Dated: February 18, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

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

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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]

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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