

SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Annette Marthaler, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850-3229, 240-276-1717, annette.marthaler@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On June 22, 2009, the President signed the Tobacco Control Act (Public Law 111-31) into law. The Tobacco Control Act amended the act (21 U.S.C. 301 *et seq.*) by, among other things, adding a new chapter granting FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

Section 911 of the act, as amended by the Tobacco Control Act, states: “(a) No person may introduce or deliver for introduction into interstate commerce any modified risk tobacco product unless an order issued pursuant to subsection (g) is effective with respect to such product” and “(d) Any person may file with the Secretary an application for a modified risk tobacco product. * * *” Section 911(g) of the act provides the criteria under which the agency determines whether to issue an order that an MRTP may be commercially marketed. The Tobacco Control Act provides that, within 2 years and 9 months of the enactment of the Tobacco Control Act, the agency shall issue regulations or guidance regarding MRTP applications, and those regulations or guidance shall “establish a reasonable timetable for the Secretary to review an application under this section.” FDA is issuing this guidance to describe a preliminary timetable the agency intends to follow until such time as the agency issues more comprehensive guidance or regulations on MRTP applications. Pending further guidance or rulemaking, FDA intends to issue a decision on an MRTP application within 360 days of its receipt by FDA.

II. Significance of Guidance

FDA is issuing this draft guidance document consistent with FDA’s good

guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency’s current thinking on “Preliminary Timetable for the Review of Applications for Modified Risk Tobacco Products under the Federal Food, Drug, and Cosmetic Act.” It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

An electronic version of the guidance document is available on the Internet at <http://www.regulations.gov> and <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm>.

Dated: November 24, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9-28515 Filed 11-24-09; 4:15 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-2476-FN]

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

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

ACTION: Final notice.

SUMMARY: This final notice announces our decision to conditionally approve, with a 180 day probationary period, the American Association for Accreditation

of Ambulatory Surgery Facilities (AAAASF) for continued recognition as a national accreditation program for ambulatory surgical centers 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, with a 180-day probationary period beginning November 27, 2009 through May 26, 2010.

FOR FURTHER INFORMATION CONTACT: Lillian Williams (410) 786-8636. 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 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 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 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 we determine. The American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF) term of approval as a recognized accreditation program for ASCs expires November 26, 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.

III. Provisions of the Proposed Notice

On June 26, 2009, we published a proposed notice (74 FR 30587) announcing AAAASF's request for re-approval as a deeming organization for ASCs. In the proposed notice, we detailed our evaluation criteria. Under section 1865(a)(2) of the Act and our regulations at § 488.4 (Application and reapplication procedures for accreditation organizations), we conducted a review of the AAAASF 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 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 AAAASF's ASC accreditation standards to our current

Medicare ASC conditions for coverage (CfC); and,

- A documentation review of AAAASF's survey processes to—
 - Determine the composition of the survey team, surveyor qualifications, and the ability of AAAASF to provide continuing surveyor training;
 - Compare AAAASF'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 AAAASF's procedures for monitoring providers or suppliers found to be out of compliance with AAAASF's program requirements. The monitoring procedures are used only when AAAASF identifies noncompliance. If noncompliance is identified through validation reviews, the State survey agency monitors corrections as specified at § 488.7(d);
 - Assess AAAASF's ability to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner;
 - Establish AAAASF's ability to provide us with electronic data and reports necessary for effective validation and assessment of AAAASF's survey process;
 - Determine the adequacy of staff and other resources;
 - Review AAAASF's ability to provide adequate funding for performing required surveys;
 - Confirm AAAASF's policies with respect to whether surveys are announced or unannounced; and,
 - Obtain AAAASF'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, the June 26, 2009 proposed notice (74 FR 30587) also solicited public comments regarding whether AAAASF's requirements met or exceeded the Medicare CfCs for ASCs. We received no public 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's Conditions and Survey Requirements

We compared AAAASF's accreditation requirements and survey process with the Medicare CfCs and survey process as outlined in the State Operations Manual (SOM). Our review and evaluation of the AAAASF's deeming application, which were conducted as described in section III of this final notice, yielded the following:

