DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–2138–N]

RIN 0938–ZA28

Medicare, Medicaid, and CLIA Programs; Continuance of Approval of the American Osteopathic Association (AOA) as an CLIA Accreditation Organization

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

ACTION: Notice.

SUMMARY: This notice announces the continued approval of the American Osteopathic Association (AOA) as an accreditation organization for clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program. We have determined that the accreditation process of this organization provides reasonable assurance that the laboratories accredited by AOA meet the conditions required by CLIA statute and its implementing regulations. Consequently, laboratories that voluntarily become accredited by AOA, in lieu of direct Federal oversight, and continue to meet AOA requirements would meet the CLIA condition level requirements for laboratories and, therefore, are not subject to routine inspection by State survey agencies to determine their compliance with CLIA requirements. However, these laboratories are subject to Federal validation and complaint investigation surveys.

EFFECTIVE DATE: This notice is effective for the period March 22, 2002 through March 24, 2008.

FOR FURTHER INFORMATION CONTACT: Kathy Todd, (410) 786–3385.

SUPPLEMENTARY INFORMATION:

I. Background and Legislative Authority

On October 31, 1988, the Congress enacted the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100–578. CLIA replaced in its entirety section 353(e)(2) of the Public Health Service Act, as enacted by the Clinical Laboratories Improvement Act of 1967. In the July 31, 1992 **Federal Register** (57 FR 33992), we issued a final rule implementing the accreditation provisions of CLIA. Under this rule, we may approve a private, nonprofit organization as an approved accreditation organization to accredit clinical laboratories under the CLIA program if the organization meets certain requirements. An organization's requirements for accredited laboratories must be equal to, or more stringent than, the applicable CLIA program requirements in 42 CFR part 493 (Laboratory Requirements). Therefore, a laboratory accredited by an approved accreditation organization that meets and continues to meet all of the accreditation organization's requirements would be considered to meet CLIA condition level requirements if it were inspected against CLIA regulations. The regulations in part 493, subpart E (Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program) specify the requirements an accreditation organization must meet in order to be an approved. We approve an accreditation organization for a period not to exceed 6 years.

In general, the approved accreditation organization must, among other conditions and requirements:

- Use inspectors qualified to evaluate laboratory performance and agree to inspect laboratories with the frequency determined by us.
- Apply standards and criteria that are equal to, or more stringent than, those condition level requirements established by us when taken as a whole.
- Provide reasonable assurance that these standards and criteria are continuously met by its accredited laboratories.
- Provide us with the name of any laboratory that has had its accreditation denied, suspended, withdrawn, limited, or revoked within 30 days of the action taken.
- Notify us at least 30 days before implementing any proposed changes in its standards.
- If we withdraw our approval, notify the accredited laboratories of the withdrawal within 10 days of the withdrawal. A laboratory can be accredited if, among other things, it meets the standards of an approved accreditation organization and authorizes the accreditation organization to submit records and other information to us as required.

In addition to requiring the promulgation of criteria for approving an accreditation organization and withdrawing this approval, CLIA regulations require us to perform an annual evaluation by inspecting a sufficient number of laboratories accredited by an approved accreditation organization, as well as, by any other means that we determine appropriate.

II. Notice of Continued Approval of AOA as an Accreditation Organization

In this notice, we approve AOA as an organization that may continue to accredit laboratories for purposes of establishing their compliance with CLIA. The Centers for Disease Control and Prevention (CDC) and CMS have examined the AOA application and all subsequent submissions to determine equivalency with the requirements under 42 CFR part 493, subpart E that an accreditation organization must meet to be granted approved status under CLIA. We have determined that AOA complied with the applicable CLIA requirements and grant AOA approval as an accreditation organization under 42 CFR part 493, subpart E, as of March 21, 2002 through March 24, 2002 for all specialty and subspecialty areas under CLIA.

