• To meet the requirements at § 416.44, AAAHC updated the requirements on its Physical Environment Checklist (PEC) and modified its policies to clearly reflect that life safety code (LSC) waivers may only be granted by a CMS regional office.

• To meet the requirements at § 416.44(d), AAAHC revised its standards to require that ASCs train personnel in the use of all types of emergency equipment, not just cardiopulmonary and cardiac emergency equipment.

• To meet the requirements at § 416.45(b), AAAHC revised its standards to require that the scope of procedures performed in the ASC be periodically reviewed and amended as appropriate.

• To meet the requirements at § 416.46(a), AAAHC revised its standards to require a registered nurse be available for emergency treatment whenever there is a patient in the ASC.

• To meet the requirements at § 416.47(b), AAAHC revised its survey procedures to ensure that surveyors use a random selection of medical records for review during an onsite survey.

• To meet the requirements at § 488.4(a)(4), AAAHC revised its policies related to surveyor credentialing and privileging to ensure that surveyor's were appropriately privileged, credentialed and trained.

• AAAHC modified its surveyor training program to strengthen the Physical Environment and Life Safety Code training to ensure that surveyors thoroughly understand Physical Environment and Life Safety Code and can translate the teachings into practice on survey.

• CMS will conduct a survey observation, in 1 year, to validate the implementation of AAAHC's revised surveyor training program for Physical Environment and Life Safety Code and assess the competency of the surveyor's ability to conduct Physical Environment and Life Safety Code surveys in accordance with Medicare requirements.

• AAAHC amended its policies and procedures to address any real or perceived conflict of interest issues between AAAHC's accreditation activities and AAAHC's consultative services.

• To meet the requirements at § 488.4(a)(6) AAAHC amended its policies and procedures for complaints to comply with the Medicare requirements in Chapter 5 of the SOM.

• AAAHC revised its accreditation decision letters to ensure they are accurate and contain all of the required elements necessary for the CMS Regional Office to render a decision regarding deemed status of a provider.

• AAAHC modified its policies regarding condition-level noncompliance identified during an initial certification survey for participation in Medicare in accordance with section 2005A of the SOM.

• To meet the Medicare requirements at § 488.20(a) and § 488.28(a), AAAHC developed a policy regarding CMS requirements for submission of a plan of correction by the ASC and the completion of an onsite follow-up survey to determine compliance with the Medicare conditions for coverage (CFCs) after citing condition level noncompliance during a recertification survey.

• AAAHC modified its policies regarding timeframes for sending and receiving a required plan of correction in accordance with section 2728 of the SOM.

• To meet the Medicare requirements related to unannounced surveys at 2700A of the SOM, AAAHC expanded its survey window in which organizations could receive an accreditation survey for deemed status.

• AAAHC modified the language related to deferred decisions and early survey option in its accreditation handbook to provide clarification and consistency between its policies and the Medicare requirements.

• AAAHC amended its policies regarding subsequent revisions of its Accreditation Handbook and surveyor tools to ensure all documents are consistent in language and reflect CMS's requested changes.

B. Term of Approval

Based on the 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, 2008 through December 20, 2012.

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. Chapter 35).

Authority: Section 1865 of the Social Security Act (42 U.S.C. 1395bb).

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

Dated: October 2, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E8–27122 Filed 11–13–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–2898–FN]

Medicare and Medicaid Programs; Approval of the Joint Commission for Continued Deeming Authority for Ambulatory Surgical Centers

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

ACTION: Final notice.

SUMMARY: This notice announces our decision to approve the Joint Commission for continued recognition as a national accreditation program for ambulatory surgical centers (ASCs) seeking to participate in the Medicare or Medicaid programs.

DATES: *Effective Date:* This final notice is effective December 20, 2008, through December 20, 2014.

FOR FURTHER INFORMATION CONTACT: Laura Weber, (410) 786–0227. Patricia Chmielewski (410) 786–6899.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive selected covered services in an ASC provided certain requirements are met. Sections 1832(a)(2)(f)(i) of the Social Security Act (the Act) authorizes the Secretary to establish distinct criteria for facilities 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 (as redesignated under section 125 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275)) 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 as having met Medicare requirements. (We note that section 125 of MIPPA redesignated subsections (b) through (e) of subsection 1865 of the Act as (a) through (d) respectively.) 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 reapproval of accrediting organizations are set forth at § 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 we determine. The Joint Commission's term of approval as a recognized accreditation program for ASCs expires December 20, 2008.

II. Deeming Applications Approval Process

Section 1865(a)(3)(A) of the Act (formerly section 1865(b)(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 that a 30-day public comment period. At the end of the 210-day period, we must publish an approval or denial of the application.

III. Provisions of the Proposed Notice

In the June 27, 2008, **Federal Register** (73 FR 36518), we published a proposed notice announcing the Joint Commission's request for reapproval as a deeming organization for ASCs. In the proposed notice, we detailed our evaluation criteria. Under section 1865(a)(2) of the Act (formerly section 1865(b)(2)) of the Act and our regulations at § 488.4 (Application and reapplication procedures for accreditation organizations), we conducted a review of the Joint Commission application in accordance with the criteria specified by our regulation, which include but are not limited to the following:

- An onsite administrative review of the Joint Commission'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.
- A comparison of the Joint Commission's ASC accreditation standards to our current Medicare ASC conditions for coverage.
- A documentation review of the Joint Commission's survey processes to—

++ Determine the composition of the survey team, surveyor qualifications, and the ability of the Joint Commission to provide continuing surveyor training;

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

++ Assess the Joint Commission's ability to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner;

++ Establish the Joint Commission's ability to provide us with electronic data and reports necessary for effective validation and assessment of the Joint Commission's survey process;

++ Determine the adequacy of staff and other resources;

++ Review the Joint Commission's ability to provide adequate funding for performing required surveys;

++ Confirm the Joint Commission's policies with respect to whether surveys are announced or unannounced; and,

++ Obtain the Joint Commission's agreement to provide us 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 (formerly section 1865(b)(3)(A) of the Act), the June 27, 2008 proposed notice also solicited public comments regarding whether the Joint Commission's requirements met or exceeded the Medicare conditions of coverage for ASCs. We received no public comments in response to our proposed notice.