- To meet the requirements at § 416.2, AAAASF revised their standards to include the current definition of an ASC.
- To meet the requirements at § 416.41(a), AAAASF revised their standards to ensure contracted services of an ASC are provided in a safe and effective manner.
- To meet the requirements at § 416.41(b)(2) and 416.41(b)(3), AAAASF revised their standards to ensure that an ASC has a transfer agreement with a local Medicare participating hospital and a procedure for transferring patients with emergency needs to a Medicare hospital, or a non-participating hospital that meets the requirements for payment at § 482.2.
- To meet the requirements at § 416.41(c)(1), AAAASF revised their standards to ensure ASCs maintain a written disaster preparedness plan.
- To meet the requirements at § 416.42, AAAASF revised their standards to ensure surgical procedures provided in the ASC are performed in a safe manner.
- To meet the requirements at § 416.42(a)(1), AAAASF revised their standards to require a physician examine a patient to evaluate the risk of anesthesia and the procedure to be performed immediately before surgery.
- To meet the requirements at § 416.44(a), AAAASF revised their standards to include the requirement that ASCs provide a functional and sanitary environment for the provision of surgical services.
- To meet the requirements at § 416.44(b)(5)(iii), AAAASF revised their standards to require alcohol-based hand rub dispensers be installed in a manner that adequately protects against inappropriate access.
- To meet the requirements at § 416.44(c), AAAASF revised their standards to ensure that ASCs that utilize an automated external defibrillator (AED) have policies and procedures to indicate an AED is sufficient given the patient population and types of procedures performed. In addition, AAAASF revised their standards to include the requirement that emergency medical equipment and supplies be available in the operating room.
- To meet the requirements at § 416.46, AAAASF revised their standards to ensure the nursing services of the ASC are directed and staffed to meet all of the patient's nursing needs.
- To meet the requirements at § 416.47 (b), AAAASF revised their standards to include the requirement that every medical record must be accurate and promptly completed.

- To meet the requirements at § 416.47(b)(2), AAAASF revised their standards to require medical records include a significant medical history and results of physical examination.
- To meet the requirements at § 416.49, AAAASF revised their standards to require ASCs that do not provide laboratory services to have procedures for obtaining laboratory services.
- To meet the requirements at § 416.49(b)(1), AAAASF revised their standards to include the requirement that ASCs have procedures for obtaining radiologic services.
- To meet the requirements at § 416.49(b)(2), AAAASF revised their standards to ensure that radiologic services provided in an ASC meet the hospital conditions of participation for radiologic services specified at § 482.26.
- To meet the requirements at § 416.50, AAAASF revised their standards to include the requirement that an ASC must inform the patient of his or her rights.
- To meet the requirements at § 416.50(b) through § 416.50(d) AAAASF revised their standards to include patient rights requirements.
- To meet the requirements at § 416.51(a), AAAASF revised their standards to include the requirement that ASCs provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice.
- To meet the requirements at § 416.51(b), AAAASF revised their standards to ensure ASCs maintain an infection control and prevention program.
- To meet the requirements at § 416.52, AAAASF revised their standards to include the requirements that the ASC must ensure each patient has the appropriate pre- and post-surgical assessments completed and that all elements of the discharge requirements are completed.
- To meet the requirements at § 488.4(a)(4), AAAASF developed and implemented internal monitoring procedures to ensure their surveyors are trained and qualified.
- To eliminate any real or perceived conflict of interest between AAAASF's accreditation activities and the financial, consulting and professional activities of AAAASF's surveyors, AAAASF developed and implemented policies and procedures that adequately address conflicts of interest issues for surveyors.
- To meet the requirements at § 488.6(a), AAAASF developed an action plan to ensure that deemed status

survey files are complete, accurate, and consistent.

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

- To meet the requirements at § 488.20(b) and § 488.28(a), AAAASF developed a policy to ensure that facilities with condition level non-compliance on a recertification survey submit an acceptable plan of correction (PoC) and receive a follow-up onsite focused survey.

- To meet the requirements at § 489.13, AAAASF modified its policies related to the accreditation effective date for new providers.

- AAAASF develop a policy regarding condition level noncompliance identified during an initial certification survey for participation in Medicare in accordance with section 2005A2 of the SOM.

- To meet the requirements at 2728 of the SOM, AAAASF modified its policies regarding timeframes for sending and receiving a PoC.

- To meet our requirements related to a PoC, AAAASF amended its policies to ensure approved PoCs contain all elements specified in section 2728 of the SOM.

- To meet the requirements at 2700A of the SOM, AAAASF developed and implemented new policies and procedures that ensure all surveys are unannounced.

- AAAASF revised its policies to ensure timeframes for investigation of complaints are consistent with the requirements at section 5075.9 of the SOM.

- AAAASF revised its accreditation decision letters to ensure that they are accurate and contain all the required elements for the CMS Regional Office to render a decision regarding the deemed status of an accredited ASC.

- To meet the requirements at § 488.20(b)(1), AAAASF revised its policies to allow resurveys of a provider as frequently as necessary to ascertain compliance and confirm correction of deficiencies.

- AAAASF revised its policies to require that all deficiencies identified during a deemed survey visit be cited and documented, including deficiencies corrected onsite at the time of survey.

- To ensure AAAASF surveyors are properly trained and can effectively apply knowledge and skills acquired in training, AAAASF expanded its surveyor training program to include a Medicare surveyor handbook,

comprehensive interpretive guidelines, random validation surveys to assess surveyor performance, and an onsite preceptor training and evaluation program.

To verify AAAASF's continued compliance with the provisions of this final notice, we will conduct a follow-up corporate onsite visit and survey observation within 6 months of the date of publication of this notice.

