C—"NATIONAL DISEASE SURVEILLANCE PROGRAM III—CDC SUPPORT FOR CASE INVESTIGATION, CONTACT TRACING, AND CASE REPORTS"—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
State, Territorial, and Local Public Health Authorities and Their Delegates.	C8—Daily and Weekly Report	15	42	10/60	105
Total					14,721

D—"CDC EMERGENCY OPERATIONS CENTER CLINICAL INQUIRIES"

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
State and Local Health Departments.	D1—Clinical Inquiries Database	420	1	15/60	105
Clinicians and Other Providers.	D1—Clinical Inquiries Database	800	1	15/60	200
Total					305

Leroy A. Richardson

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2015–07037 Filed 3–26–15; 8:45 am]

BILLING CODE 4163–18–P

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.

DATES: *Effective Date:* This notice is effective from March 27, 2015 to March 29, 2021.

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.

Dated: March 6, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2015–07115 Filed 3–26–15; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3308–N]

Medicare, Medicaid, and CLIA Programs; Clinical Laboratory Improvement Amendments of 1988 Exemption of Permit-Holding Laboratories in the State of New York

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

ACTION: Notice.

SUMMARY: This notice announces that laboratories located in and licensed by the State of New York that possess a valid permit under New York State Public Health Law Article 5, Title V, are exempt from the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) for a period of 6 years.

DATES: The exemption granted by this notice is effective from March 27, 2015 to March 27, 2021.

FOR FURTHER INFORMATION CONTACT: Melissa Singer, (410) 786–3531.

SUPPLEMENTARY INFORMATION:

I. Background and Legislative Authority

Section 353 of the Public Health Service Act (PHSA), as amended by the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Pub. L. 100–578, enacted on October 31, 1988), generally provides that no laboratory may perform tests on human specimens for the diagnosis, prevention or treatment of any disease or impairment of, or assessment of the health of, human beings unless it has a certificate to perform that category of tests issued by the Secretary of the Department of Health and Human Services (HHS). Under section 1861(s)(17)(A) of the Social Security Act (the Act), the Medicare program will only pay for laboratory services if the laboratory has a CLIA certificate. Under section 1902(a)(9)(C) of the Act, state Medicaid plans generally pay only for laboratory services furnished by CLIA-certified laboratories. Thus, although subject to specified exemptions and exceptions, laboratories generally must have a current and valid CLIA certificate to test human specimens for the purposes noted above to be eligible for payment for those tests from the Medicare or Medicaid programs. Regulations implementing section 353 of the PHSA are contained in 42 CFR part 493.

Section 353(p) of the PHSA provides for the exemption of laboratories from CLIA requirements in states that enact legal requirements that are equal to or more stringent than CLIA's statutory and regulatory requirements. Section 353(p) of the PHSA is implemented in subpart E of our regulations at 42 CFR part 493. Sections 493.551(b) and 493.553 provide that we may exempt from CLIA requirements, for a period not to exceed 6 years, all state-licensed or state-approved laboratories in a state if the state licensure program meets the specified conditions. Section 493.559 provides that we will publish a notice in the **Federal Register** when we grant an exemption to an approved state licensure program. It also provides that the notice will include the following:

- The basis for granting the exemption.
- A description of how the state's laboratory requirements are equal to or more stringent than those of CLIA.
- The term of approval, not to exceed 6 years.

A. State of New York's Application for CLIA Exemption of Its Laboratories

The State of New York has applied for exemption of its Clinical Laboratory Evaluation Program (CLEP) permit-holding laboratories from CLIA program requirements. New York State law is applicable to all clinical laboratories operating within the State of New York except those operated by the federal government and those operated by a licensed physician, osteopath, dentist, midwife, nurse practitioner or podiatrist who performs laboratory tests or procedures, personally or through his or her employees, solely as an adjunct to the treatment of his or her own patients. The State of New York submitted all of the applicable information and attestations required by § 493.551(a), § 493.553, and § 493.557(b) for state licensure programs seeking exemption of their licensed laboratories from CLIA program requirements. (Please note that although the CLEP issues ''permits'' rather than ''licenses'' or ''certificates,'' for the purposes of this notice, we will hereinafter refer to the CLEP as a ''state licensure program.'') Examples of documents and information submitted include a comparison of its laboratory licensure requirements with comparable CLIA condition-level requirements (that is, a crosswalk); and a description of the following: Its inspection process; its proficiency testing (PT) monitoring process; its data management and analysis system; its investigative and response procedures for complaints received against laboratories; and its policy regarding announced and unannounced inspections.

B. CMS Analysis of New York's Application and Supporting Documentation

To determine whether we should grant a CLIA exemption to laboratories licensed by a state, we review the application and additional documentation that the state submits to us and conduct a detailed and in-depth comparison of the state licensure program and CLIA's statutory and regulatory requirements to determine whether the state program meets the requirements at subpart E of part 493.

In summary, the state generally must demonstrate that:

- It has state laws in effect that provide for a state licensure program that has requirements that are equal to or more stringent than CLIA condition-level requirements for laboratories.
- It has implemented a state licensure program with requirements that are equal to or more stringent than the CLIA condition-level requirements such that a laboratory licensed by the state program would meet the CLIA condition-level requirements if it were inspected against those requirements.
- The requirements under that state licensure program meet or exceed the requirements of § 493.553, § 493.555, and § 493.557(b) and is suitable for approval by us under § 493.551(a). For example, among other things, the program would need to:

++ Demonstrate that it has enforcement authority and administrative structures and resources adequate to enforce its laboratory requirements.

++ Permit us or our agents to inspect laboratories within the state.

++ Require laboratories within the state to submit to inspections by us or our agents as a condition of state licensure.

++ Agree to pay any costs associated with our activities to validate its state licensure program, as well as the state's pro rata share of the general overhead to develop and implement CLIA as specified in § 493.645(a), § 493.646(b), and § 493.557(b).

++ Take appropriate enforcement action against laboratories found by us or our agents to be out of compliance with requirements comparable to CLIA condition-level requirements, as specified in § 493.557(b).