DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10161]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency's function; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection. *Title of Information Collection:* New Freedom Initiative—Web-based Reporting System for Grantees. *Use:* CMS awards competitive grants to states and other eligible entities for the purpose of designing and implementing effective and enduring improvements in community-based long-term services and support systems. CMS requires that grantees report on a quarterly, semi-annual, and/or annual basis depending upon the grant type. CMS requires the information obtained through web-based grantee reporting for two reasons: To effectively monitor the grants and to report to Congress and other interested stakeholders the progress and obstacles experienced by the grantees. The grantees are the respondents to the web-based reporting system. *Form Number:* CMS–10161 (OCN 0938–0979). *Frequency:* Annually, semi-annually, and quarterly. *Affected Public:* State, Local or Tribal Governments. *Number of Respondents:* 171. *Total Annual Responses:* 428. *Total Annual Hours:* 3,764. (For policy questions regarding this collection contact Effie George at 410–786–8639. For all other issues call 410–786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web Site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995,* or Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

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 October 29, 2012.

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–6974, Email: *OIRA_submission@omb.eop.gov.*

Dated: September 25, 2012.

Martique Jones,

Director, Regulations Development Group, Division-B, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2012–23899 Filed 9–27–12; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3264–FN]

Medicare and Medicaid Programs; Approval of the American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA/HFAP) Application for Continuing CMS-Approval of Its Ambulatory Surgical Center (ASC) Accreditation Program

AGENCY: Centers for Medicare and Medicaid Services, HHS.

ACTION: Final notice.

SUMMARY: This final notice announces our decision to approve the American Osteopathic 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 and/or Medicaid programs.

DATES: *Effective Date:* This final notice is effective October 23, 2013 through October 23, 2017.

FOR FURTHER INFORMATION CONTACT:

Barbara Easterling (410) 786–0482.

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 ASC provided certain health, safety, and other requirements are met. Section 1832(a)(2)(F)(i) of the Act permits the Secretary to establish distinct criteria for facilities seeking designation as an ASC. 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. Regulations pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488.

Generally, in order to enter into an agreement, an ASC must first be certified by a State survey agency as complying with the conditions or requirements set forth in Part 416. Thereafter, the ASC is subject to regular surveys by a State survey agency to determine whether it continues to meet these 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 accrediting organization that all applicable Medicare conditions are met or exceeded, we will deem those provider entities as having met the requirements. Accreditation by an accrediting organization is voluntary and is not required for Medicare participation. In accordance with the requirements at 416.26, an ASC may be deemed to meet conditions for coverage if it is accredited by a national accrediting body.

If an accrediting organization is recognized by the Secretary as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program would be deemed to meet the Medicare conditions. A national accrediting organization applying for approval of its accreditation program under Part 488 subpart A must provide us with reasonable assurance that the accrediting organization requires the 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 488.4 and 488.8. The regulations at 488.8(d)(3) require accrediting organizations to reapply for continued approval of its accreditation program

every 6 years or sooner as determined by CMS.

AOA/HFAP's current term of approval for their ASC accreditation program expires October 23, 2012.

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 May 25, 2012, we published a proposed notice in the **Federal Register** (77 FR 31361) announcing AOA/HFAP's request for continued approval of its 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 488.4 and 488.8, we conducted a review of AOA/HFAP's 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 surveyors; (4) ability to investigate and respond appropriately to complaints against accredited facilities; and (5) survey review and decision-making process for accreditation.
- The comparison of AOA/HFAP's accreditation to our current Medicare ASC conditions for coverage.
- A documentation review of AOA/HFAP's survey process for the following:

+ 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 of State survey agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

+ Evaluate AOA/HFAP's procedures for monitoring ASC's found to be out of compliance with AOA/HFAP's program requirements. The monitoring procedures are used only when AOA/HFAP identifies noncompliance. If noncompliance is identified through validation reviews, the State survey agency monitors corrections as specified at 488.7(d).

+ Assess AOA/HFAP's ability to report deficiencies to the surveyed facilities and respond to the facility's 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 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 whether surveys are announced or unannounced.

