**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

**[CMS-3369-FN]**

# Medicare and Medicaid Programs: Application from the American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF) for its Outpatient Physical Therapy and Speech Language Pathology Services Accreditation Program.

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

**ACTION**: Final 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 clinics, rehabilitation agencies, or public health agencies that furnish outpatient physical therapy and speech language pathology services that wish to participate in the Medicare or Medicaid programs.

**DATES**: The approval announced in this notice is effective on April 4, 2019 through April 4, 2025.

**FOR FURTHER INFORMATION CONTACT:**

Erin Imhoff, (410) 786-2337; Monda Shaver, (410) 786-3410; or Tara Lemons, (410) 786-3030.

**SUPPLEMENTARY INFORMATION:**

## I. Background

Under Section 1861(p) of the Social Security Act (the Act), eligible beneficiaries may receive outpatient physical therapy and speech language pathology (OPT) services from a provider of services, a clinic, rehabilitation agency, a public health agency, or others, provided certain

requirements are met. Section 1832(a)(2)(C) of the Act permits payment for OPT services. 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 485 subpart H, specify the conditions that a clinic, rehabilitation agency or public health agency ("OPT providers") must meet in order to participate in the Medicare program, the scope of covered services, and the conditions for Medicare payment for OPT providers.

Generally, to enter into an agreement, an OPT provider must first be certified by a State survey agency as complying with the conditions of participation set forth in part 485, subpart H of our Medicare regulations. Thereafter, the OPT provider is subject to regular surveys by a state survey agency to determine whether it continues to meet these requirements.

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

If an AO is recognized by the Secretary of the Department of Health and Human Services (the Secretary) as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program may be deemed to meet the Medicare conditions. An AO applying for approval of its accreditation program under part 488, subpart A, must provide CMS with reasonable assurance that the AO

requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the approval of AOs 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 October 30, 2018, we published a proposed notice in the **Federal Register** (83 FR 54591) announcing the American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF's) request for continued approval of its Medicare OPT 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 OPT 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 OPT surveyors; (4) ability to investigate and respond appropriately to complaints against accredited OPTs; and, (5) survey review and decision-making process for accreditation.

- The comparison of AAAASF's Medicare OPT accreditation program standards to our current Medicare OPT CoPs.
- 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 we require of state survey agencies, including periodic resurvey and the ability to investigate and respond appropriately to complaints against accredited OPTs.

++ Evaluate AAAASF's procedures for monitoring OPTs 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 OPT and respond to the OPTs 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 October 30, 2018 proposed notice also solicited public comments regarding whether AAAASF's requirements met or exceeded the Medicare CoPs for OPTs. 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 OPT accreditation program requirements and survey process with the Medicare CoPs at part 485 subpart H, and the survey and certification process requirements of parts 488 and 489. Our review and evaluation of AAAASF's OPT 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:

- Section 485.701, to ensure AAAASF's standards appropriately reference the CMS standards;

- Section 485.703, definition of "supervision" at (2)(ii), to ensure AAAASF's standards appropriately reference the CMS standards;
- Section 485.705(a), to ensure AAAASF's standards appropriately reference the CMS standards;
- Section 485.705(c)(2) through (c)(6), to ensure AAAASF's standards appropriately reference the CMS standards;
- Section 485.719(b)(3), to ensure AAAASF's standards appropriately reference the statutory requirements;
- Section 488.5(a)(4)(ii), to ensure that an appropriate number of medical records are fully reviewed during the survey process and that survey record totals are accurately reflected in the overall deficiency statement;
- Section 488.5(a)(4)(iv), to ensure all deficiencies found on survey are cited in AAAASF's final survey report;
- Section 488.5(a)(4)(vii), to ensure appropriate monitoring of non-compliance correction;
- Section 488.5(a)(11)(ii), to ensure accurate survey findings are reported to CMS;
- Section 488.5(a)(13)(ii), to ensure AAAASF notifies CMS regarding any decision to revoke, withdraw, or revise the accreditation status of a deemed status supplier;
- Section 488.26(b) and (c), to ensure deficiencies are cited at the appropriate level based on manner and degree of findings;
- Section 488.28(a), to ensure AAAASF's policies for an acceptable plan of correction meet the CMS requirements;

- Section 488.28(d), to ensure that AAAASF's policies for correction of deficiencies in OPTs is comparable to CMS requirements, requiring that deficiencies normally must be corrected within 60 days; and

- Section 489.13(b)(1), to ensure all enrollment requirements are met prior to AAAASF surveying an initial applicant.

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 OPTs that request participation in the Medicare program, effective April 4, 2019 through April 4, 2025.

## 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. Chapter 35).

**Dated:** March 15, 2019.

**Seema Verma**,
*Administrator,*
*Centers for Medicare & Medicaid Services.*

[FR Doc. 2019-06149 Filed: 3/29/2019 8:45 am; Publication Date: 4/1/2019]