



## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Centers for Medicare & Medicaid Services**

**[CMS-3358-FN]**

### **Medicare and Medicaid Programs: Application from the American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF) for Continued Approval of its Ambulatory Surgical Center Accreditation Program.**

**AGENCY:** Centers for Medicare & Medicaid Services, HHS.

**ACTION:** Notice.

**SUMMARY:** This final notice announces our decision to approve the American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF) for continued recognition as a national accrediting organization for ambulatory surgical centers (ASCs) that wish to participate in the Medicare or Medicaid programs.

**DATES:** This notice is applicable November 27, 2018 through November 27, 2024.

**FOR FURTHER INFORMATION CONTACT:** Erin McCoy, (410) 786-2337, 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, 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.

## **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 June 22, 2018, we published a proposed notice in the **Federal Register** (83 FR 29120) announcing the American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF'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 AAAASF'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 AAAASF'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 AAAASF's Medicare ASC accreditation program standards to our current Medicare ASC Conditions for Coverage (CfCs).

- A documentation review of AAAASF's survey process to:

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

++ Compare AAAASF's processes to those CMS require of state survey agencies, including periodic resurvey and the ability to investigate and respond appropriately to complaints against accredited ASCs.

++ Evaluate AAAASF's procedures for monitoring ASCs it has found to be out of compliance with AAAASF's program requirements. (This pertains only to monitoring procedures when AAAASF 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 AAAASF's ability to report deficiencies to the surveyed ASC and respond to the ASCs plan of correction in a timely manner.

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

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

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

++ Obtain AAAASF'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, 2018 proposed notice also solicited public comments regarding whether AAAASF'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 AAAASF's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements

We compared AAAASF's ASC accreditation program requirements and survey process with the Medicare CfCs at 42 CFR Part 416, and the survey and certification process requirements of Parts 488 and 489. Our review and evaluation of AAAASF'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, AAAASF has revised its standards and certification processes in order to meet the requirements at:

- §416.2, to ensure its standards appropriately reference §416.2 subparts B and C;
- §416.44(b)(1) to ensure its standards appropriately reference Life Safety Code requirements;
- §416.44(b)(2) to ensure its standards appropriately reference that only Life Safety Code deficiencies may request a time-limited waiver as part of the ASC's plan of correction;
- §416.47(b)(4) to ensure its standards appropriately address each required element of §416.47(b)(4);
- §416.47(b)(5) to ensure its standards appropriately address §416.47(b)(5);
- §416.52(a)(1) through (3) to ensure its standards appropriately address the requirements for a comprehensive medical history and physical assessment;
- §488.5(a)(4)(i) to ensure that its policies clearly support and convey the unannounced nature of Medicare deemed status surveys;
- §488.5(a)(4)(ii) to ensure comparability of AAAASF'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)(iii) to ensure that copies of AAAASF's guidelines and instructions to surveyors appropriately address Medicare requirements;
- §488.5(a)(7) through (9) to ensure its surveyors are qualified and evaluated on performance;
- §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;
- §488.26(b) and (c) 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.

#### B. Term of Approval

Based on our review and observations described in section III of this final notice, we approve AAAASF as a national accreditation organization for ASCs that request participation in the Medicare program, effective November 27, 2018 through November 27, 2024.

#### **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).

Dated: November 7, 2018.

**Seema Verma,**

*Administrator,*

*Centers for Medicare & Medicaid Services.*

[FR Doc. 2018-25013 Filed: 11/16/2018 8:45 am; Publication Date: 11/19/2018]