

and merely reflect accepted standards of management and care to which rural health clinics must adhere. *Form Number:* CMS-R-38 (OMB#: 0938-0334); *Frequency:* Recordkeeping and Reporting—Annually and upon initial application for Medicare approval; *Affected Public:* Business or other for-profits; *Number of Respondents:* 3,937; *Total Annual Responses:* 3,937; *Total Annual Hours:* 18,932. (For policy questions regarding this collection contact Mary Collins at 410-786-3189. For all other issues call 410-786-1326.)

4. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Durable Medical Equipment Medicare Administrative Contractors (MAC), Certificates of Medical Necessity; *Use:* The certificate of medical necessity (CMN) collects information required to help determine the medical necessity of certain items. CMS requires CMNs where there may be a vulnerability to the Medicare program. Each initial claim for these items must have an associated CMN for the beneficiary. Suppliers (those who bill for the items) complete the administrative information (e.g., patient's name and address, items ordered, etc.) on each CMN. The 1994 Amendments to the Social Security Act require that the supplier also provide a narrative description of the items ordered and all related accessories, their charge for each of these items, and the Medicare fee schedule allowance (where applicable). The supplier then sends the CMN to the treating physician or other clinicians (e.g., physician assistant, LPN, etc.) who completes questions pertaining to the beneficiary's medical condition and signs the CMN. The physician or other clinician returns the CMN to the supplier who has the option to maintain a copy and then submits the CMN (paper or electronic) to CMS, along with a claim for reimbursement.

Due to a technical oversight on the part of CMS, an important question on CMN Form 10269 was omitted from the last OMB submission that would allow claims with an apnea-hypopnea index (AHI) or respiratory disturbance index (RDI) greater than or equal to 5 without symptoms for Criterion 2 be paid for by the Medicare program. The omission of the following question "Does the patient have documented evidence of at least one of the following: Excessive daytime sleepiness, impaired cognition, mood disorders, insomnia, hypertension, ischemic heart disease or history of stroke" could cause improper payment of claims without regards as to whether the patient has signs or symptoms in support of meeting the applicable

coverage criteria for PAP devices. We are resubmitting this information collection request to have the revised CMN Form 10269 approved. None of the other CMN forms have changed. *Form Number:* CMS-846-849, 854, 10125, 10126, 10269 (OMB# 0938-0679); *Frequency:* Occasionally; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 59,200; *Total Annual Responses:* 6,480,000; *Total Annual Hours:* 1,296,000. (For policy questions regarding this collection contact Doris Jackson at 410-786-4459. 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 e-mail 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 September 28, 2009.

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

Dated: August 21, 2009.

Michelle Shortt,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Availability of Draft Policy Document for Comment

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: This Policy Information Notice (PIN) describes the documentation that will be considered by the Health Resources and Services Administration (HRSA) to establish whether an organization can qualify as a "public agency" (also referred to in previous PINs as "public entities" or "public applicants") for the purpose of determining eligibility for a Health

Center Program grant under Section 330 of the Public Health Service (PHS) Act ("Section 330") and/or Federally Qualified Health Center (FQHC) Look-Alike designation. This draft PIN is available on the Internet at <http://bphc.hrsa.gov/draftsforcomment/publiccenter>.

DATES: Comments must be received by October 13, 2009.

ADDRESSES: Comments should be submitted to OPPDGeneral@hrsa.gov by close of business October 13, 2009.

SUMMARY: HRSA believes that community input is valuable to the development of policies and policy documents related to the implementation of HRSA programs, including the Health Center Program. Therefore, we are requesting comments on the PIN referenced above. Comments will be reviewed and analyzed, and a summary and general response will be published as soon as possible after the deadline for receipt of comments.

Background: HRSA administers the Health Center Program, which supports more than 1,100 organizations operating more than 7,500 health care delivery sites, including community health centers, migrant health centers, health care for the homeless centers, and public housing primary care centers. Health centers serve medically underserved communities delivering preventive and primary care services to patients regardless of their ability to pay. The Health Center Program's authorizing statute and implementing regulations (Section 330 of the PHS Act and 42 CFR Part 51c) state that any public or non-profit private entity is eligible to apply for a grant under the Health Center Program. The term "public agency" is not explicitly defined in Section 330 or in the Health Center Program's regulations; however, reference is made in Section 330 to these types of organizations within the definition of a public center as "a health center funded (or to be funded) through a grant under this section to a public agency" (Section 330(k)(3)(M) of the PHS Act). HRSA is issuing this PIN to describe the documentation that will be considered to establish whether an organization can qualify as a "public agency" (also referred to in previous PINs as "public entities" or "public applicants") for purposes of determining eligibility for a Health Center Program grant under Section 330 of the PHS Act and/or FQHC Look-Alike designation.

FOR FURTHER INFORMATION CONTACT: For questions regarding this notice, please contact the Office of Policy and Program

Development, Bureau of Primary Health Care, HRSA, at 301-594-4300.

Dated: August 24, 2009.

Mary K. Wakefield,
Administrator.

[FR Doc. E9-20818 Filed 8-27-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-2299-FN]

Medicare and Medicaid Programs; Application of the American Osteopathic Association for Continued Deeming Authority for Hospitals

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

ACTION: Final notice.

SUMMARY: This notice announces our decision to approve the American Osteopathic Association (AOA) for continued recognition as a national accreditation program for hospitals seeking to participate in the Medicare or Medicaid programs.

DATES: *Effective Date:* This final notice is effective September 25, 2009 through September 25, 2013.

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 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 conditions 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 those pertaining to activities relating 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 the statute and part 482 of the regulations. Then, the hospital is subject to routine State agency surveys to determine whether it

continues to meet the Medicare requirements. There is an alternative, however, to State compliance surveys.

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.

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 organization approved program would be deemed to meet the Medicare conditions.

Accreditation by an accreditation organization is voluntary and is not required for Medicare participation.

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 reapproval 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 sooner as determined by CMS.

AOA’s term of approval as a recognized accreditation program for hospitals expires September 25, 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 a complete application, with any documentation necessary to make a determination, to complete our survey activities and application review. Within 60 days of receiving a complete application, we must publish a notice in the **Federal Register** that identifies the national accreditation organization 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 and Response to Comments

On April 24, 2009, we published a proposed notice in the **Federal Register** (74 FR 18728) announcing AOA’s

request for reapproval as a deeming organization for hospitals. In this notice, we detailed the evaluation criteria. Under section 1865(a)(2) of the Act and our regulations at § 488.4, we conducted a review of the AOA’s application in accordance with the criteria specified by our regulations, which include, but are not limited to the following factors:

- 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 hospital accreditation standards to our current Medicare hospital CoPs.

- A documentation review of AOA’s survey processes to:

- + Determine the composition of the survey team, surveyor qualifications, and AOA’s ability 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 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.

- + 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 April 24, 2009 proposed notice also solicited public comments regarding whether