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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3370-FN]

Medicare and Medicaid Programs: Approval of an Application from the Accreditation Association for Hospitals and Health Systems/Healthcare Facilities Accreditation Program for Continued CMS Approval of its Hospital Accreditation Program

AGENCY: Centers for Medicare and Medicaid Services, HHS.

ACTION: Final notice.

SUMMARY: This final notice announces our decision to approve the Accreditation Association for Hospitals and Health Systems/Healthcare Facilities Accreditation Program (AAHHS/HFAP) (formerly known as the 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, 2019 through September 25, 2023.

FOR FURTHER INFORMATION CONTACT: Tara Lemons (410) 786-3030, Mary Ellen Palowitch (410) 786-4496, or Monda Shaver, (410) 786-3410

SUPPLEMENTARY INFORMATION:

I. Background

A healthcare provider may enter into an agreement with Medicare to participate in the program as a hospital provided certain requirements are met. Section 1861(e) of the Social

Security Act (the Act) establishes criteria for providers seeking participation in Medicare as a hospital. Regulations concerning Medicare provider agreements in general are at 42 CFR part 489 and those pertaining to the survey and certification for Medicare participation of providers and certain types of suppliers are at 42 CFR part 488. The regulations at 42 CFR part 482 specify the specific conditions that a provider must meet to participate in the Medicare program as a hospital. Hospitals that wish to be paid under the Medicaid program must be approved to participate in Medicare, in accordance with 42 CFR §440.10(a)(3)(iii).

Generally, to enter into a Medicare hospital provider agreement, a facility must first be certified as complying with the conditions set forth in part 482 and recommended to the Centers for Medicare & Medicaid Services (CMS) for participation by a State survey agency. Thereafter, the hospital is subject to periodic surveys by a State survey agency to determine whether it continues to meet these conditions. However, there is an alternative to certification surveys by State agencies. Accreditation by a nationally recognized Medicare accreditation program approved by CMS may substitute for both initial and ongoing state review.

Section 1865(a)(1) of the Act provides that, if the Secretary of the Department of Health and Human Services (the Secretary) finds that accreditation of a provider entity by an approved national accrediting organization meets or exceeds all applicable Medicare conditions, we may treat the provider entity as having met those conditions, that is, we may “deem” the provider entity to be in compliance. Accreditation by an accrediting organization is voluntary and is not required for Medicare participation.

Part 488, subpart A, implements the provisions of section 1865 of the Act and requires that a national accrediting organization applying for approval of its Medicare accreditation

program must provide CMS with reasonable assurance that the accrediting organization requires its 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 §488.5. The regulations at §488.5(e)(2)(i) require an accrediting organization to reapply for continued approval of its Medicare accreditation program every 6 years or sooner as determined by CMS. On January 14, 2019, CMS recognized the change in ownership from American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA/HFAP) to the new owner, Accreditation Association for Hospitals and Health Systems/Healthcare Facilities Accreditation Program (AAHHS/HFAP). This recognition included a transfer and continuation of CMS-approval for AAHHS/HFAP's hospital accreditation program, as was published under the AOA/HFAP approval on August 28, 2013. AAHHS/HFAP's term of approval as a recognized Medicare accreditation program for hospitals expires September 25, 2019.

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 provide 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 October 17, 2018, we published a proposed notice in the **Federal Register** (83 FR 52458) announcing AAHHS/HFAP's request for continued approval of its Medicare 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 §488.5, we conducted a review of AAHHS/HFAP's Medicare hospital accreditation application in accordance with the criteria specified by our regulations, which include, but are not limited to the following:

- An onsite administrative review of AAHHS/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 hospital surveyors; (4) ability to investigate and respond appropriately to complaints against accredited hospitals; and, (5) survey review and decision-making process for accreditation.

- A comparison of AAHHS/HFAP's Medicare accreditation program standards to our current Medicare hospital Conditions of Participation (CoP).

- A documentation review of AAHHS/HFAP's survey process to do the following:
 - ++ Determine the composition of the survey team, surveyor qualifications, and AAHHS/HFAP's ability to provide continuing surveyor training.

- ++ Compare AAHHS/HFAP's processes to those we require of State survey agencies, including periodic resurvey and the ability to investigate and respond appropriately to complaints against accredited hospitals.

- ++ Evaluate AAHHS/HFAP's procedures for monitoring hospitals it has found to be out of compliance with AAHHS/HFAP's program requirements. (This pertains only to monitoring

procedures when AAHHS/HFAP identifies non-compliance. If non-compliance is identified by a State survey agency through a validation survey, the State survey agency monitors corrections as specified at §488.9(c)).

