

Development, Bureau of Primary Health Care, HRSA, at 301-594-4300.

Dated: August 24, 2009.

Mary K. Wakefield,  
Administrator.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-2299-FN]

#### Medicare and Medicaid Programs; Application of the American Osteopathic Association for Continued Deeming Authority for Hospitals

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

ACTION: Final notice.

**SUMMARY:** This notice announces our decision to approve the American Osteopathic Association (AOA) for continued recognition as a national accreditation program for hospitals seeking to participate in the Medicare or Medicaid programs.

**DATES:** *Effective Date:* This final notice is effective September 25, 2009 through September 25, 2013.

**FOR FURTHER INFORMATION CONTACT:**

Lillian Williams, (410) 786-8636.

Patricia Chmielewski, (410) 786-6899.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

Under the Medicare program, eligible beneficiaries may receive covered services from a hospital provided certain requirements are met. The regulations specifying the Medicare conditions of participation (CoPs) for hospitals are located at 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 located at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities are located 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 requirements set forth in the statute and part 482 of the regulations. Then, the hospital is subject to routine State agency surveys to determine whether it

continues to meet the Medicare requirements. There is an alternative, however, to State compliance surveys.

Section 1865(a)(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 may "deem" those provider entities as having met the requirements.

If an accreditation organization is recognized by the Secretary as having standards for accreditation that meet or exceed Medicare requirements, a provider entity accredited by the national accreditation organization approved program would be deemed to meet the Medicare conditions.

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

A national accreditation organization applying for 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 the reapproval of accreditation 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 deeming authority every 6 years or sooner as determined by CMS.

AOA's term of approval as a recognized accreditation program for hospitals expires September 25, 2009.

#### II. Deeming Applications Approval Process

Section 1865(a)(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 a complete application, with any documentation necessary to make a determination, to complete our survey activities and application review. Within 60 days of receiving a complete application, we must publish a notice in the **Federal Register** that identifies the national accreditation organization 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. Provisions of the Proposed Notice and Response to Comments

On April 24, 2009, we published a proposed notice in the **Federal Register** (74 FR 18728) announcing AOA's

request for reapproval as a deeming organization for hospitals. In this notice, we detailed the evaluation criteria.

Under section 1865(a)(2) of the Act and our regulations at § 488.4, we conducted a review of the AOA's application in accordance with the criteria specified by our regulations, which include, but are not limited to the following factors:

- An onsite administrative review of AOA'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 AOA's hospital accreditation standards to our current Medicare hospital CoPs.

- A documentation review of AOA's survey processes to:

- + Determine the composition of the survey team, surveyor qualifications, and AOA's ability to provide continuing surveyor training.

- + Compare AOA'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 AOA's procedures for monitoring providers or suppliers found to be out of compliance with AOA program requirements. The monitoring procedures are used only when AOA identifies noncompliance. If noncompliance is identified through validation reviews, the State survey agency monitors corrections as specified at § 488.7(d).

- + Assess AOA's ability to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

- + Establish AOA's ability to provide us with electronic data and reports necessary for effective validation and assessment of AOA's survey process.

- + Determine the adequacy of staff and other resources.

- + Review AOA's ability to provide adequate funding for performing required surveys.

- + Confirm AOA's policies with respect to whether surveys are announced or unannounced.

- + Obtain AOA'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(a)(3)(A) of the Act, the April 24, 2009 proposed notice also solicited public comments regarding whether

AOA's requirements met or exceeded the Medicare CoPs for hospitals. We received 28 comments in response to our proposed notice.

All commenters expressed support for AOA's continued deeming authority for hospitals. Commenters stated that AOA's standards are clearly written and closely aligned with the Medicare CoPs, and that AOA's accreditation program provides hospitals with a viable alternative to other healthcare accreditation organizations.

