DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3314-N]

Medicare, Medicaid, and CLIA Programs; Announcement of the Re-Approval of the American Osteopathic Association/Healthcare Facilities Accreditation Program (formerly known as the American Osteopathic Association) as an Accreditation Organization under the Clinical Laboratory Improvement Amendments of 1988

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

ACTION: Notice.

SUMMARY: This notice announces the application of the American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA/HFAP) for approval as an accreditation organization for clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program. We have determined that AOA/HFAP meets or exceeds the applicable CLIA requirements. In this notice, we announce the approval and grant AOA/HFAP deeming authority for a period of 6 years.

EFFECTIVE DATE: This notice is effective from **[OFR-insert date of publication in Federal Register]** to **[OFR-insert date 6 years after date of publication in Federal Register].**

FOR FURTHER INFORMATION CONTACT:

Kathleen 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) (Pub. L. 100-578). CLIA amended section 353 of the Public Health Service Act. We issued a final rule implementing the accreditation provisions of CLIA on July 31, 1992 (57 FR 33992). Under those provisions, we may grant deeming authority to an accreditation organization if its requirements for laboratories accredited under its program are equal to or more stringent than the applicable CLIA program requirements in 42 CFR part 493 (Laboratory Requirements), subpart E of part 493 (Accreditation by a Private, Nonprofit Accreditation Organization or Exemption under an Approved State Laboratory Program), which specifies the requirements an accreditation organization must meet to be approved by CMS as an accreditation organization under CLIA.

II. Notice of Approval of the American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA/HFAP) as an Accreditation Organization

In this notice, we approve the American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA/HFAP) as an organization that may accredit laboratories for purposes of establishing their compliance with CLIA requirements for all specialty and subspecialty areas under CLIA. We have examined the initial AOA/HFAP application and all subsequent submissions to determine its accreditation program's equivalency with the requirements for approval of an accreditation organization under subpart E of part 493. We have determined that AOA/HFAP meets or exceeds the applicable CLIA requirements. We have also determined that AOA/HFAP will ensure that its accredited laboratories will meet or exceed the applicable requirements in subparts H, I, J, K, M, Q, and the applicable sections of subpart R. Therefore, we grant AOA/HFAP approval as an accreditation organization under subpart E of part 493, for the period stated in the "DATES" section of this notice for all specialty and subspecialty areas under CLIA. As a result of this determination, any laboratory that is accredited by AOA/HFAP during the time period stated in the "DATES" section of this notice

will be deemed to meet the CLIA requirements for all subspecialties and specialties, and therefore, will generally not be subject to routine inspections by a state survey agency to determine its compliance with CLIA requirements. However, the accredited laboratory is subject to validation and complaint investigation surveys performed by CMS, or its agent(s).

III. Evaluation of the AOA/HFAP Request for Approval as an Accreditation Organization Under CLIA

The following describes the process used to determine that the AOA/HFAP accreditation program meets the necessary requirements to be approved by CMS as an accreditation program with deeming authority under the CLIA program. AOA/HFAP formally applied to CMS for approval as an accreditation organization under CLIA for all specialty and subspecialty areas under CLIA. In reviewing these materials, we reached the following determinations for each applicable part of the CLIA regulations:

A. Subpart E--Accreditation by a Private, Nonprofit Accreditation Organization or Exemption under an Approved State Laboratory Program

AOA/HFAP submitted its mechanism for monitoring compliance with all requirements equivalent to condition-level requirements, a list of all its current laboratories and the expiration date of their accreditation, and a detailed comparison of the individual accreditation requirements with the comparable condition-level requirements. We have determined that AOA/HFAP policies and procedures for oversight of laboratories performing laboratory testing for all CLIA specialties and subspecialties are equivalent to those required by our CLIA regulations in the matters of inspection, monitoring proficiency testing (PT) performance, investigating complaints, and making PT information available. AOA/HFAP submitted documentation regarding its requirements for monitoring and inspecting laboratories, and describing its own standards regarding accreditation organization data management, inspection processes, procedures for

removal or withdrawal of accreditation, notification requirements, and accreditation organization resources. We have determined that the requirements of the accreditation program submitted for approval are equal to or more stringent than the requirements of the CLIA regulations.

