DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

CMS-3265-FN

Medicare and Medicaid Programs; Approval of the Accreditation Association for Ambulatory Health Care (AAAHC) Application for Continuing CMS Approval of its Ambulatory Surgical Center 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 Ambulatory Health Care (AAAHC) for continued recognition as a national accrediting organization for ambulatory surgical centers (ASCs) that wish to participate in the Medicare and/or Medicaid programs.

EFFECTIVE DATE: This notice is effective December 20, 2012 through December 20, 2018.

FOR FURTHER INFORMATION CONTACT:

Lillian Williams, (410) 786-8636.

Cindy Melanson, (410) 786-0310.

Patricia Chmielewski, (410) 786-6899.

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. Section 1832(a)(2)(F)(i) of the Social Security Act (the Act) requires ASCs to meet health, safety, and other standards specified by the Secretary. 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 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 by a State survey agency as complying with the conditions or requirements set forth in part 416. Thereafter, the ASC 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.

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

If an accrediting organization is recognized by the Secretary as having standards for accreditation that meet or exceed Medicare requirements, a provider entity accredited by the national accrediting body's approved program would be deemed to meet the Medicare conditions. A national accrediting organization applying for approval of its accreditation program under part 488, subpart A, must provide us 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 Ambulatory Health Care's (AAAHC) current term of approval for their ASC accreditation program expires on December 20, 2012.

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 June 22, 2012, we published a proposed notice in the **Federal Register** (77 FR 37678) entitled, "Application from the Accreditation Association for Ambulatory Health Care for Continued Approval of its Ambulatory Surgical Centers Accreditation Program" announcing the AAAHC's request for continued approval of its ASC accreditation program.

Under section 1865(a)(2) of the Act and in our regulations at §488.4 and §488.8, we conducted a review of AAAHC'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 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 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 AAAHC's accreditation to CMS's current Medicare ASC conditions for coverage.
- 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 of State survey agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

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

+ Assess AAAHC's ability to report deficiencies to the surveyed facilities and respond to the facility's 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 staff and other resources.

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

+ Confirm AAAHC's policies with respect to whether surveys are announced or

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 June 22, 2012 proposed notice also solicited public comments regarding whether AAAHC's requirements met or exceeded the Medicare conditions for coverage for ASCs. We received no public 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's Conditions and Survey Requirements

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

- To meet the requirements at §416.41(a), AAAHC revised its standards to address all contracts.
- To meet the requirements at §416.41(c)(1), AAAHC revised its standards to address "the emergency care of patients."
- To meet the requirements at §416.44, AAAHC revised its standards to address the Life Safety Code (LSC) survey and created a policy to ensure all ASCs receive a complete and comprehensive LSC survey.

- To meet the requirements at §416.47(a), AAAHC revised its standards to address the use of patients records.
- To meet the requirements at §416.47(b), AAAHC revised its standards to address the requirement that every record must be accurate, legible, and promptly completed.
- To meet the requirements at §416.50(b)(1)(ii), AAAHC revised its standards to ensure patients have the right to "voice grievances regarding treatment or care that is (or fails to be) provided."
- To meet the requirements at §488.4(a)(5), AAAHC modified its policies to improve the accuracy and consistency of data submissions to CMS.
- To meet the requirements at §488.4(a)(6), AAAHC modified its policies to ensure that all compliant investigations are conducted in accordance with the requirements in the SOM, chapter 5.
- To meet the requirements at §488.28(a) and Section 2726 of the SOM, AAAHC amended its policies to require a Plan of Correction (PoC) for all deficiencies cited.
- To meet the requirements at section 2728A of the SOM, AAAHC modified its policies to include all of the required elements in an acceptable PoC.
- To meet the requirements at 2728B of the SOM, AAAHC modified its policies regarding timeframes for requesting PoCs.
- To meet the requirements at section 2728B of the SOM, AAAHC modified its policies to ensure that accepted PoCs contain all elements specified in the SOM.
- To meet the Medicare requirements at section 3012 of the SOM related to focused and follow-up surveys, AAAHC amended its policies to include the 45-day response

timeframe.

- To meet the requirements at Appendix L of the SOM-- Sampling for Initial Surveys, Recertification Surveys, or Representative Sample Validation Surveys, AAAHC revised its policies to ensure surveyors review at least the required minimum number of medical records during a survey.
- To meet the requirements at Appendix L of the SOM-- Use of the Infection Control Tool, AAAHC revised its survey protocol to ensure consistency, completeness and proper implementation of the Infection Control Tool.
- To verify AAAHC's continued compliance with the provisions of the LSC, CMS will conduct a follow-up survey observation within 1 year of the date of publication of this final notice.

B. Term of Approval

Based on our review and observations described in section III of this final notice, we have determined that AAAHC's requirements for ASCs meet or exceed our requirements. Therefore, we approve AAAHC as a national accreditation organization for ASCs that request participation in the Medicare program, effective December 20, 2012 through December 20, 2018.

V. Collection of Information Requirements

This document does not impose any reporting, recordkeeping or third-party disclosure 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).

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

Dated: November 20, 2012

_____

Marilyn Tavenner,

Acting Administrator,

Centers for Medicare & Medicaid Services.

BILLING CODE 4120-01-P

[FR Doc. 2012-28728 Filed 11/23/2012 at 8:45 am; Publication Date: 11/27/2012]