survey Requirements

We compared the standards contained in JCAHO's "Comprehensive Accreditation Manual for Home Care" and its survey process in the "Request for Continued Deeming Authority for Home Health Agencies Handbook" with the Medicare HHA conditions for participation and our State Operations

Manual. Our review and evaluation of JCAHO's deeming application, which were conducted as described in section III of this final notice yielded the following:

- To comply with the requirements at § 484.20(a), JCAHO has agreed not to schedule the unannounced home health survey without written confirmation of a successful Outcomes and Assessment Information Set (OASIS) transmission.
- To meet the requirements at § 488.4(b)(3)(v), JCAHO amended its policies and procedures to permit its surveyors to serve as witnesses if we take an adverse action based on accreditation findings.

B. Term of Approval

Based on the review and observations described in sections III and IV of this final notice, we have determined that JCAHO's requirements for HHAs meet or exceed our requirements. Therefore, we recognize the JCAHO 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 JCAHO'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 JCAHO 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 JCAHO 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 18, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 05-5033 Filed 3-24-05; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-2208-FN]

Medicare and Medicaid Programs; Recognition of the American Osteopathic Association (AOA) for Continued Approval of Deeming Authority for Hospitals

AGENCY: Centers for Medicare and Medicaid Services, HHS.

ACTION: Final notice.

SUMMARY: This notice announces the Centers for Medicare & Medicaid Services' (CMS') reapproval of the American Osteopathic Association (AOA) as a national accreditation organization for hospitals that request participation in the Medicare program. We have determined that accreditation of hospitals by AOA demonstrates that all Medicare hospital conditions of participation are met or exceeded. Thus, CMS will continue to grant deemed status to those hospitals accredited by AOA.

DATES: *Effective Date:* This final notice is effective March 25, 2005 through September 25, 2009.

FOR FURTHER INFORMATION CONTACT: Marjorie Eddinger (410) 786-0375.

SUPPLEMENTARY INFORMATION:

I. Background

A. Laws and Regulations

Under the Medicare program, eligible beneficiaries may receive covered services in a hospital provided certain requirements are met. The regulations specifying the Medicare conditions of participation for hospitals are located in 42 CFR part 482. These conditions implement section 1861(e) of the Social Security Act (the Act), which specifies services covered as hospital care and the conditions that a hospital program must meet in order to participate in the Medicare program.

Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to the activities relating to the survey and certification of facilities are at 42 CFR part 488.

Generally, in order to enter into a provider agreement, a hospital must first

be certified by a State survey agency as complying with the conditions or standards set forth in the statute and part 482 of the regulations. Then, the hospital is subject to regular surveys by a State survey agency to determine whether it continues to meet Medicare requirements. There is an alternative, however, to surveys by State agencies.

Section 1865(b)(1) of the Act permits hospitals accredited by the AOA to be exempt from routine surveys by State survey agencies to determine compliance with Medicare conditions of participation. Accreditation by an accreditation organization is voluntary and is not required for Medicare participation. Section 1865(b)(1) of the Act provides that, if a provider demonstrates through accreditation that all applicable conditions are met or exceed the Medicare conditions, we shall "deem" the hospital as having met the health and safety requirements.

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 reapplication at least every 6 years and permit us to determine the required materials from those enumerated in § 488.4 and the deadline to reapply for continued approval of deeming authority.

II. Approval of Deeming Organizations

Section 1865(b)(2) of the Act further requires that our findings concerning review of national accrediting organizations consider, among other factors, the accreditation organization's requirements for accreditation, its survey procedures, its ability to provide adequate resources for conducting required surveys and ability to supply information for use in enforcement activities, its monitoring procedures for provider entities found out of compliance with the conditions or requirements, and its ability to provide us with necessary data for validation.

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

The purpose of this notice is to notify the public of our decision to approve AOA's request for continuation of its deeming authority. This decision is based on our finding that the AOA's

separate accreditation program for hospital care meets or exceeds the Medicare hospital conditions of participation.

