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