#### IV. Provision of the Final Notice

##### A. Differences Between AOA's Standards and Requirements for Accreditation and Medicare's Conditions and Survey Requirements

We compared AOA's hospital accreditation requirements and survey process with the Medicare CoPs and survey process as outlined in the State Operations Manual (SOM). Our review and evaluation of AOA's deeming application, which were conducted as described in section III of this final notice, yielded the following:

- AOA revised its standards to ensure that a medical history and physical is completed and documented in accordance with the requirements at § 482.51(b)(1).
- To meet the requirements in the SOM Appendix A, AOA amended its surveyor team handbook to ensure all hospital survey teams include a Registered Nurse.
- AOA modified its policies related to the accreditation effective date in accordance with the requirements at § 489.13.
- AOA modified its policies regarding timeframes for sending and receiving a plan of correction (PoC) in accordance with section 2728 of the SOM.
- AOA revised its policies to include timeframes for investigation of complaints in accordance with the requirements at section 5075.9 of the SOM.
- AOA developed and implemented internal monitoring procedures to ensure its surveyors are trained and qualified to meet the requirements at § 488.4(a)(4).
- AOA developed an action plan to ensure that deemed status survey files are complete, accurate, and consistent with the requirements at § 488.6(a).
- AOA developed and conducted surveyor training on the documentation of deficiencies to ensure that all cited deficiencies contain a regulatory reference, a clear and detailed description of the deficient practice, and relevant finding.
- To meet the requirements at § 488.20(a) and § 488.28(a), AOA

developed a policy to ensure that facilities with condition level non-compliance on a recertification survey submit an acceptable PoC, and receive a follow up onsite focused survey.

- To meet the requirements at section 2005A2 of the SOM, AOA revised its policies and developed an internal tracking tool to ensure that facilities with condition level non-compliance on an initial survey receive an onsite follow-up full survey.

- To meet the requirements at § 488.4(b), AOA developed and incorporated measures to improve the accuracy and consistency of data submissions to CMS.

- To meet the requirements at 2700A of the SOM, AOA revised its policies on blackout dates.

- AOA revised its accreditation decision letters to ensure that they are accurate and contain all the required elements for the CMS Regional Office to render a decision regarding the deemed status of an accredited hospital.

- To meet the survey process requirements in Appendix A of the SOM, AOA developed a policy outlining the minimum number of inpatient records required for review during a certification survey.

- AOA removed all references to mandatory consultative services from its policies to avoid potential conflict of interest issues.

- To verify AOA's continued compliance with the provisions of this final notice, CMS will conduct a follow-up corporate onsite visit within one year of the date of publication of this notice.

##### B. Term of Approval

Based on the review and observations described in section III of this final notice, we have determined that AOA's requirements for hospitals meet or exceed our requirements. Therefore, we approve AOA as a national accreditation organization for hospitals that request participation in the Medicare program, effective September 25, 2009 through September 25, 2013.

#### V. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

#### VI. Regulatory Impact Statement

In accordance with the provisions of Executive Order 12866, this regulation

was not reviewed by the Office of Management and Budget.

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)

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: July 30, 2009.

Charlene Frizzera,

Acting Administrator, Centers for Medicare & Medicaid Services.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-7016-N]

#### Medicare Program; Request for Nominations for the Advisory Panel on Medicare Education

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

ACTION: Notice.

**SUMMARY:** This notice requests nominations for individuals to serve on the Advisory Panel on Medicare Education (the Panel) to fill current vacancies and vacancies that will become available in 2009. The Panel advises and makes recommendations to the Secretary of Health and Human Services and the Administrator of the Centers for Medicare & Medicaid Services on the effectiveness of consumer education strategies concerning the Medicare program.

**DATES:** *Deadline for Nominations by Regular Mail:* Monday, September 14, 2009 at 5 p.m., eastern daylight time (e.d.t.).

*Deadline for Nominations by Electronic Mail:* Monday, September 14, 2009 at 5 p.m., e.d.t.

**ADDRESSES:** *Regular Mail:* Dwayne E. Campbell, Office of External Affairs, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, S1-05-14, Baltimore, MD 21244-1850.

*Electronic Mail:*  
Dwayne.Campbell@cms.hhs.gov.

**FOR FURTHER INFORMATION CONTACT:** Dwayne E. Campbell, Health Insurance Specialist, Division of Forum and Conference Development, (410) 786-0291. Please refer to the CMS Advisory Committees Information Line (1-877-