++ Assess AAHHS/HFAP's ability to report deficiencies to the surveyed hospitals and respond to the hospital's plan of correction in a timely manner.

++ Establish AAHHS/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 AAHHS/HFAP's staff and other resources.

++ Confirm AAHHS/HFAP's ability to provide adequate funding for performing required surveys.

++ Confirm AAHHS/HFAP's policies with respect to surveys being unannounced.

++ Obtain AAHHS/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 October 17, 2018 proposed notice also solicited public comments regarding whether AAHHS/HFAP's requirements met or exceeded the Medicare CoP for hospitals. There were no comments submitted.

IV. Provisions of the Final Notice

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

We compared AAHHS/HFAP's hospital accreditation requirements and survey process with the Medicare CoP at part 482, and the survey and certification process requirements of parts

488 and 489. AAHHS/HFAP's standards crosswalk, which maps AAHHS/HFAP's standards with the corresponding requirements under the Medicare CoP, was also examined to ensure that the appropriate CMS regulation was included in citations as appropriate. We reviewed and evaluated AAHHS/HFAP's hospital application, as described in section III of this final notice. This review yielded the following areas where, as of the date of this notice, AAHHS/HFAP has revised its standards and certification processes:

- §482.13(e), to ensure that AAHHS/HFAP's crosswalk reflects the comparable restraint and seclusion requirements.
- §482.13(h)(1) through §482.13(h)(4) regarding patient visitation rights, to ensure that redundant language in its standards is removed.
- §482.15(d)(1)(i) regarding emergency preparedness training, to ensure AAHHS/HFAP's standards require a comparable standard to this CMS requirement.
- §482.15(d)(1)(iii) regarding documentation of emergency preparedness training, to ensure AAHHS/HFAP's standards require compliance with this CMS requirement.
- §482.15(d)(1)(iv) regarding demonstration of staff knowledge of emergency preparedness procedures, to ensure AAHHS/HFAP's standards require compliance with this CMS requirement.
- §482.15(d)(2)(i) through §482.15(d)(2)(ii)(B), to ensure AAHHS/HFAP's standards require compliance with these CMS requirements regarding staff emergency preparedness testing.
- §482.15(e)(3), to clarify its requirement related to maintaining an emergency onsite fuel source.

- §482.15(f)(4) through §482.15(f)(5), to address these CMS requirements regarding emergency plans, policies and procedures for integrated health care systems.
- §482.21, to ensure that redundant language regarding the Quality Assessment and Performance Improvement Condition of participation is removed.
- §482.23(b)(1) regarding nursing services, to ensure that CMS references are accurately referenced.
- §482.27(b)(11) regarding hepatitis C virus notifications, to ensure that redundant language in its standard is removed.
- §482.41(a)(2), to ensure that the requirement for emergency water supply for structures is adequately addressed.
- §482.41(b)(1)(i) and §482.41(b)(2), to ensure that the 2012 edition of the Life Safety Code is accurately referenced.
- §482.41(b)(7), to clarify that Alcohol-Based Hand Rub dispensers are permitted to be installed in areas other than exit access corridors.
- §482.41(b)(8)(ii), to ensure that fire watches are to be maintained until the system is back in service.
- §488.5(a)(4)(ii), to ensure that survey activities, including the review of all records, are administered in a comprehensive method comparable to CMS processes.
- §488.5(a)(4)(iii), to ensure that patient sample sizes are based on the hospital's average daily census and meets minimum sample requirements; and to ensure compliance with AAHHS/HFAP's policies related to documentation related to

medical record review.

- §488.5(a)(4)(iv), to ensure findings of non-compliance are documented under all appropriate CMS standards where non-compliance is found; and to ensure that all citations of noncompliance accurately identify the appropriate CMS requirement.
- §488.5(a)(12), to ensure that its complaint investigations address the minimum patient sample size for review, as applicable.
- §488.26(b), to ensure that surveyor documentation is reviewed for manner and degree of non-compliance and subsequently cited at the appropriate level (that is, condition versus standard level).
- §488.28(a), to ensure that facility plans of correction contain all required elements to be considered comparable to CMS.

B. Term of Approval

Based on our review and observations described in section III of this final notice, we have determined that AAHHS/HFAP's hospital program requirements meet or exceed our requirements. Therefore, we approve AAHHS/HFAP as a national accreditation organization for hospitals that request participation in the Medicare program, effective September 25, 2019 through September 25, 2023.

V. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

Dated: March 12, 2019.

Seema Verma,

Administrator,

Centers for Medicare & Medicaid Services.

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