Review of AAAASF's renewal application for ASCs deeming authority revealed that AAAASF has ongoing, serious, widespread areas of non-compliance, specifically AAAASF's—

- Inability to provide us with 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 ASCs deeming authority, we have concerns that AAAASF's accreditation program for ASCs may no longer provide reasonable assurance that its accredited entities meet the Medicare requirements.

In accordance with § 488.8(d)(3), every 6 years, or sooner as determined by us, an approved accreditation organization must reapply for continued approval of deeming authority. We notify the organization of the materials they must submit as part of the reapplication procedure. An accreditation organization that is not meeting the requirements of this subpart, as determined through a comparability review, must furnish us, upon request and at any time, with the reapplication materials upon request. We will establish a deadline by which the materials are to be submitted.

In accordance with § 488.8(f)(3)(i), if we determine that an accreditation organization has failed to adopt requirements comparable to our requirements, we may grant a conditional approval of the accreditation organization's deeming authority for a period of up to 1 year to adopt comparable requirements; in this case, we are providing AAAASF with a probationary period of 180 days. Within 60 days after the end of AAAASF's probationary period, we will make a final determination as to whether or not AAAASF's ASCs accreditation requirements are comparable to our requirements and issue an appropriate notice that includes reasons for our determination, no later than August 23, 2010. If AAAASF has not made improvements acceptable to us during

the 180-day probationary period, we may remove recognition of deemed authority for its ASC program effective 30 days after the date we provide written notice to AAAASF that its ASC deeming authority will be removed.

B. Term of Approval

Based on the review and observations described in section III of this final notice, we have determined that AAAASF's accreditation program for ASCs requires further revision and subsequent review. We are confident that with additional time, AAAASF will make the necessary revisions to ensure AAAASF's accreditation program for ASCs meets or exceeds the Medicare requirements as stated at 42 CFR part 416. Therefore, we conditionally approve AAAASF as a national accreditation organization for ASCs that request participation in the Medicare program, effective November 27, 2009 through November 27, 2012, with a 180-day probationary period beginning November 27, 2009 through May 26, 2010.

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: October 29, 2009.

Charlene Frizzera,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E9-28048 Filed 11-25-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-2302-FN]

Medicare and Medicaid Programs; Approval of the Application by the Joint Commission for Continued Deeming Authority for Hospitals

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

ACTION: Final notice.

SUMMARY: This final notice announces the approval of a deeming application from the Joint Commission for continued recognition as a national accreditation program for hospitals that request participation in the Medicare or Medicaid programs.

DATES: *Effective Date:* This final notice is effective July 15, 2010 through July 15, 2014.

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 from a hospital, provided certain requirements are met. The regulations specifying the Medicare conditions of participation (CoPs) for hospitals are located at 42 CFR part 482. These CoPs implement section 1861(e) of the Social Security Act (the Act), which specifies services covered as hospital care and the conditions that a hospital program must meet in order to participate in the Medicare program. Regulations concerning provider agreements are located at 42 CFR part 489 and regulations pertaining to the survey and certification of facilities are located at 42 CFR part 488.

Generally, in order to enter into a provider agreement, a hospital must first be certified by a State survey agency as complying with the conditions or requirements set forth in part 482 of our regulations. Then, the hospital is subject to routine surveys by a State survey agency to determine whether it continues to meet the Medicare requirements. There is, however, an alternative to State compliance surveys.

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 would "deem" those provider entities as having 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 accreditation body's approved

program would be deemed to meet the Medicare conditions. A national accreditation organization applying for 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 the re-approval of accreditation 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 deeming authority every 6 years or as we determine.

In July 2008, section 125 of MIPPA revoked the Joint Commission's statutorily-guaranteed deeming authority for their hospital program and required the Joint Commission subsequently to be recognized as a national accreditation body for hospitals only after applying to CMS, subject to terms and conditions required by the Secretary. These terms and conditions are set out at 42 CFR part 488, subpart A, as described above. Based on the 24-month transition period allowed by section 125 of MIPPA, the Joint Commission's term of approval as a recognized accreditation program for hospitals expires July 15, 2010.

II. Deeming Applications Approval Process

Section 1865(a)(3)(A) of the Act provides a statutory timetable to ensure that our review of applications for deeming authority is conducted in a timely manner. We must complete our review of an accreditation organization's application within 210 calendar days after the date of receipt of the completed application (including all documentation necessary to make a determination). Within 60 days after receiving a complete 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 a notice in the **Federal Register** approving or denying the application.

III. Provisions of the Proposed Notice and Response to Comments

On June 26, 2009, we published a proposed notice in the **Federal Register** (74 FR 30588) announcing the Joint Commission's request for re-approval as a deeming organization for hospitals. In that notice, we specified in detail our evaluation criteria. Under section 1865(a)(2) of the Act and in our