As a result of this determination, any laboratory that is accredited by AOA during this time period for an approved specialty or subspecialty is deemed to meet the applicable CLIA condition level requirements for the laboratories found in part 493 and, therefore, is not subject to routine inspection by a State survey agency to determine its compliance with CLIA requirements. The accredited laboratory, however, is subject to validation and complaint investigation surveys performed by CMS, or by any other Federal State, local public agency, or nonprofit organization under an agreement with the Secretary.

III. Evaluation of American Osteopathic Association (AOA)

The following describes the process used to determine that the American Osteopathic Association (AOA), as a private, nonprofit organization, provides reasonable assurance that laboratories it accredits will meet the applicable requirements of CLIA.

A. Requirements for Approving an Accreditation

Organization Under CLIA

To determine whether we should grant approved status to AOA as a private, nonprofit organization for accrediting laboratories under CLIA for all specialty or subspecialty areas of human specimen testing it requested, we conducted a detailed and in-depth comparison of AOA's requirements for its laboratories to those of CLIA. In summary, we evaluated whether AOA meets the following requirements:

- Provides reasonable assurance to us that it requires the laboratories it accredits to meet requirements that are equal to, or more stringent than, the

CLIA condition level requirements (for the requested specialties and subspecialties) and would, therefore, meet the condition level requirements of CLIA if those laboratories had not been granted deemed status and had been inspected against condition level requirements.

• Meets the applicable requirements of part 493, subpart E.

As specified in the regulations of part 493, subpart E, the review of a private, nonprofit accreditation organization seeking approved status under CLIA includes, but is not limited to, an evaluation of the following:

• Whether the organization's requirements for its accredited laboratories are equal to, or more stringent than, the condition levels requirements of the CLIA regulations.

• The organization's inspection process to determine the following:

+ The composition of the inspection teams, qualifications of the inspectors, and the ability of the organization to provide continuing education and training to all of its inspectors.

+ The comparability of the organization's full inspection and complaint inspection requirements to the Federal requirements including, but not limited to, inspection frequency, and the ability to investigate and respond to complaints against its accredited laboratories.

+ The organization's procedures for monitoring laboratories that it has found to be out of compliance with its requirements.

+ The ability of the organization to provide us with electronic data and reports that are necessary for effective validation and assessment of the organization's inspection process.

+ The ability of the organization to provide us with electronic data related to the adverse actions resulting from unsuccessful proficiency testing (PT) participation in CMS-approved PT programs, as well as data related to the PT failures, within 30 days of the initiation of the action.

+ The ability of the organization to provide us with electronic data for all its accredited laboratories and the area of specialty and subspecialty testing.

+ The adequacy of the numbers of staff and other resources.

+ The organization's ability to provide adequate funding for performing the required inspections.

• Whether the organization has an agreement with us that requires it, among other things, to meet the following:

+ Notify us of any laboratory that has had its accreditation denied, limited, suspended, withdrawn, or revoked by the accreditation organization, or that has had any other adverse action taken against it by the accreditation organization, within 30 days of the date the action is taken.

+ Notify us within 10 days of a deficiency identified in an accredited laboratory if the deficiency poses an immediate jeopardy to the laboratory's patients or a hazard to the general public.

+ Notify us of all newly accredited laboratories, or laboratories whose areas of specialty or subspecialty are revised, within 30 days.

+ Notify each laboratory accredited by the organization within 10 days of our withdrawal of approval of the organization as an accreditation organization.

+ Provide us with inspection schedules, on request, for the purpose of conducting onsite validation inspections.

+ Provide our agent, the State survey agency, or CMS with any facility-specific data that include, but are not limited to, PT results that constitute unsuccessful participation in an approved PT program and notification of the adverse actions or corrective actions imposed by the accreditation organization as a result of unsuccessful PT participation.

+ Provide us with written notification at least 30 days in advance of the effective date of any proposed changes in its requirements.

+ Provide upon the request by any person, on a reasonable basis (under State confidentiality and disclosure requirements, if applicable), any laboratory's PT results with the explanatory information needed to assist in the interpretation of the results.

