

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on *September 20, 2010*.

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer. *Fax Number:* (202) 395-6974. *E-mail:*

OIRA_submission@omb.eop.gov.

Dated: August 13, 2010.

Michelle Shortt,

*Director, Regulations Development Group,
Office of Strategic Operations and Regulatory Affairs.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-2476-FN2]

Medicare and Medicaid Programs; Approval of the American Association for Accreditation of Ambulatory Surgery Facilities for Continued Deeming Authority for Ambulatory Surgical Centers

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

ACTION: Final notice.

SUMMARY: This final notice announces our decision to approve without condition the American Association for Accreditation of Ambulatory Surgery Facilities' (AAAASF) request for continued recognition as a national accreditation program for ambulatory surgical centers (ASC) seeking to participate in the Medicare or Medicaid programs.

DATES: *Effective Date:* This final notice is effective on November 27, 2009 through November 27, 2012.

FOR FURTHER INFORMATION CONTACT: 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) establishes distinct criteria for a facility seeking designation as an ASC. Under this authority, the minimum requirements that an ASC must meet to participate in Medicare are

set forth in regulations at 42 CFR part 416, which determine the basis and scope of ASC covered services, and the conditions for Medicare payment for facility 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.

Generally, to enter into an agreement, an ASC must first be certified by a State survey agency as complying with conditions or requirements set forth in part 416 of our regulations. Then, the ASC is subject to regular surveys by a State survey agency to determine whether it continues to meet those requirements. There is an alternative, however, 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 accreditation organization that all applicable Medicare conditions are met or exceeded, we may "deem" those provider entities to have met the requirements. Accreditation by an accreditation organization is voluntary and is not required for Medicare participation.

If an accreditation 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 may be deemed to meet the Medicare conditions. A national accreditation organization applying for approval of deeming authority under part 488, subpart A, must provide us with reasonable assurance that the accreditation organization requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning re-approval of accrediting organizations are set forth at section § 488.4 and § 488.8(d)(3). The regulations at § 488.8(d)(3) require accreditation organizations to reapply for continued approval of deeming authority every 6 years, or sooner as determined by CMS. The regulation at § 488.8(f)(3)(i) provides CMS the authority to grant conditional approval of an accreditation organization's deeming authority, with a probationary period of up to 180 days, if the accreditation organization has not adopted comparable standards during the reapplication process.

We received a complete application from AAAASF for continued recognition as a national accreditation organization for ASCs on March 31, 2009. In accordance with the requirements at § 488.4 and § 488.8(d)(3), we published a proposed

notice on June 26, 2009 (74 FR 30587) and a final notice on November 27, 2009 (74 FR 62330). This final notice provides CMS' final determination in response to the conditional approval with a 180-day probationary period granted to the American Association for Accreditation of Ambulatory Surgery Facilities on November 27, 2009.

II. Deeming Applications Approval Process

Section 1865(a)(3)(A) of the Act provides a statutory timetable to ensure that our review of deeming applications is conducted in a timely manner. The Act provides us with 210 calendar days after the date of receipt of an application to complete our survey activities and application review process. Within 60 days of receiving a completed application, we must publish a notice in the **Federal Register** that identifies the national accreditation 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 an approval or denial of the application. In accordance with § 488.8(f)(2), if CMS determines following the deeming authority review that the organization has failed to adopt requirements comparable to CMS requirements, the accreditation organization may be given a conditional approval of its deeming authority for a probationary period of up to 180 days to adopt comparable requirements. Within 60 days after the end of this period, we must make a final determination as to whether or not the AAAASF's accreditation program for ASCs is comparable to CMS requirements and issue an appropriate notice that includes our reasons for our determination.

III. Provisions of the November 27, 2009 Final Notice

Our review of AAAASF's renewal application for ASC deeming authority revealed that AAAASF had on-going, serious, widespread areas of non-compliance. Specifically, AAAASF's inability to provide accurate and timely data on deemed providers; lack of complete and accurate deemed facility survey files; and, inadequate surveyor training and evaluation program. Due to the significant number of areas of noncompliance identified during the review of AAAASF's renewal application for deeming authority, we conditionally approved AAAASF's ASC accreditation program for 3 years with a 180 day probationary period. Under section 1865(a)(2) of the Act and our regulations at § 488.4 and § 488.8, we conducted a comparability review of

AAAASF's ASC accreditation program to determine compliance with the Medicare requirements for ASCs at 42 CFR part 416.

