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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3362-FN]

Medicare and Medicaid Programs: Approval of the Accreditation Association for Ambulatory Health Care, Inc. (AAAHC) Application for Continued Approval of its Ambulatory Surgical Center Accreditation Program

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

ACTION: Final notice.

SUMMARY: This final notice announces our decision to approve the Accreditation Association for Ambulatory Health Care, Inc. for continued recognition as a national accrediting organization for ambulatory surgical centers that wish to participate in the Medicare or Medicaid programs.

DATES: Applicable *Date*: December 20, 2018 through December 20, 2024.

FOR FURTHER INFORMATION CONTACT: Lillian Williams, (410) 786-8636, Monda Shaver, (410) 786-3410, or Renee Henry, (410) 786-7828.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in an Ambulatory Surgical Center (ASC) provided certain requirements are met. Sections 1832(a)(2)(F)(i) of the Social Security Act (the Act) establishes distinct criteria for facilities seeking designation as an ASC. 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 416, specify the conditions that

an ASC must meet in order to participate in the Medicare program, the scope of covered services and the conditions for Medicare payment for ASCs.

Generally, to enter into an agreement, an ASC must first be certified as complying with the conditions set forth in part 416 and recommended to the Centers for Medicare & Medicaid Services (CMS) for participation by a state survey agency. Thereafter, the ASC 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 finds that accreditation of a provider entity by an approved national accrediting organization meets or exceeds all applicable Medicare conditions or requirements, we may deem the provider entity as having met those conditions or requirements. Accreditation by an accrediting organization is voluntary and is not required for Medicare participation.

A national accrediting organization applying for approval of its Medicare accreditation program under part 488, subpart A, 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 §488.4.

II. Application Approval Process

Section 1865(a)(3)(A) of the Act requires that we publish, within 60 days of receipt of an organization's complete application, a notice identifying the national accrediting body making the request, describing the nature of the request, and providing at least a 30-day public comment period. We have 210 days from the receipt of a complete application to publish a notice of

approval or denial of the application.

III. Provisions of the Proposed Notice

On July 26, 2018, we published a proposed notice entitled "Application from the Accreditation Association for Ambulatory Health Care, Inc. (AAAHC) for Continued Approval of its Ambulatory Surgical Center Accreditation Program" in the **Federal Register** (83 FR 35486) announcing AAAHC's request for continued approval of its Medicare ASC 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 AAAHC's Medicare ASC accreditation renewal application in accordance with the criteria specified by our regulations, which include, but are not limited to the following:

• An onsite administrative review of AAAHC's: (1) Corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its ASC surveyors; (4) ability to investigate and respond appropriately to complaints against accredited ASCs; and, (5) survey review and decision-making process for accreditation.

• The comparison of AAAHC's Medicare ASC accreditation program standards to our current Medicare ASC conditions for coverage (CfCs).

• A documentation review of AAAHC's survey process to:

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

++ Compare AAAHC'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 ASCs.

++ Evaluate AAAHC's procedures for monitoring ASCs it has found to be out of compliance with AAAHC's program requirements. (This pertains only to monitoring procedures when AAAHC identifies non-compliance. If noncompliance is identified by a state survey agency through a validation survey, the state survey agency monitors corrections as specified at §488.9(c).)

++ Assess AAAHC's ability to report deficiencies to the surveyed ASC and respond to the ASCs plan of correction in a timely manner.

++ Establish AAAHC'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 AAAHC's staff and other resources.

++ Confirm AAAHC's ability to provide adequate funding for performing required surveys.

++ Confirm AAAHC's policies with respect to surveys being unannounced.

++ Obtain AAAHC'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 July 26, 2018 proposed notice also solicited public comments regarding whether AAAHC's requirements met or exceeded the Medicare CfCs for ASCs. We received no comments in response to our proposed notice.

IV. Provisions of the Final Notice

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

We compared AAAHC's ASC accreditation program requirements and survey process with the Medicare CfCs at part 416, and the survey and certification process requirements of

parts 488 and 489. Our review and evaluation of AAAHC's ASC application, which were conducted as described in section III of this final notice, yielded the following areas where, as of the date of this notice, AAAHC has revised its standards and certification processes in order to meet the requirements at:

- § 416.44(b)(1), to ensure its standards appropriately reference Life Safety Code requirements;
- § 416.44(c), to ensure its standards appropriately reference Life Safety Code requirements;
- § 416.44(c)(1)(iv), to ensure its standards appropriately reference Life Safety Code requirements;
- § 488.5(a)(4)(ii), to ensure comparability of AAAHC's survey process and surveyor guidance to those required for state survey agencies conducting federal Medicare surveys for the same provider or supplier type;
- § 488.5(a)(4)(iv), to ensure all identified areas of non-compliance are clearly documented and cited appropriately in the final survey report.
- § 488.5(a)(7) through (9), to ensure its surveyors are appropriately qualified, trained and maintain competence during extended periods of time without conducting a survey;
- § 488.5(a)(11)(ii), to ensure accurate survey findings are reported to CMS;
- § 488.5(a)(12), to ensure complaints are triaged appropriately and surveyed within the required timeframes;
- § 488.18(a), to ensure that the findings are documented and written within the principles of documentation.

- § 488.26(b), to ensure deficiencies are cited at the appropriate level based on manner and degree of findings; and

- § 488.28(d), to ensure that its policies for correction of deficiencies in ASCs is comparable to CMS requirements, requiring that deficiencies normally must be corrected within 60 days.

- § 489.13(c), to ensure that all accreditation requirements have been met before granting accreditation and making a recommendation for participation or continued participation in the Medicare program comparable to CMS requirements, requiring that deficiencies normally must be corrected within 60 days.

B. Term of Approval

Based on our review and observations described in section III of this final notice, we approve AAAHC as a national accreditation organization for ASCs that request participation in the Medicare program, effective December 20, 2018 through December 20, 2024.

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: December 14, 2018.

Seema Verma,

Administrator,

Centers for Medicare & Medicaid Services.

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