IV. Provisions of the Final Notice

A. Differences Between the Joint Commission's Standards and Requirements for Accreditation and Medicare's Conditions and Survey Requirements

We compared the standards contained in the Joint Commission's accreditation requirements for ASCs and its survey process in the Joint Commission's application for renewal of deeming authority for ASCs with the Medicare ASC conditions for participation and our State Operations Manual (SOM). Our review and evaluation of the Joint Commission's deeming application, which were conducted as described in section III. of this final notice, yielded the following:

- The Joint Commission amended their policies to eliminate the use of supplemental findings. All survey findings will be identified as a requirement for improvement, and will, therefore, require resolution through the evidence of standards compliance process.
- The Joint Commission modified its evidence of standards compliance process (ESC) to ensure that accepted ESCs contain the critical information necessary to provide assurance that an identified deficiency had been adequately corrected.
- The Joint Commission modified its survey report to clearly identify whether an identified deficient practice represented condition level- or standard-level noncompliance.

• The Joint Commission developed and conducted surveyor training on CMS documentation requirements to ensure that issues cited provide a clear and detailed description of the deficient practice and relevant finding.

• The Joint Commission modified its policies regarding complaint investigation activities to comply with the requirements at § 488.4(a)(6) and Chapter 5 of the SOM.

• To meet the Medicare requirements related to unannounced surveys at 2700A of the SOM, the Joint Commission modified its electronic application process to no longer allow an ASC to indicate ''avoid dates'' or ''a ready month'' in which organizations could receive an accreditation survey for deemed status.

• The Joint Commission revised its accreditation decision letters to ensure they are accurate and contain all the required elements necessary for the CMS Regional Office to render a decision regarding deemed status of a provider.

• The Joint Commission modified its policies regarding condition-level noncompliance identified during an initial certification survey for participation in Medicare in accordance with section 2005A of the SOM.

• To meet the requirements at § 416.41, the Joint Commission revised its standards to require that patients in Medicare-certified ASC that require emergency treatment beyond the capability of the ASC be transferred to local hospitals that meet requirements for payment of emergency services.

• To meet the requirements at § 416.44(a)(2), the Joint Commission revised its standards to require Medicare certified ASCs to provide a separate waiting area and post-anesthesia room.

• To meet the requirements at § 416.44(b)(1) and § 416.44(b)(5), § 416.45(a), and § 416.48(a), the Joint Commission amended its Medicare crosswalk to reflect current regulatory language.

• To meet the requirements at § 416.45, the Joint Commission added a standard requiring Medicare-certified ASCs to ensure that licensed independent practitioners are accountable to the governing body.

• To meet the requirements at § 416.45(b), the Joint Commission added a standard requiring Medicare-certified ASCs to periodically review and amend the scope of procedures performed.

• To meet the requirements at § 416.48, the Joint Commission added a new standard requiring Medicare-certified ASCs to designate one individual responsible for pharmaceutical services.

• To meet the requirements at § 416.49, the Joint Commission added a standard requiring Medicare-certified ASCs to comply with 42 CFR part 493 which requires organizations who perform laboratory testing to maintain compliance with Clinical Laboratory Improvement Amendments of 1988 (CLIA '88).

B. Term of Approval

Based on the review and observations described in section III. of this final notice, we have determined that the Joint Commission's requirements for ASCs meet or exceed our requirements. Therefore, we approve the Joint Commission as a national accreditation organization for ASCs that request participation in the Medicare program, effective December 20, 2008 through December 20, 2014.

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. Chapter 35).

Authority: Section 1865 of the Social Security Act (42 U.S.C. 1395bb).

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

Dated: October 2, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E8–27120 Filed 11–13–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0578]

Pediatric Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pediatric Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues. The committee also advises and makes recommendations to the Secretary of Health and Human Services under 45 CFR 46.407 on research involving children as subjects that is conducted or supported by the Department of Health and Human Services (DHHS), when that research is also regulated by the FDA.

Date and Time: The meeting will be held on Tuesday, December 9, 2008, from 3:30 p.m. to 6 p.m.

Location: The Legacy Hotel & Meeting Centre, 1775 Rockville Pike, Rockville, MD 20852.

Contact Person: Carlos Peña, Office of Science and Health Coordination, Office of the Commissioner (HF–33), Food and Drug Administration, 5600 Fishers Lane (for express delivery, rm. 14B–08), Rockville, MD 20857, 301–827–3340, or by e-mail: *carlos.peña@fda.hhs.gov* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 8732310001. Please call the Information Line for up to date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On December 9, 2008, the Pediatric Advisory Committee will hear and discuss the recommendation of the Pediatric Ethics Subcommittee from its meeting on December 9, 2008, regarding a referral by an Institutional Review Board of a clinical investigation that involves both an FDA-regulated product and research involving children as subjects that is conducted or supported by DHHS.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*, click on the