best assured of having their full effect if received within 60-days of the date of this publication.

Dated: September 17, 2009.

Joe Ellis,

Director, OPERA, OER, National Institutes of Health.

[FR Doc. E9–23078 Filed 9–24–09; 8:45 am]

BILLING CODE 4140–10–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0449]

Enforcement of General Tobacco Standard Special Rule for Cigarettes

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Family Smoking Prevention and Tobacco Control Act (FSPTCA), establishes a tobacco standard special rule for cigarettes. This special rule for cigarettes prohibits a cigarette or any of its component parts (including the tobacco, filter, or paper) from containing, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke. The Food and Drug Administration (FDA) is providing this notice to remind regulated industry that as of the effective date identified in the FSPTCA, cigarettes that contain certain characterizing flavors are considered adulterated under the act. FDA is also providing in this notice contact information to which individuals who observe violative products after the effective date of the tobacco standard special rule may report their observations to FDA.

DATES: Effective September 22, 2009.

ADDRESSES: To report tobacco products that fail to comply with section 907(a)(1)(A) of the act after September 22, 2009, please contact the Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229, 877–287–1373 or *http://www.fda.gov/flavoredtobacco*.

FOR FURTHER INFORMATION CONTACT: Michele Mital, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229, 877–287–1373, *Michele.Mital@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Smoking is the leading preventable cause of death in the United States. An important way to reduce the death and disease caused by smoking is to prevent children and adolescents from starting to smoke. Congress has stated that flavors make cigarettes more appealing to youth and often result in exposure to additional carcinogens and other toxic constituents. The removal from the market of cigarettes that contain certain characterizing flavors is an important step in FDA's efforts to reduce the burden of illness and death caused by tobacco products.

The FSPTCA provides FDA with regulatory authority over the manufacture, marketing, and distribution of tobacco products. Specifically, section 907(a)(1)(A) of the act, as amended by the FSPTCA, establishes a tobacco product standard special rule for cigarettes that states in part: ''* * * a cigarette or any of its component parts (including the tobacco, filter, or paper) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke.''

This standard applies to all tobacco products that meet the definition of a ''cigarette'' in section 900(3) of the act, as amended, even if they are not labeled as ''cigarettes'' or are labeled as cigars or as some other product.

As of the September 22, 2009, effective date, cigarettes and their component parts that fail to comply with the special rule established under section 907 of the act, as amended, are deemed adulterated under section 902 of the act, as amended. Under the act, adulterated products sold or held for sale in the United States may be subject to seizure under section 304 of the act (21 U.S.C. 334). In addition, manufacturers, distributors, and retailers may be subject to injunction actions, civil money penalties, and/or criminal prosecution for violating the requirements of the act (sections 301, 302, and 303 of the act (21 U.S.C. 331, 332, and 333, respectively)). FDA intends to use the full range of enforcement tools within the agency's authority to ensure compliance with the new requirement.

FDA encourages individuals who observe violative products after September 22, 2009, to report their observations to FDA. This collection of information was approved under OMB control number 0910–0647 and expires on March 31, 2010. Individuals may report products in violation of this standard to FDA through the contact information provided in the **ADDRESSES** section of this document.

Dated: September 21, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–23144 Filed 9–22–09; 11:15 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–2487–FN]

Medicare and Medicaid Programs; Application by the American Osteopathic Association 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 approve the American Osteopathic Association (AOA) 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 on October 23, 2009 through October 23, 2013.

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. Sections 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 § 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.

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 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

On May 26, 2009, we published a proposed notice (74 FR 24857) announcing the American Osteopathic Association's (AOA) 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 AOA application in accordance with the criteria specified by our regulation, which include, but are not limited to the following:

- An onsite administrative review of AOA'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 AOA's ASC accreditation standards to our current Medicare ASC conditions for coverage; and
- A documentation review of AOA's survey processes to:
  - Determine the composition of the survey team, surveyor qualifications, and the ability of AOA to provide continuing surveyor training;
  - Compare AOA'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 AOA's procedures for monitoring providers or suppliers found to be out of compliance with AOA's program requirements. The monitoring procedures are used only when AOA identifies noncompliance. If noncompliance is identified through validation reviews, the State survey agency monitors corrections as specified at § 488.7(d);
  - Assess AOA's ability to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner;
  - Establish AOA's ability to provide us with electronic data and reports necessary for effective validation and assessment of AOA's survey process;
  - Determine the adequacy of staff and other resources;
  - Review AOA's ability to provide adequate funding for performing required surveys;
  - Confirm AOA's policies with respect to whether surveys are announced or unannounced; and
  - Obtain AOA'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 May 26, 2009 proposed notice (74 FR 24857) also solicited public comments regarding whether AOA's requirements met or exceeded the Medicare conditions for coverage (CfC) for ASCs. We received no public comments in response to our proposed notice.