+ Obtain AOA/HFAP's agreement to provide CMS 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 25, 2012 proposed notice also solicited public comments regarding whether AOA/HFAP's requirements met or exceeded the Medicare conditions for coverage for ASCs. We received one comment in response to our proposed notice. The commenter expressed 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's Conditions and Survey Requirements

We compared AOA/HFAP's ASC requirements and survey process with the Medicare conditions for certification and survey process as outlined in the State Operations Manual (SOM). 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:

- To meet the requirements at 416.44(b)(1), AOA/HFAP revised its standards to include thresholds for new and existing Life Safety Code (LSC) requirements. In addition, AOA/HFAP revised its standards to ensure all waivers for LSC deficiencies are reviewed and approved by the CMS Regional Office.
- To meet the requirement at 416.44(b)(4), AOA/HFAP revised its standards to ensure all ASCs are in compliance with the emergency lighting requirements.
- To meet the requirement at 416.50, AOA/HFAP revised its crosswalk to include the patient rights condition for coverage requirements.
- To meet the requirements at 488.4, AOA/HFAP revised its policies to ensure the survey process requirements for ASCs is accurate, clear and complete.
- To meet the requirements at 488.8, AOA/HFAP modified its policies and procedures to ensure all complaints are appropriately triaged, and investigated.
- To meet the requirements at section 2728 of the SOM, AOA/HFAP modified its policies to ensure all accepted plans of correction include the citation cited, the procedure implementing the plan, and the monitoring procedure.
- To meet the requirements of 2728B, AOA/HFAP revised its policies to ensure all plans of correction contain the procedure for implementing the plan and the monitoring procedure to ensure cited deficiencies remain corrected and in compliance with the regulatory requirements.
- AOA/HFAP also made extensive organization-wide changes to their internal processes in response to an 18 month accreditation program review that was concluded in July 2012. AOA/HFAP demonstrated compliance with our requirements across their organization and accreditation programs.

B. Term of Approval

Based on our review and observations described in section III of this final notice, we have determined that AOA/HFAP's requirements for ASCs meet or exceed our requirements. Therefore, we approve AOA/HFAP as a national accreditation organization for ASCs that request participation in the Medicare program, effective October 23, 2013 through October 23, 2017.

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; No. 93.773 Medicare—ASC Insurance Program; and No. 93.774,

Medicare—Supplementary Medical Insurance Program)

Dated: September 25, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2012–23996 Filed 9–27–12; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–4158–N]

Medicare Program; Medicare Appeals; Adjustment to the Amount in Controversy Threshold Amounts for Calendar Year 2013

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, 2013. The calendar year 2013 AIC threshold amounts are $140 for ALJ hearings and $1,400 for judicial review.

EFFECTIVE DATE: This notice is effective on January 1, 2013.

FOR FURTHER INFORMATION CONTACT: Liz Hosna (*Katherine.Hosna@cms.hhs.gov*), (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 the amount in controversy (AIC) threshold amounts for Administrative Law Judge (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 (MMA), 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 405.1006(b) and (c). 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 Medicare Part C (MA) appeals by amending section 1852(g)(5) of the Act. The implementing regulations for Medicare Part C (MA) 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, in part, that any party, including the MA organization, may request judicial review if the AIC meets the threshold requirement established annually by the Secretary.

C. Health Maintenance Organizations, Competitive Medical Plans, and Health Care Prepayment Plans

Section 1876(c)(5)(B) of the Act states that the annual adjustment to the AIC dollar amounts set forth in section 1869(b)(1)(E) of the Act applies to certain beneficiary appeals within the context of health maintenance organizations and competitive medical plans. The applicable implementing regulations for Medicare Part C appeals are set forth in 42 CFR part 422, subpart M, and as discussed previously, apply to these appeals. The Medicare Part C appeals rules also apply to health care prepayment plan appeals.

D. Medicare Part D (Prescription Drug Plan) Appeals

The annually adjusted AIC threshold amounts for ALJ hearings and judicial review that apply to Medicare Parts A, B, and C appeals also apply to Medicare Part D appeals. Section 101 of the MMA added section 1860D–4(h)(1) of the Act regarding Part D appeals. This statutory provision requires a prescription drug plan sponsor to meet the requirements set forth in sections 1852(g)(4) and (g)(5) of the Act, in a similar manner as MA organizations. As noted previously, the annually adjusted AIC threshold requirement was added to section 1852(g)(5) of the Act by section 940(b)(2)(A) of the MMA. The implementing regulations for Medicare Part D appeals can be found at 42 CFR part 423, subparts M and U. The regulations at § 423.562(c) prescribe that, unless the Part D appeals rules provide otherwise, the Part C appeals rules (including the annually adjusted AIC threshold amount) apply to Part D appeals to the extent they are appropriate. More specifically, § 423.1970 and § 423.1976 of the Part D appeals rules discuss the AIC threshold amounts for ALJ hearings and judicial review. Section 423.1970(a) grants a Part D enrollee, who is dissatisfied with the independent review entity (IRE) reconsideration determination, a right to an ALJ hearing if the amount remaining in controversy after the IRE reconsideration meets the threshold amount established annually by the Secretary. Sections 423.1976(a) and (b) allow a Part D enrollee to request judicial review of an ALJ or MAC decision if, in part, the AIC meets the threshold amount established annually by the Secretary.