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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

CMS-3281-FN

Medicare and Medicaid Programs: Continued Approval of American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA/HFAP's) Hospital Accreditation Program

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Final notice.

SUMMARY: This final notice announces our decision to approve American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA/HFAP) for continued recognition as a national accrediting organization for hospitals that wish to participate in the Medicare or Medicaid programs.

DATES: This final notice is effective September 25, 2013 through September 25, 2019.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in a hospital provided certain requirements are met. Section 1861(e) of the Social Security Act (the Act) establishes distinct criteria for facilities seeking designation as a hospital. 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. The regulations at 42 CFR part 482 specify the conditions that a hospital must meet to participate in the Medicare program, the scope of covered services, and the conditions for Medicare payment for hospitals.

Generally, to enter into an agreement, a hospital must first be certified by a State survey agency as complying with the conditions or requirements set forth in part 482. Thereafter, the hospital is subject to regular surveys by a State survey agency to determine whether it continues to meet these requirements. However, there is an alternative to surveys by state agencies. Certification by a nationally recognized accreditation program can substitute for ongoing state review.

Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by an approved national accrediting organization that all applicable Medicare conditions are met or exceeded, CMS will deem those provider entities as having met the requirements. Accreditation by an accrediting organization is voluntary and is not required for Medicare participation.

If an accrediting organization is recognized by the Secretary of the Department of Health and Human Services 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 have met the Medicare conditions. A national accrediting organization applying for approval of its accreditation program under part 488, subpart A, must provide CMS with reasonable assurance that the accrediting organization requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions.

Our regulations concerning the approval of accrediting organizations are set forth at §488.4 and §488.8(d)(3). The regulations at §488.8(d)(3) require accrediting organizations to

reapply for continued approval of its accreditation program every 6 years or sooner as determined by CMS.

The American Osteopathic Association/Healthcare Facilities Accreditation Program's (AOA/HFAP) current term of approval for their hospital accreditation program expires September 25, 2013.

II. Application Approval Process

Section 1865(a)(3)(A) of the Act provides a statutory timetable to ensure that our review of applications for CMS-approval of an accreditation program is conducted in a timely manner. The Act provides us 210 days after the date of receipt of a complete application, with any documentation necessary to make the determination, to complete our survey activities and application process. Within 60 days after receiving a complete application, we must publish a notice in the **Federal Register** that identifies the national accrediting 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 a notice in the **Federal Register** approving or denying the application.

III. Provisions of the Proposed Notice

On March 22, 2013, we published a proposed notice in the **Federal Register** (78 FR 17677) announcing AOA/HFAP's request for approval of its hospital accreditation program. In the proposed notice, we detailed our evaluation criteria. Under section 1865(a)(2) of the Act and in our regulations at §488.4 and §488.8, we conducted a review of AOA/HFAP's application in accordance with the criteria specified by our regulations, which include, but are not limited to the following:

- An onsite administrative review of AOA/HFAP'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.

- The comparison of AOA/HFAP's accreditation to our current Medicare hospital conditions of participation.

- A documentation review of AOA/HFAP's survey process to:

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

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

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

- ++ Establish AOA/HFAP's ability to provide CMS with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

- ++ Determine the adequacy of staff and other resources.

- ++ Confirm AOA/HFAP's ability to provide adequate funding for performing required

surveys.

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

++ Obtain AOA/HFAP's agreement to provide CMS 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 March 22, 2013 proposed notice also solicited public comments regarding whether AOA/HFAP's requirements met or exceeded the Medicare conditions of participation for hospitals. We received no comments in response to our proposed notice.

IV. Provisions of the Final Notice

A. Differences Between AOA/HFAP's Standards and Requirements for Accreditation and Medicare's Conditions and Survey requirements

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

- To meet the requirements at §482.41(a)(1), AOA/HFAP revised its standards to include the requirement for Type 1 Essential Electrical Systems (EES) generators in all hospitals.
- To meet the requirements at §482.41(b)(1)(ii), AOA/HFAP revised its standards to ensure roller latches no longer exist on hospital corridor doors.
- To meet the requirements at §482.41(c)(4), AOA/HFAP revised its standards to include the National Fire Protection Association (NFPA) 99:1999: 5-4.1.1 requirement that

addresses the capability of controlling the relative humidity at a level of 35 percent or greater within anesthetizing locations.

- To meet the requirements at §488.4 (a) (6), AOA/HFAP revised its “Complaint/Incident Management Policy,” to ensure all onsite complaint surveys are documented on a survey report.
- To meet the requirements of Section 2728 of the SOM, AOA/HFAP will continue to use its internal monitoring plan to ensure timeframes for sending or receiving a plan of correction (PoC) are met.
- To meet the requirements of Section 2728B of the SOM, AOA/HFAP will continue to conduct monthly internal audits to ensure accepted PoC’s contain all of the required elements.

B. Term of Approval

Based on our review and observations described in section III of this final notice, we have determined that AOA/HFAP’s hospital accreditation program requirements meet or exceed our requirements. Therefore, we approve AOA/HFAP as a national accreditation organization for hospitals that request participation in the Medicare program, effective September 25, 2013 through September 25, 2019.

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).

CMS-3281-FN

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program;
No. 93.773 Medicare--Hospital Insurance Program; and No. 93.774, Medicare--Supplementary
Medical Insurance Program)

Dated: July 19, 2013

Marilyn Tavenner,

Administrator,

Centers for Medicare & Medicaid Services.

BILLING CODE:

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