breastfeeding woman who agrees to participate, the TIS will then conduct 3 telephone interviews: At enrollment; approximately one month after enrollment; and 3 months after enrollment, if the woman is still taking medication and still breastfeeding. The interviews will assess maternal and fetal health throughout pregnancy, maternal and infant health at delivery, during the newborn and early infancy period, and while breastfeeding, and correlate these outcomes with medication exposure during pregnancy and while breastfeeding. There is no cost to respondents other than their time.

ESTIMATE OF ANNUALIZED BURDEN HOURS

Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Pregnancy Exposure Group	338	5	23/60	648
Lactation Exposure Group	74	4	20/60	99
Pregnancy and Lactation Exposure Group (pregnant women who subsequently breastfeed)	338	5	30/60	845
Total	750			1,592

Dated: November 14, 2007.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E7–22811 Filed 11–21–07; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–2272-FN]

Medicare and Medicaid Programs; Approval of the American Osteopathic Association's Deeming Authority for Critical Access Hospitals

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

ACTION: Final notice.

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

DATES: *Effective Date:* This final notice is effective December 28, 2007 through December 28, 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 a CAH provided certain requirements are met. Sections 1820(c)(2)(B) and 1861(mm) of the Social Security Act (the Act) establish distinct criteria for facilities seeking designation as a CAH. Under this authority, the minimum requirements that a CAH must meet to participate in Medicare are set forth in regulations at 42 CFR part 485, subpart F (Conditions of Participation: Critical Access Hospitals (CAHs)) which determine the basis and scope of CAH covered services. Conditions for Medicare payment for CAHs can be found at 42 CFR 413.70. Applicable regulations concerning provider agreements are at 42 CFR part 489 (Provider Agreements and Supplier Approval) and those pertaining to facility survey and certification are at part 488, subparts A and B.

A. Verifying Medicare Conditions of Participation

In general, we approve a CAH for participation in the Medicare program if it is participating as a hospital at the time it applies for CAH designation, and it is in compliance with parts 482 (Conditions of Participation for Hospitals) and 485, subpart F (*Conditions of Participation:* Critical Access Hospital (CAHs)).

For a CAH to enter into a provider agreement, a State survey agency must certify that the CAH is in compliance with the conditions or standards set forth in Section 1820 of the Social Security Act and part 485 of our regulations. Thereafter, the CAH is subject to ongoing review by a State survey agency to determine whether it continues to meet the Medicare requirements. There is, however, an alternative to State compliance surveys. Certification by a nationally-recognized accreditation program can substitute for ongoing State review.

Section 1865(b)(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 six years, or sooner as we determine. The American Osteopathic Association's (AOA) term of approval as a recognized accreditation program for CAHs expires December 27, 2007.

II. Deeming Applications Approval Process

Section 1865 (b) (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. Proposed Notice

On July 27, 2007, we published a proposed notice (72 FR 41331) announcing the AOA's request for re-approval as a deeming organization for CAHs. In the proposed notice, we detailed our evaluation criteria. Under section 1865(b)(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 CAH accreditation standards to our current Medicare CAH conditions for participation; 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 program requirements. The monitoring procedures are used only when the AOA identifies noncompliance. If noncompliance is identified through validation reviews, the 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 in ASCII-comparable code 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(b)(3)(A) of the Act, the July 27, 2007 proposed notice (72 FR 41331) also solicited public comments regarding whether AOA's requirements met or exceeded the Medicare conditions of participation for CAHs. We received no public comments in response to our proposed notice.

IV. Provisions of the Final Notice

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

We compared the standards contained in AOA's accreditation requirements for CAHs and its survey process in AOA's Application for Renewal of Deeming Authority for CAH Facilities with the Medicare CAH conditions for participation and our State Operations Manual. Our review and evaluation of AOA's deeming application, which were conducted as described in section III of this final notice, yielded the following:

- AOA provided a list of trained surveyors that are able to provide consultative services to requesting facilities. In order to eliminate any real or perceived conflict of interest between the AOA's accreditation activities and AOA's list of surveyors able to provide consultation, AOA has formalized policies and procedures that adequately cover the conflict of interest process for surveyors that provide consultations;
- AOA has revised its complaint policies to address timeframes for addressing complaints that involve immediate jeopardy;
- AOA modified its application process for facilities undergoing a certification or recertification survey to allow fewer ''black-out'' dates to address CMS' concern of ensuring that surveys conducted by AOA comply with CMS' policy of unannounced surveys;
- AOA formalized a process to ensure that all surveyors are receiving an annual performance evaluation;
- AOA added standards to their CAH Manual to meet the requirements at § 485.603 rural health network, § 485.604 Personnel qualification, § 485.606 Designation and certification of CAHs, § 485.610 Status and location, and § 485.612 Compliance with hospital requirements at the time of application;
- In order to meet the requirements at § 485.616(b), AOA added language to its standards to address agreements for credentialing and quality assurance requirements for CAHs that are members of a rural health network;
- To meet the requirements at § 485.623(a), AOA revised its standard at 11.00.01 to address the requirement of adequate space for the provision of direct services;
- To meet the requirements at § 485.623(d)(7), AOA revised its standards to address alcohol based hand rubs;
- AOA revised its standards to address the supervision requirements for patients cared for by nurse practitioners, clinical nurse specialists, certified nurse midwives, and physician assistants in order to meet the requirements at § 485.631(b)(1)(v) and § 485.631(b)(1)(vi);
- In order to meet the requirements at § 485.635(a)(1), AOA added clarifying language to specify that health care services provided in the CAH are consistent with applicable State laws;
- To meet the requirements of § 485.635(a)(2), AOA added language to its standard to address the requirement that policies are developed with at least one member of a group of professional personnel that is not a member of the CAH staff;
- In order to meet the requirements of § 485.635(a)(3)(vii), AOA inserted language to address the requirements at § 483.25(i) with respect to inpatients receiving post-hospital skilled nursing facility (SNF) care;
- AOA revised its standard to include a representative sample of active and closed records in the periodic evaluation of its total program in order to meet the requirements at § 485.641(a)(1)(ii);
- AOA added language to its standards to address the requirements at § 482.30(b)(1) through § 482.30(b)(3) regarding requirements for utilization review;
- In order to meet the additional criteria in a distinct part unit of the CAH, the language addressed in the Medicare requirements § 412.25 Excluded hospital units: Common requirements and § 412.29 Excluded rehabilitation units: Additional requirements were adopted and added to AOA standards;
- AOA added additional standards to meet the eligibility requirements for CAH distinct part units found at § 485.647;
- Once AOA has implemented their revised standards, CMS will conduct a survey observation at the next available