III. Proposed Notice

On September 24, 2004, we published a proposed notice in the **Federal Register** (69 FR 57308) announcing AOA's request for reapproval as a deeming organization for hospitals. In the notice, we detailed the evaluation criteria. As set forth under section 1865(b)(2) of the Act and our regulations at § 488.8(d)(3)(i), our review and evaluation of the AOA application included the following:

1. An on-site administrative review of the corporate policies, resources to accomplish the accreditation surveys, program and surveyor evaluation and monitoring, AOA's ability to investigate and respond appropriately to complaints against accredited facilities, and the survey review and decision-making process for accreditation.

2. A determination of the equivalency of AOA's standards for a hospital to our comparable hospital conditions of participation.

3. A review through documentation and on-site observation of AOA's survey processes to determine the following:

- The comparability of AOA's processes to those of State agencies, including survey frequency and whether surveys are announced or unannounced.
- The adequacy of the guidance and instructions and survey forms AOA provides to surveyors.

- AOA's procedures for monitoring providers or suppliers found to be out of compliance with program requirements. (These procedures are used only when AOA identifies noncompliance.)

4. AOA's procedures for responding to complaints and for coordinating these activities with appropriate licensing bodies and ombudsmen programs.

5. AOA's policies and procedures for identifying potential fraud and abuse and its coordination with, or reporting to, CMS.

6. AOA's survey team, the content and frequency of the in-service training provided, the evaluation systems used to assess the performance of surveyors, and potential conflict-of-interest policies and procedures.

7. AOA's data management system and reports used to assess its surveys and accreditation decisions, and its ability to provide us with electronic data and new statistical validation information including the number, accreditation status, and resurvey cycle for facilities; the number, types, and resolution times for follow up when

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”

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.

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.

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

Dated: February 18, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 05-5033 Filed 3-24-05; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-2208-FN]

Medicare and Medicaid Programs; Recognition of the American Osteopathic Association (AOA) for Continued Approval of Deeming Authority for Hospitals

AGENCY: Centers for Medicare and Medicaid Services, HHS.

ACTION: Final notice.

SUMMARY: This notice announces the Centers for Medicare & Medicaid Services' (CMS') reapproval of the American Osteopathic Association (AOA) as a national accreditation organization for hospitals that request participation in the Medicare program. We have determined that accreditation of hospitals by AOA demonstrates that all Medicare hospital conditions of participation are met or exceeded. Thus, CMS will continue to grant deemed status to those hospitals accredited by AOA.

DATES: *Effective Date:* This final notice is effective March 25, 2005 through September 25, 2009.

FOR FURTHER INFORMATION CONTACT: Marjorie Eddinger (410) 786-0375.

SUPPLEMENTARY INFORMATION:

I. Background

A. Laws and Regulations

Under the Medicare program, eligible beneficiaries may receive covered services in a hospital provided certain requirements are met. The regulations specifying the Medicare conditions of participation for hospitals are located in 42 CFR part 482. These conditions implement section 1861(e) of the Social Security Act (the Act), which specifies services covered as hospital care and the conditions that a hospital program must meet in order to participate in the Medicare program.

Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to the activities relating to the survey and certification of facilities are at 42 CFR part 488.

Generally, in order to enter into a provider agreement, a hospital must first

be certified by a State survey agency as complying with the conditions or standards set forth in the statute and part 482 of the regulations. Then, the hospital is subject to regular surveys by a State survey agency to determine whether it continues to meet Medicare requirements. There is an alternative, however, to surveys by State agencies.

Section 1865(b)(1) of the Act permits hospitals accredited by the AOA to be exempt from routine surveys by State survey agencies to determine compliance with Medicare conditions of participation. Accreditation by an accreditation organization is voluntary and is not required for Medicare participation. Section 1865(b)(1) of the Act provides that, if a provider demonstrates through accreditation that all applicable conditions are met or exceed the Medicare conditions, we shall "deem" the hospital as having met the health and safety requirements.

