

accompanying requirements are used by Federal or State surveyors as a basis for determining whether a hospice qualifies for approval or re-approval under Medicare. We believe that the availability to the hospice of the type of records and general content of records, which the final rule (72 FR 32088) specifies, is standard medical practice, and is necessary in order to ensure the well-being and safety of patients and professional treatment accountability. There are no program changes to this information collection request, meaning there are no new requirements; however, we are currently adjusting the numbers of respondents and responses. The final numbers will be present in the 30-day notice. *Form Number*: CMS-10277 (OCN: 0938-1067); *Frequency*: Yearly; *Affected Public*: Private sector—Business or other for-profit and Not-for-profit institutions; *Number of Respondents*: 2,872; *Total Annual Responses*: 1,808,345; *Total Annual Hours*: 2,152,396. (For policy questions regarding this collection contact Danielle Shearer at 410-786-6617.)

Dated: November 22, 2013.

Martique Jones,

Deputy 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-3285-FN]

Medicare and Medicaid Programs; Continued Approval of American Osteopathic Association/Healthcare Facilities Accreditation Program's Critical Access Hospital Accreditation Program

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Final notice.

SUMMARY: This final notice announces our decision to approve the American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA/HFAP) for continued recognition as a national accrediting organization (AO) for critical access hospitals (CAH) that wish to participate in the Medicare or Medicaid programs.

DATES: This final notice is effective December 27, 2013 through December 27, 2019.

FOR FURTHER INFORMATION CONTACT:

James Cowher, (410) 786-41948, Cindy Melanson, (410) 786-0310, or Patricia Chmielewski, (410) 786-6899.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in a CAH provided certain requirements are met. Sections 1820(c)(2)(B), 1820(e), and 1861(mm)(1) of the Social Security Act (the Act) establish distinct criteria for facilities seeking designation as a CAH. 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. The regulations at 42 CFR 485, subpart F specify the conditions that a CAH must meet to participate in the Medicare program, the scope of covered services, and the conditions for Medicare payment for CAHs.

Generally, to enter into an agreement, a CAH must first be certified by a state survey agency as complying with the conditions or requirements set forth in part 485, subpart F. Thereafter, the CAH is subject to regular surveys by a state survey agency to determine whether it continues to meet these requirements. However, there is an alternative to surveys by state agencies. Certification by a nationally recognized accreditation program can substitute for ongoing state review.

Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by an approved national AO that all applicable Medicare conditions are met or exceeded, we will deem those provider entities as having met the requirements. Accreditation by an AO is voluntary and is not required for Medicare participation. A national AO applying for approval of its accreditation program under part 488, subpart A, must provide CMS with reasonable assurance that the AO requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions.

Our regulations concerning the approval of AOs are set forth at § 488.4 and § 488.8(d)(3). The regulations at § 488.8(d)(3) require AOs to reapply for continued approval of its accreditation program every 6 years or sooner as determined by CMS. The AOA/HFAP's current term of approval for their CAH accreditation program expires December 27, 2013.

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 June 25, 2013, we published a proposed notice in the **Federal Register** (78 FR 38043) announcing AOA/HFAP's request for approval of its CAH 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 decisionmaking process for accreditation.

- The comparison of AOA/HFAP's accreditation to our current Medicare CAH conditions of participation (CoPs).

- A documentation review of AOA/HFAP's survey process to:

- ++ 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 CAHs 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 us 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 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 25, 2013 proposed notice also solicited public comments regarding whether AOA/HFAP's requirements met or exceeded the Medicare conditions of participation for CAHs. We received no comments in response to our proposed notice.

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 CAH requirements and survey process with the Medicare CoPs and survey process as outlined in the State Operations Manual (SOM). Our review and evaluation of AOA/HFAP's CAH application, which were conducted as described in section III of this final notice, yielded the following:

- To meet the requirements at § 485.623(b)(5), AOA/HFAP revised its standards to require all ventilation systems, both new and existing, supplying operating rooms to meet the humidity control requirements..

- To meet the requirements at § 485.623(c)(1), AOA/HFAP revised its standards to incorporate specific staff training requirements for protection in place or methods for the evacuation of patients, when necessary.

- To meet the requirements at § 485.635(e), AOA/HFAP revised its standards to include staff qualification requirements for rehabilitation therapy services.

- To meet the requirements at § 488.4(a)(6), AOA/HFAP revised its "Complaint/Incident Management Policy," to ensure all onsite complaint

surveys are documented on a survey report.

- To meet the requirements of section 2728 of the SOM, AOA/HFAP will continue to use its internal monitoring plan to ensure timeframes for sending or receiving a plan of correction (PoC) are met.

- To meet the requirements of section 2728B of the SOM, AOA/HFAP will continue to conduct monthly internal audits to ensure accepted PoC's contain all of the required elements.

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 CAH accreditation program requirements meet or exceed our requirements. Therefore, we approve AOA/HFAP as a national AO for CAHs that request participation in the Medicare program, effective December 27, 2013 through December 27, 2019.

V. Collection of Information Requirements

This document does not impose information collection, recordkeeping or third party disclosure 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: (Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: November 12, 2013.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-1439]

Agency Information Collection Activities; Proposed Collection; Comment Request; Adverse Event Program for Medical Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain

information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information regarding the Adverse Event Program for medical devices.

DATES: Submit either electronic or written comments on the collection of information by January 28, 2014.

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

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, PRStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and