



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

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

**[CMS-3343-FN]**

### **Medicare and Medicaid Programs; Continued Approval of the American Osteopathic Association/Healthcare Facilities Accreditation Program's (AOA/HFAP's) Ambulatory Surgical Center Accreditation Program**

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

**ACTION:** Final notice.

**SUMMARY:** This final notice announces our decision to approve the American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA/HFAP) 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 final notice is effective [INSERT PUBLICATION DATE] through [INSERT DATE 6 YEARS FROM PUBLICATION DATE].

#### **FOR FURTHER INFORMATION CONTACT:**

Monda Shaver, (410) 786-3410, Erin McCoy, (410) 786-2337, or 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. 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 of 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 (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.

## 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 13, 2017, we published a proposed notice (82 FR 27067) in the **Federal Register**, announcing AOA/HFAP'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 AOA/HFAP'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 AOA/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 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 AOA/HFAP's Medicare ASC accreditation program standards to our current Medicare ASC condition of coverage (CfC's).

- A documentation review of ASC's survey process to:
  - ++ Determine the composition of the survey team, surveyor qualifications, and AOA/HFAP's ability to provide continuing surveyor training.
  - ++ Compare AOA/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 ASCs.
  - ++ Evaluate AOA/HFAP's procedures for monitoring ASCs found to be out of compliance with AOA/HFAP's program requirements. (This pertains only to monitoring procedures when AOA/HFAP 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 AOA/HFAP's ability to report deficiencies to the surveyed ASC and respond to the ASCs plan of correction in a timely manner.
  - ++ Establish AOA/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 AOA/HFAP's staff and other resources.
  - ++ Confirm AOA/HFAP's ability to provide adequate funding for performing required surveys.
  - ++ Confirm AOA/HFAP's policies with respect to surveys being unannounced.
  - ++ Obtain AOA/HFAP's agreement to provide CMS with a copy of the most current accreditation survey, along 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 13, 2017 proposed notice also solicited public comments regarding whether AOA/HFAP's requirements met or exceeded

the Medicare CfCs for ASCs. We received 2 comments in response to our proposed notice. All of the comments received expressed unanimous support for AOA/HFAP's ASC accreditation program.

#### **IV. Provisions of the Final Notice**

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

We compared AOA/HFAP'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 AOA/HFAP'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, AOA/HFAP has revised its standards and certification processes in order to meet the requirements at:

- Section 416.2, to ensure its standards appropriately reference §416.2 and Part 416 subparts B and C.
- Section 416.25, to ensure its standards to require facilities meet the definition at §416.2.
- Section 416.41(b)(3)(i), to ensure its standards appropriately reference §416.41(b)(2).
- Section 416.41(b)(3)(ii), to ensure its standards appropriately reference §416.41(b)(2).
- Section 416.42(b)(2), to ensure its standards appropriately reference §416.42(c)
- Section 416.49(b)(2), to ensure standards appropriately reference §416.49(c).
- Section 416.50(a), to ensure its standards appropriately reference §416.50.
- Section 416.50(b), to ensure its standards appropriately reference Part 420.
- Section 488.5(a)(4)(ii), to ensure AOA/HFAP's surveyors review the minimum number of medical records as specified by CMS and AOA/HFAP policy.

- Section 488.5(a)(4)(iv), to ensure each that all observations of non-compliance are documented in the survey report.
- Section 488.5(a)(7) through (9), to ensure AOA/HFAP complies with its policy and criteria for surveyor qualifications, education and evaluation system to monitor the performance of surveyors and teams.
- Section 488.26(b), to ensure AOA/HFAP cites findings of observed non-compliance at the appropriate level (condition versus standard level).

#### B. Term of Approval

Based on our review and observations described in section III of this final notice, we approve AOA/HFAP as a national accreditation organization for ASCs that request participation in the Medicare program, effective [INSERT PUBLICATION DATE] through [INSERT DATE 6 YEARS FROM PUBLICATION DATE].

#### **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.).

CMS-3343-FN

Dated: September 14, 2017.

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**Seema Verma,**

Administrator,

Centers for Medicare & Medicaid Services.

**BILLING CODE 4120-01-P**

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