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 reapplication at least every 6 years and permit us to determine the required materials from those enumerated in § 488.4 and the deadline to reapply for continued approval of deeming authority.

II. Approval of Deeming Organizations

Section 1865(b)(2) of the Act further requires that our findings concerning review of national accrediting organizations consider, among other factors, the accreditation organization's requirements for accreditation, its survey procedures, its ability to provide adequate resources for conducting required surveys and ability to supply information for use in enforcement activities, its monitoring procedures for provider entities found out of compliance with the conditions or requirements, and its ability to provide us with necessary data for validation.

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

The purpose of this notice is to notify the public of our decision to approve AOA's request for continuation of its deeming authority. This decision is based on our finding that the AOA's

separate accreditation program for hospital care meets or exceeds the Medicare hospital conditions of participation.

III. Proposed Notice

On September 24, 2004, we published a proposed notice in the **Federal Register** (69 FR 57308) announcing AOA's request for reapproval as a deeming organization for hospitals. In the notice, we detailed the evaluation criteria. As set forth under section 1865(b)(2) of the Act and our regulations at § 488.8(d)(3)(i), our review and evaluation of the AOA application included the following:

1. An on-site administrative review of the corporate policies, resources to accomplish the accreditation surveys, program and surveyor evaluation and monitoring, AOA's ability to investigate and respond appropriately to complaints against accredited facilities, and the survey review and decision-making process for accreditation.

2. A determination of the equivalency of AOA's standards for a hospital to our comparable hospital conditions of participation.

3. A review through documentation and on-site observation of AOA's survey processes to determine the following:

- The comparability of AOA's processes to those of State agencies, including survey frequency and whether surveys are announced or unannounced.
- The adequacy of the guidance and instructions and survey forms AOA provides to surveyors.

- AOA's procedures for monitoring providers or suppliers found to be out of compliance with program requirements. (These procedures are used only when AOA identifies noncompliance.)

4. AOA's procedures for responding to complaints and for coordinating these activities with appropriate licensing bodies and ombudsmen programs.

5. AOA's policies and procedures for identifying potential fraud and abuse and its coordination with, or reporting to, CMS.

6. AOA's survey team, the content and frequency of the in-service training provided, the evaluation systems used to assess the performance of surveyors, and potential conflict-of-interest policies and procedures.

7. AOA's data management system and reports used to assess its surveys and accreditation decisions, and its ability to provide us with electronic data and new statistical validation information including the number, accreditation status, and resurvey cycle for facilities; the number, types, and resolution times for follow up when

deficiencies are detected during surveys; the top 10 deficiencies found, and the number of actionable cases of noncompliance and the method and time frame for resolution.

8. A review of all types of accreditation status AOA offers and an assessment of the appropriateness of those for which AOA seeks deemed status.

9. A review of the pattern of AOA's deemed facilities (that is, types and duration of accreditation and its schedule of all planned full and partial surveys).

10. The adequacy of AOA's staff and other resources to perform the surveys, and its financial viability.

11. AOA's written agreement to:

- Meet our requirements to provide to all relevant parties, timely notifications of changes to accreditation status or ownership, to report to all relevant parties remedial actions or immediate jeopardy, and to conform its requirements to changes in Medicare requirements; and
- Permit its surveyors to serve as witnesses for us in adverse actions against its accredited facilities.

IV. Summary of Public Comments Received on the Proposed Notice and Our Responses

We received no public comments.

V. Review and Evaluation

Our review and evaluation of the AOA application, which were conducted as detailed above, yielded the following information.

We compared the standards contained in the AOA "Accreditation Requirements for Healthcare Facilities" and the AOA's survey process outlined in its "Survey Team Handbook" supplemented by flow charts of the survey process with the Medicare conditions of participation and the "State Operations Manual". The AOA has made the following revisions or clarifications.

1. AOA developed and implemented standards and survey processes to address the new Quality Assessment and Performance Improvement Program Condition of Participation in accordance with the provisions of § 482.21.