Laboratories that are accredited by an approved accreditation organization must, among other things, meet the following requirements:

• Authorize the organization to release to us all records and information required.

• Permit inspections as required by the CLIA regulations at part 493, subpart Q (Inspection).

• Obtain a certificate of accreditation under § 493.55 (Application for registration certificate and certificate of accreditation).

B. Evaluation of the AOA Request for Continued Approval as an Accreditation Organization Under CLIA

We have examined AOA's assurance that it requires the laboratories it accredits to be, and that the organization is, in compliance with the following subparts of part 493: 1. Subpart E—Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program

AOA has requested continued approval to accredit all specialties and subspecialties and has submitted the following:

• Description of its PT monitoring process, inspection processes, policies, and data management and analysis system.

• List of its inspection team size, composition, and education and experience.

• Investigative and complaint response procedures.

• Our notification agreements.

• Procedures for the removal or withdrawal of accreditation from a laboratory.

• Current list of accredited laboratories with announced or unannounced inspection process.

We have determined that AOA has complied with the requirements under CLIA for approval as an accreditation organization under this subpart.

Our evaluation identified several areas of AOA requirements that are more stringent that the CLIA requirements and apply to the laboratory when taken as a whole. Rather than include them in the appropriate subparts multiple times, we have listed them here:

• AOA lists extensive requirements for the laboratory information system (LIS) that include but are not limited to the following:

+ The laboratory must ensure that test results generated by the LIS are reported, archived and maintained in an accurate and reliable manner.

+ The laboratory must perform and document the necessary system maintenance required by the LIS manufacturer or established by and validated by the laboratory.

+ All input/output devices must be maintained to ensure accurate, clear, and interference-free transmission of reports.

+ The laboratory must validate new or revised software and/or hardware before their use.

+ LIS access must be used to limit access to only those functions the personnel are authorized to use.

plus The LIS must be protected against power and electrical interruptions.

+ The laboratory must validate and have records of that validation for all calculations performed by the LIS at least twice a year or as specified by the manufacturer.

• AOA requires the establishment of protocols to protect the confidentiality of patient-identified information and

considers all patient identified information received or generated in the laboratory as confidential information that must be so defined in laboratory protocols for employees and agents of the laboratory who have knowledge of test results.

• AOA has specific requirements for autopsy pathology that include but are not limited to the following:

+ Clinical records are reviewed with the attending physician before conducting the autopsy.

+ Written policies and procedures for the storage and release of bodies must be available and followed.

+ Written policies and procedures for the autopsy consent must be available and followed.

+ Autopsy policies and procedures must be available at nursing stations, admitting office and other appropriate places.

+ Requirements for autopsy pathology environmental conditions, equipment, materials and supplies.

+ Requirements for autopsy pathology safety.

+ Requirements for autopsy pathology reports.

2. Subpart H (regarding participation in proficiency testing)

AOA's requirements for PT are equivalent to those of CLIA.

3. Subpart J (regarding patient test management)

AOA's requirements in patient test management are equivalent to those of CLIA.

4. Subpart K (regarding quality control)

The quality control (QC) requirements of AOA have been evaluated against the applicable requirements of CLIA and its implementing regulations. We have determined that AOA's requirements, when taken as a whole, are more stringent than the CLIA requirements. Specifically, the AOA has laboratory safety requirements that are specific and detailed. AOA requires laboratories to have an appointed safety officer and maintain quarterly written safety reports. AOA also has requirements for fire safety and prevention of fire hazards, universal precautions, hazardous waste management, and environmental safety requirements to address electrical grounding and emergency power.

5. Subpart M (regarding personnel)

We have found that AOA's personnel requirements, when taken as a whole, are equal to the CLIA requirements.

6. Subpart P (regarding quality assurance)

We have determined that AOA's requirements are equal to the CLIA requirements of this subpart. AOA has adopted the CLIA quality assurance requirements in their entirety and included them in AOA's checklist.