IV. Provisions of the Final Notice

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

We compared the AOA's ASCs 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 AOA's deeming application, which were conducted as described in section III of this final notice, yielded the following:

- AOA modified its policies related to the accreditation effective date in accordance with the requirements at § 489.13;
- AOA modified its policies regarding timeframes for sending and receiving a plan of correction (PoC) in accordance with section 2728 of the SOM;
- AOA revised its policies to include timeframes for investigation of complaints in accordance with the requirements at section 5075.9 of the SOM;
- AOA developed and implemented internal monitoring procedures to ensure its surveyors are trained and qualified to meet the requirements at § 488.4(a)(4);
- AOA developed an action plan to ensure that deemed status survey files are complete, accurate, and consistent with the requirements at § 488.6(a);
- AOA developed and conducted surveyor training on the documentation of deficiencies to ensure that all cited deficiencies contain a regulatory reference, a clear and detailed description of the deficient practice, and relevant finding;
- AOA developed a policy to ensure that facilities with condition level non-compliance on a recertification survey submit an acceptable PoC, and receive a follow-up onsite focused survey, in order to meet the requirements at § 488.20(b) and § 488.28(a);
- AOA revised its policies and developed an internal tracking tool to

ensure that facilities with condition level non-compliance on an initial survey receive an onsite follow-up full survey, in order to meet the requirements at section 2005A2 of the SOM;

• AOA developed and incorporated measures to improve the accuracy and consistency of data submissions to CMS in order to meet the requirements at § 488.4(b);

• AOA revised its policies on blackout dates to meet the requirements at 2700A of the SOM;

• AOA revised its accreditation decision letters to ensure that they are accurate and contain all the required elements for our Regional Office to render a decision regarding the deemed status of an accredited ASC;

• AOA revised and updated its surveyor team handbook to include references to its ASC deeming program;

• AOA extended its onsite survey time allotted for review of the CfCs from 1 day to 2 days in order to meet the requirements at § 488.26; and

• AOA removed all references to mandatory consultative services from its policies to avoid potential conflict of interest issue.

To verify AOA's continued compliance with the provisions of this final notice, we will conduct a follow-up corporate onsite visit within 1 year of the date of publication of this notice.

B. Term of Approval

Based on the review and observations described in section III of this final notice, we have determined that the AOA's requirements for ASCs meet or exceed our requirements. Therefore, we approve AOA as a national accreditation organization for ASCs that request participation in the Medicare program, effective October 23, 2009 through October 23, 2013.

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: September 10, 2009.

Charlene Frizzera,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E9–22956 Filed 9–24–09; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–4141–N]

Medicare Program; Medicare Appeals; Adjustment to the Amount in Controversy Threshold Amounts for Calendar Year 2010

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

ACTION: Notice.

SUMMARY: This notice announces the annual adjustment in the amount in controversy (AIC) threshold amounts for Administrative Law Judge (ALJ) hearings and judicial review under the Medicare appeals process. The adjustment to the AIC threshold amounts will be effective for requests for ALJ hearings and judicial review filed on or after January 1, 2010. The 2010 AIC threshold amounts are $130 for ALJ hearings and $1,260 for judicial review.

DATES: *Effective Date:* This notice is effective on January 1, 2010.

FOR FURTHER INFORMATION CONTACT: Liz Hosna, (410) 786–4993.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1869(b)(1)(E) of the Social Security Act (the Act), as amended by section 521 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), established AIC threshold amounts for ALJ hearing requests and judicial review at $100 and $1000, respectively, for Medicare Part A and Part B appeals. Section 940 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, amended section 1869(b)(1)(E) of the Act to require the AIC threshold amounts for ALJ hearings and judicial review to be adjusted annually. The AIC threshold amounts are to be adjusted, as of January 2005, by the percentage increase in the medical care component of the consumer price index for all urban consumers (U.S. city average) for July 2003 to July of the year preceding the year involved and rounded to the nearest multiple of $10. Section 940(b)(2) of the MMA provided conforming amendments to apply the AIC adjustment requirement to Medicare Part C (Medicare Advantage ''MA'') appeals and certain health maintenance organization and competitive health plan appeals. Health care prepayment plans are also subject to MA appeals rules, including the AIC adjustment requirement. Section 101 of the MMA provides for the application of the AIC adjustment requirement to Medicare Part D appeals.

A. Medicare Part A and Part B Appeals

The statutory formula for the annual adjustment to the AIC threshold amounts for ALJ hearings and judicial review of Medicare Part A and Part B appeals, set forth at section 1869(b)(1)(E) of the Act, is included in the applicable implementing regulations, 42 CFR part 405, subpart I, at § 405.1006(b). The regulations require the Secretary of the Department of Health and Human Services (the Secretary) to publish changes to the AIC threshold amounts in the **Federal Register** (§ 405.1006(b)(2)). In order to be entitled to a hearing before an ALJ, a party to a proceeding must meet the AIC requirements at § 405.1006(b). Similarly, a party must meet the AIC requirements at § 405.1006(c) at the time judicial review is requested for the court to have jurisdiction over the appeal (§ 405.1136(a)).

B. Medicare Part C (Medicare Advantage) Appeals

Section 940(b)(2) of the MMA applies the AIC adjustment requirement to Part C (MA) appeals by amending section 1852(g)(5) of the Act. The implementing regulations for Medicare Part C appeals are found at 42 CFR part 422, subpart M. Specifically, § 422.600 and § 422.612 discuss the AIC threshold amounts for ALJ hearings and judicial review.

Section 422.600 grants any party to the reconsideration, except the MA organization, who is dissatisfied with the reconsideration determination, a right to an ALJ hearing as long as the amount remaining in controversy after reconsideration meets the threshold requirement established annually by the Secretary. Section 422.612 states that any party, including the MA organization, may request judicial review if, in part, the amount in controversy meets the threshold requirement established annually by the Secretary.