2. AOA developed and implemented standards and survey processes to address the new Life Safety from Fire Standard (which implements the use of the 2000 edition of the Life Safety Code of the National Fire Protection Association) in accordance with the provisions of § 482.41(b).

3. AOA developed and implemented standards and survey processes to address changes in the Discharge

Planning Condition of Participation in accordance with § 482.43.

4. AOA developed and implemented standards and survey processes to address changes in the Nursing Services Condition of Participation in accordance with § 482.23.

5. AOA developed and implemented standards and survey processes to address changes in the requirements for physician supervision of certified registered nurse anesthetists (CRNAs) in Anesthesia Services Condition of Participation in accordance with § 482.52.

6. AOA developed and implemented standards, explanations, and survey processes that are consistent with the Regulations at 42 CFR part 482 and CMS Interpretive Guidelines for the Hospital Conditions of Participation in Appendix A of the State Operations Manual which include the following:

- In order to meet the requirements of § 482.13(a)(2), AOA added wording to its standard that makes the governing body responsible for the grievance process.

- AOA added language to its standard 1.00.13 that the hospital must maintain a list of all contracted services, including scope and nature of services provided to meet the standard of § 482.12(e)(2).

- AOA included criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges in order to meet the requirements of § 482.22(c)(6).

- In order to comply with the requirements at § 482.27(c)(3)(i) and § 482.27(c)(3)(ii), AOA added language to its standard concerning the hospital's policies about the disposition of blood or blood products and quarantine all blood and blood products from previous donations in inventory.

- In order to meet the requirements of § 482.27(c)(1), AOA added the FDA definition of potentially infectious blood and blood products to its standard.

- AOA reworded its standard at 15.05.02 to address CMS restraint requirements at § 482.13(e)(2) and § 482.13(f)(2).

- In order to meet the requirements of §§ 482.13(b)(1) and § 482.13(b)(2), AOA added standards that included the patient's right to participate in the development and implementation of his or her plan of care, and the right to be informed of his or her health status, care planning, and treatment.

- In order to meet the requirements of § 482.23(b)(1), AOA added language to its standard to include that the

hospital must provide 24-hour registered nursing services at all times, except for rural hospitals that have in effect a 24-hour registered nursing waiver granted under § 488.54.

- AOA added standards to its chapter on Respiratory Services in order to meet the requirements at § 482.57, § 482.57(a), § 482.57(b), and § 482.57(b)(2).

- In order to meet the requirements of § 482.53(b) and § 482.53(b)(3), AOA added language to its chapter 23.00.01 on Nuclear Medicine Services.

- AOA added language to its standard to address the responsibility of daily management of the dietary services and that the individual was qualified by experience or training in order to meet the requirements at § 482.28(a)(1)(ii) and § 482.28(a)(1)(iii).

- To meet the requirements at § 482.28(b)(2), AOA added the language that nutritional needs must be met in accordance with recognized dietary practices and in accordance with orders of the practitioner or practitioners responsible for the care of the patients.

- AOA added language to its chapter on Surgical Services language that the organization of the surgical services must be appropriate to the scope of the services offered in order to meet CMS standards at § 482.51(a).

- In order to meet the requirements at § 482.51(b)(4), AOA added to its standard wording to state that there must be adequate provisions for immediate post-operative care.

7. All AOA hospital surveys will be unannounced effective January 1, 2006 in accordance with the CMS policy of unannounced hospital surveys.

8. AOA revised procedures and clarified its timeframes for complaint investigations in accordance with the State operations Manual.

9. AOA redesigned its survey process to emphasize the use of interviews and surveyor observations of patient care and other compliance activities in order to determine the hospital compliance with requirements.

VI. Results of Evaluation

We completed a standard-by-standard comparison of AOA's conditions or requirements for hospitals to determine whether they met or exceeded Medicare requirements. We found that, after requested revisions were made, AOA's requirements for hospitals did meet or exceed our requirements. In addition, we visited the corporate headquarters of AOA to validate the information it submitted and to verify that its administrative systems could adequately monitor compliance with its standards and survey processes and that

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