7. Subpart Q—Inspections

AOA will continue to perform on-site inspections on a biennial basis. Therefore, we have determined that AOA's inspections are equivalent to CLIA.

8. Subpart R—Enforcement

AOA meets the requirements of subpart R to the extent that it applies to accreditation organizations. AOA policy stipulates the action it takes when laboratories it accredits do not comply with its requirements. AOA must deny, revoke, or limit accreditation of a laboratory as appropriate and report the action to us within 30 days. AOA also provides an appeal process for laboratories that have had accreditation denied, revoked, suspended, or limited.

We have determined that AOA's laboratory enforcement and appeal policies are equivalent to the requirements of this subpart as they apply to accreditation organizations.

IV. Federal Validation Inspections and Continuing Oversight

The Federal validation inspections of AOA-accredited laboratories may be conducted on a representative sample basis or in response to substantial allegations of noncompliance (complaint inspections). The outcome of those validation inspections, performed by our agent, or the State survey agency, or us, will be our principal means for verifying that the laboratories accredited by AOA remain in compliance with CLIA requirements. This Federal monitoring is an ongoing process.

V. Removal of Approval as an Accrediting Organization

Our regulations provide, in part, that we may remove the approval of an accreditation organization, such as that of AOA, for cause, before the end of the effective date of approval. If validation inspection outcomes and the comparability or validation review produce findings as described in § 493.573 (Continuing Federal oversight of private nonprofit accreditation organizations and approved State licensure programs), we will conduct a review of an approved accreditation organization's program. In addition, we will conduct a review, when the validation review findings, irrespective of the rate of disparity (as defined in § 493.2), indicate widespread or systemic problems in the organization's accreditation processes that provide evidence that the organization's requirements, taken as a whole, are no longer equivalent to the CLIA requirements, taken as a whole. If validation inspection results over a 1-year period indicate a rate of disparity of 20 percent or more between our findings and those of the organization, we will conduct a review under § 493.575(a)(4).

If we determine that AOA has failed to adopt or maintain requirements that are equal to, or more stringent than the CLIA requirements, or systematic problems exist in its inspection process, a probationary period as determined by us, not to exceed 1 year, may be given to AOA to adopt equal or more stringent requirements. We will make a final determination as to whether or not AOA retains its approved status as an accreditation organization under CLIA. If approved status is withdrawn, an accreditation organization such as AOA may resubmit its application if it revises its program to address the rationale for the denial, demonstrates that it can reasonably assure that its accredited laboratories meet CLIA condition level requirements, and resubmits its application for approval as an accreditation organization in its entirety. However, if an approved accreditation organization requests reconsideration of an adverse determination in accordance with subpart D (Reconsideration of Adverse Determinations—Deeming Authority for Accreditation Organizations and CLIA Exemption of Laboratories Under State Programs) of part 488 (Survey, Certification, and Enforcement Procedures) of our regulations, it may not submit a new application until we issue a final reconsideration determination. Should circumstances result in AOA having its approval withdrawn, we will publish a notice in the **Federal Register** explaining the basis for removing its approval.

VI. Federalism

We have reviewed this notice under the threshold criteria of Executive Order 13132, Federalism, and have determined that this notice will not have any negative impact on the rights, roles, and responsibilities of State, local, or tribal governments.

VII. OMB Review

In accordance with the provisions of Executive Order 12866, the Office of Management and Budget did not review this notice.

Authority: Section 353 of the Public Health Service Act (42 U.S.C. 263a).

Dated: January 15, 2002.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 02–6953 Filed 3–21–02; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[CMS–2140–PN]

Medicare and Medicaid Programs; Application by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) for Approval of Deeming Authority for Critical Access Hospitals

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

ACTION: Proposed notice.

SUMMARY: This proposed notice with comment period acknowledges the receipt of an initial application by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) for consideration as a national accreditation program for critical access hospitals that wish to participate in the Medicare or Medicaid programs. Section 1865(b)(3)(A) of the Social Security Act (the Act) requires that within 60 days of receipt of an organization's complete application, we publish a notice that identifies the national accrediting body making the request, describes the nature of the request, and provides at least a 30-day public comment period.