B. Subpart H--Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing

We have determined that the AOA/HFAP's requirements are equal to the CLIA requirements at §493.801 through §493.865. Like CLIA, all of AOA/HFAP's accredited laboratories are required to participate in an HHS-approved PT program for tests listed in subpart I.

C. Subpart J--Facility Administration for Nonwaived Testing

We have determined that the AOA/HFAP's requirements are equal to the CLIA requirements at §493.1100 through §493.1105.

D. Subpart K--Quality System for Nonwaived Testing

We have determined that the AOA/HFAP requirements are equal to or more stringent than the CLIA requirements at §493.1200 through §493.1299.

E. Subpart M--Personnel for Nonwaived Testing

We have determined that the AOA/HFAP requirements are equal to the CLIA requirements at §493.1403 through §493.1495 for laboratories that perform moderate and high complexity testing.

F. Subpart Q--Inspections

We have determined that the AOA/HFAP requirements are equal to the CLIA requirements at §493.1771 through §493.1780. AOA/HFAP will continue to conduct biennial onsite inspections.

G. Subpart R--Enforcement Procedures

We have determined that the AOA/HFAP meets the requirements of subpart R to the extent that such requirements are utilized by accreditation organizations. AOA/HFAP policy sets forth the actions the organization takes when laboratories it accredits do not comply with its requirements and standards for accreditation. When appropriate, AOA/HFAP will deny, suspend, or revoke accreditation in a laboratory accredited by AOA/HFAP and report that action to us within 30 days. AOA/HFAP also provides an appeals process for laboratories that have had accreditation denied, suspended, or revoked.

We have determined that AOA/HFAP's laboratory enforcement and appeal policies are equal to or more stringent than the requirements of part 493, subpart R as they apply to accreditation organizations.

IV. Federal Validation Inspections and Continuing Oversight

The federal validation inspections of laboratories accredited by AOA/HFAP may be conducted on a representative sample basis or in response to substantial allegations of noncompliance (that is, complaint inspections). The outcome of those validation inspections, performed by CMS or our agents, or the state survey agencies, will be our principal means for verifying that the laboratories accredited by AOA/HFAP remain in compliance with CLIA requirements. This federal monitoring is an ongoing process.

V. Removal of Approval as an Accrediting Organization

Our regulations provide that we may rescind the approval of an accreditation organization, such as that of AOA/HFAP, for cause, before the end of the effective date of approval. If we determine that AOA/HFAP has failed to adopt, maintain and enforce requirements that are equal to, or more stringent than, the CLIA requirements, or that systemic problems exist in its monitoring, inspection or enforcement processes, we may impose a probationary period, not to exceed one year, in which AOA/HFAP would be allowed to address

any identified issues. Should AOA/HFAP be unable to address the identified issues within that timeframe, CMS may, in accordance with the applicable regulations, revoke AOA/HFAP's deeming authority under CLIA.

Should circumstances result in our withdrawal of AOA/HFAP's approval, we will publish a notice in the **Federal Register** explaining the basis for removing its approval.

VI. Collection of Information Requirements

This notice does not impose any information collection and record keeping requirements subject to the Paperwork Reduction Act (PRA). Consequently, it does not need to be reviewed by the Office of Management and Budget (OMB) under the authority of the PRA. The requirements associated with the accreditation process for clinical laboratories under the CLIA program, codified in 42 CFR part 493 subpart E, are currently approved by OMB under OMB approval number 0938-0686.

VII. Executive Order 12866 Statement

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget.

CMS-3314-N

Dated: March 6, 2015.

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Andrew M. Slavitt,

Acting Administrator,

Centers for Medicare & Medicaid Services.

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