IV. Provisions of the Final Notice

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

During the 180 day probationary period, we conducted a comparison of AAAASF's accreditation requirements for ASCs to our current Medicare conditions for coverage (CfCs) as outlined in the State Operations Manual (SOM). We also conducted a corporate onsite visit and survey observation to validate proper application of the requirements. Our review and evaluations of AAAASF's deeming application yielded the following:

- AAAASF's survey files were complete, accurate, and consistent with the requirements at § 488.6(a).
- AAAASF's data submissions are accurate, complete and timely in accordance with the requirements at § 488.4(b).
- AAAASF revised its accreditation decision letters to ensure they are accurate and contain all of the elements necessary for the Regional Office to render a decision regarding the deemed status of an accredited ASC.
- AAAASF revised its policies to require its surveyors to use the surveyor tools thus ensuring accurate and complete survey files.
- AAAASF developed surveyors tools to include a medical record review sheet, personnel review sheet, and policy review to assist surveyors with accurate, and complete documentation.
- To meet the Medicare requirements related to unannounced surveys at 2700A of the SOM, AAAASF modified its policies related to the survey window in which organizations could receive an accreditation survey for deemed status.

- To meet the survey process requirements in Appendix L of the SOM, AAAASF developed a policy outlining the minimum number of medical records that must be reviewed during a certification survey.

- To meet the requirements at SOM 2200F, AAAASF revised its policies and procedures to ensure documentation of deficiencies contains a regulatory reference, a clear and detailed description of the deficient practice, and relevant finding.

- To meet the requirements at 2728 of the SOM, AAAASF modified its policies regarding timeframes for sending and receiving a plan of correction (PoC) for life safety code surveys.

- To ensure its surveyors were adequately trained, AAAASF developed a website where surveyors could access a resource library of training webinars, interpretative guidelines, principles of documentation, standards, surveyor handbook, survey forms and other materials to assist surveyors in the field.

B. Term of Approval

Based on the review and observations, we have determined that AAAASF's accreditation program for ASCs meets or exceeds our requirements. Therefore, we approve, without condition, AAAASF as a national accreditation organization for ASCs that request participation in the Medicare program, effective November 27, 2009 through November 27, 2012. Under § 488.4(f)(4), notice was given to AAAASF on November 27, 2009 (74 FR 62330) and this final notice, although not required by our regulations, is being published as a public service for informational purposes.

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).

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

Dated: August 5, 2010.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1572-N]

Medicare Program; Announcement of Five New Members to the Advisory Panel on Ambulatory Payment Classification Groups

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

ACTION: Notice.

SUMMARY: This notice announces five new members selected to serve on the Advisory Panel on Ambulatory Payment Classification (APC) Groups (the Panel). The purpose of the Panel is to review the APC groups and their associated weights and to advise the Secretary of Department of Health and Human Services (the Secretary) and the Administrator of Centers for Medicare & Medicaid Services concerning the clinical integrity of the APC groups and their associated weights. We will consider the Panel's advice as we prepare the annual updates of the hospital outpatient prospective payment system (OPPS).

FOR FURTHER INFORMATION CONTACT: For inquiries about the Panel, contact the Designated Federal Official (DFO): Shirl Ackerman-Ross, (410) 786-4474.

APC Panel E-Mail Address: The E-mail address for the Panel is as follows: CMSAPCPanel@cms.hhs.gov (Note: There is no underscore in this e-mail address; there is a space between CMS and APCPanel.)

News Media Contact: News media representatives must contact our Public Affairs Office at (202) 690-6145.

CMS Advisory Committees Hotlines: The CMS Federal Advisory Committee Hotline is 1-877-449-5659 (toll free) and (410) 786-9379 (local) for additional Panel information.

Web Sites: For additional information regarding the APC Panel membership, meetings, agendas, and updates to the Panel's activities, search our Web site at the following Uniform Resource Locator (URL): http://www.cms.hhs.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp#TopOfPage. (Note: There is an underscore after FACA/05 (like this _); there is no space.)

The public may also access the following URL for the Federal Advisory Committee Act Web site to obtain APC Panel information: <https://www.fido.gov/facadatabase/public.asp>.

A copy of the Panel's Charter and other pertinent information are on both Web sites mentioned above. You may also e-mail the Panel DFO at the above e-mail address for a copy of the Charter.

SUPPLEMENTARY INFORMATION:

I. Background

The Secretary of the Department of Health and Human Services (the Secretary) is required by section 1833(t)(9)(A) of the Social Security Act (the Act) to consult with an expert outside advisory Panel regarding the clinical integrity of the Ambulatory Payment Classification (APC) groups and relative payment weights that are