DATES: Written comments will be considered if received at the appropriate address, as provided in **ADDRESSES**, no later than 5 p.m. on April 22, 2002.

ADDRESSES: Mail written comments (an original and three copies) to the following address only: Centers for Medicare and Medicaid Services, Department of Health and Human Services, Attention: CMS–2140–PN, PO Box 8010, Baltimore, MD 21244–1850.

If you prefer, you may deliver by courier your written comments (an original and three copies) to one of the following addresses:

Room 443–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or,

Room C5–14–03, Central Building, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Comments mailed to the indicated addresses may be delayed and could be considered late.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code CMS–2140–PN.

Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the following address: 7500 Security Blvd., Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 5:00 p.m. (phone: (410) 786–7197) to schedule an appointment.

FOR FURTHER INFORMATION CONTACT: Irene H. Dustin, (410) 786–0495.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in a critical access hospital (CAH) provided the hospital meets certain requirements. 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 Secretary has set forth in regulations minimum requirements that a CAH must meet to participate in Medicare. The regulations at 42 CFR part 485, subpart F (Conditions of Participation: Critical Access Hospitals (CAHs)) determine the basis and scope of covered services provided by a CAH, set out rural health network specifications and establish staff qualifications. Conditions for Medicare payment for critical access services can be found at § 413.70. Applicable regulations concerning provider agreements are at 42 CFR part 489 (Provider Agreements and Supplier Approval) and those pertaining to the survey and certification of facilities are at 42 CFR part 488, (Survey, Certification and Enforcement Procedures), subparts A (General Provisions) and B (Special Requirements).

In order for a CAH to be approved for participation in or coverage under the Medicare program, the hospital must have a current provider agreement to participate in the Medicare program as a hospital. The provider agreement must be in place at the time the hospital applies for CAH designation and be in compliance with part 482 (Conditions of Participation for Hospitals), as well as part 485, subpart F (Conditions of Participation: Critical Access Hospitals (CAHs)). 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 standards set forth in the statute and part 482 of our regulations. Then, the hospital is subject to regular surveys by a State survey agency to determine whether it continues to meet Medicare requirements. There is an alternative, however, to surveys by State agencies.

Exceptions are provided in the Balanced Budget Refinement Act of 1999 (Pub. L. 106–113) for rural health clinics that were previously downsized from an acute care hospital, or for a closed hospital that is requesting to reopen as a CAH. In these instances, only the provisions of 42 CFR part 485, subpart F apply.

Section 1865(b)(1) of the Act permits ''accredited'' hospitals to be exempt from routine surveys by State survey agencies to determine compliance with Medicare conditions of participation. Accreditation by an accreditation organization is voluntary and is not required for Medicare participation. Section 1865(b)(1) of the Act provides that, if a provider demonstrates through accreditation that all applicable Medicare conditions are met or exceeded, CMS shall ''deem'' the hospital as having met the requirements.

If an accrediting organization is recognized in this manner, any provider accredited by a national accrediting body approved program would be deemed to meet the Medicare conditions of participation. The American Osteopathic Association (AOA) is currently the only organization recognized with deeming authority for critical access hospitals. The final notice approving the AOA for deeming authority for CAHs was published in the **Federal Register** on September 28, 2001 (66 FR 49677).

A national accreditation organization applying for approval of deeming authority under section 488, subpart A must provide us with reasonable assurance that the accreditation organization requires the accredited providers to meet requirements that are at least as stringent as the Medicare conditions of participation.

II. Approval of Deeming Organizations

Section 1865(b)(2) of the Act requires that our findings concerning review of national accrediting organizations consider, among other factors, an accreditation organization's requirements for the following: accreditation, survey procedures, resources for conducting required surveys, capacity to furnish information for use in enforcement activities, and monitoring procedures for provider entities found not in compliance with the conditions or requirements, and ability to provide us with necessary data for validation.