opportunity to validate proper application of the standards.

• In order to meet the requirements of § 488.8(a)(2)(v), AOA has agreed to provide CMS with timely electronic data for effective validation and assessment of the organization's survey process; and

• To comply with the Medicare requirements of conducting unannounced certification and recertification surveys, AOA revised its survey procedures to prohibit any advance mailings of surveyor materials to the facility prior to the survey and will not permit the hospital to mail back the surveyor findings to AOA after completion of the survey.

B. Term of Approval

Based on the review and observations described in section III of this final notice, we have determined that AOA's requirements for CAHs meet or exceed our requirements. Therefore, we approve the AOA as a national accreditation organization for CAHs that request participation in the Medicare program, effective December 28, 2007 through December 28, 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).

Authority: Section 1865 of the Social Security Act (42 U.S.C. 1395bb).

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare-Supplemental Medical Insurance Program)

Dated: October 11, 2007.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E7–22628 Filed 11–21–07; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1377–N]

Medicare Program; Listening Session on Hospital-Acquired Conditions and Present on Admission Indicator Reporting, December 17, 2007

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces a listening session being conducted as part of the selection of Hospital-Acquired Conditions (HAC) and implementation of Present on Admission (POA) Indicator Reporting, as authorized by section 5001(c) of the Deficit Reduction Act of 2005 (DRA). The purpose of this listening session is to solicit informal comments in preparation for the fiscal year 2009 inpatient prospective payment system (IPPS) rulemaking process. Hospitals, hospital associations, representatives of consumer purchasers, payors of health care services, and all interested parties are invited to attend and make comments in person or in writing. It will also be possible to listen to the session by teleconference. However, because of time constraints, telephone participants will not be able to make verbal comments. Informal written comments will be accepted. This meeting is open to the public, but registration is required due to limited space and security requirements to enter the meeting location. This Listening Session is being held as a joint partnership between the Centers for Medicare & Medicaid Services and Centers for Disease Control and Prevention.

DATES: *Meeting Date:* The listening session will be held on Monday, December 17, 2007 from 10 a.m. until 5 p.m., e.s.t.

Deadline for Meeting Registration and Submitting Requests for Special Accommodations: Registration must be completed no later than 5 p.m., e.s.t. on Monday, December 10, 2007. Requests for special accommodations must be received no later than 5 p.m., e.s.t. on Monday, December 10, 2007.

Deadline for Presentations and Written Comments: Written comments may be sent electronically to the address specified in the **ADDRESSES** section of this notice and must be received by 5 p.m., e.s.t. on Monday, December 31, 2007.

ADDRESSES: *Meeting Location:* The meeting will be held in the main auditorium of the central building of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Registration and Special Accommodations: Persons interested in attending the meeting or listening by teleconference must register by completing the on-line registration at *http://registration.intercall,com/go/cms2.* Individuals who need special accommodations should contact Colette Shatto (410) 786–6932, or via e-mail at *MFG@cms.hhs.gov.*

Written Comments or Statements: Written comments may be sent by e-mail. Please e-mail comments to *hacpoa@cms.hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Further information regarding the December 17, 2007 listening session will be posted on the HAC & POA section of the CMS Web site at *http://www.cms.hhs.gov/HospitalAcqCond/01_Overview.asp.* You may also contact Colette Shatto, *MFG@cms.hhs.gov*, in the Medicare Feedback Group. Press inquiries are handled through the CMS Press Office at 202–690–6145.

I. Background

On February 8, 2006, the President signed the Deficit Reduction Act of 2005 (Pub. L. 109–171) (DRA). Section 5001(c) of the DRA requires the Secretary to identify, by October 1, 2007, at least two conditions that: (1) Are high cost or high volume or both; (2) result in the assignment of a case to a DRG that has a higher payment when present as a secondary diagnosis; and (3) could reasonably have been prevented through the application of evidence-based guidelines.

For discharges occurring on or after October 1, 2008, hospitals will not receive additional payment for cases in which one of the selected conditions occurring during hospitalization was not present on admission. That is, the case would be paid as though the secondary diagnosis was not present. Section 5001(c) of the DRA provides that we can revise the list of conditions from time to time, as long as it contains at least two conditions. In addition, CMS Change Request (CR) 5499 required hospitals to begin reporting the Present On Admission (POA) indicator for all diagnoses on claims beginning October 1, 2007.

II. Listening Session Format

The December 17, 2007 listening session will begin at 10 a.m., e.s.t. with an overview of the objectives for the