Each public advisory committee meeting listed above may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. The dates and times reserved for the separate portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this **Federal Register** notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

The Commissioner has determined for the reasons stated that those portions of the advisory committee meetings so designated in this notice shall be closed. The Federal Advisory Committee Act (FACA) (5 U.S.C. app. 2, 10(d)), permits such closed advisory committee meetings in certain circumstances. Those portions of a meeting designated as closed, however, shall be closed for the shortest possible time, consistent with the intent of the cited statutes.

The FACA, as amended, provides that a portion of a meeting may be closed where the matter for discussion involves a trade secret; commercial or financial information that is privileged or confidential; information of a personal nature, disclosure of which would be a clearly unwarranted invasion of personal privacy; investigatory files compiled for law enforcement purposes; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and information in certain other instances not generally relevant to FDA matters.

Examples of portions of FDA advisory committee meetings that ordinarily may be closed, where necessary and in accordance with FACA criteria, include the review, discussion, and evaluation of drafts of regulations or guidelines or similar preexisting internal agency documents, but only if their premature disclosure is likely to significantly frustrate implementation of proposed agency action; review of trade secrets and confidential commercial or financial information submitted to the agency; consideration of matters involving investigatory files compiled for law enforcement purposes; and review of matters, such as personnel records or individual patient records, where disclosure would constitute a clearly unwarranted invasion of personal privacy.

Examples of portions of FDA advisory committee meetings that ordinarily shall not be closed include the review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs or devices; review of data and information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other data or information that is not exempt from public disclosure pursuant to the FACA, as amended; and, deliberation to formulate advice and recommendations to the agency on matters that do not independently justify closing.

This notice is issued under section 10(a)(1) and (2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: July 17, 1995.

Linda A. Suydam,

Interim Deputy Commissioner for Operations.

[FR Doc. 95–17977 Filed 7–20–95; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[HSQ–229–N]

CLIA Program; Approval of the American Osteopathic Association as an Accrediting Organization

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: This notice announces the approval of the American Osteopathic Association (AOA) as an accrediting organization for clinical laboratories under the Clinical Laboratory Improvement Amendments (CLIA) program. We have found that the accreditation process of this organization provides reasonable assurance that a laboratory accredited by it meets the conditions required by Federal law and regulations. Consequently, a laboratory that voluntarily becomes accredited by AOA and continues to meet AOA requirements, is deemed to meet the CLIA condition-level requirements for laboratories and, therefore, is not subject to routine inspection by State survey agencies to determine its compliance with Federal requirements. However, each laboratory is subject to validation and complaint investigation surveys conducted by HHS or its designee to determine that each laboratory meets CLIA requirements.

EFFECTIVE DATE: This notice is effective for the period July 21, 1995 through July 21, 1997.

FOR FURTHER INFORMATION CONTACT: Kathleen Todd, (410) 597–5906.

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 of the Public Health Service Act (PHSA), as enacted by the Clinical Laboratories Improvement Act of 1967, and made every laboratory in the United States and its territories that tests human specimens for health reasons subject to the requirements established by HHS, whether or not it participates in the Medicare or Medicaid programs. New section 353 requires HHS to establish certification requirements for any laboratory that performs tests on human specimens and certify through issuance of a certificate that a laboratory meets those certification requirements.

Section 6141 of the Omnibus Budget Reconciliation Act of 1989, Public Law 101–239, amended the Social Security Act (the Act) to require that a laboratory participating in the Medicare program meet the certification requirements of section 353 of the PHSA. Subject to specified exceptions, a laboratory must have a current unrevoked and unsuspended certificate to be eligible to participate in the Medicare or Medicaid programs or both. A laboratory that is accredited by an accreditation organization approved under section 353 of the PHSA is automatically eligible for Medicare and Medicaid participation as long as it meets applicable State licensure requirements.

Several additional rules have been published since the Congress enacted the CLIA requirements. Many of these rules gave non-Federal organizations the authority to act as an accrediting body to assure that a laboratory meets conditions required by Federal law and regulations. On February 28, 1992, we published several final rules in the **Federal Register** (57 FR 7002–7243) that implemented the amendments to section 353 of the PHSA. Specifically, regulations were established at 42 CFR part 493 that set forth the following:

- Require laboratories to pay fees for issuance of registration certificates, certificates of waiver, certificates of accreditation, or other applicable certificates and to fund activities to determine compliance with our performance requirements. (In a subsequent rule published January 19, 1993, 58 FR 5215, we added ''certificate for physician-performed microscopy procedures.'')
- Specify the performance requirements that apply to laboratories subject to CLIA (some of which were amended by the January 19, 1993 rule) and list requirements for laboratories performing certain limited testing to be eligible for a certificate of waiver.
- Set forth the rules for the enforcement of CLIA requirements on laboratories that are found not to meet Federal requirements.

On July 31, 1992, we issued a final rule (57 FR 33992), under the authority found in section 353(e)(2) of the PHSA, that permits us to approve a private, nonprofit organization as an accreditation organization for clinical laboratories under the CLIA program if that organization's requirements for its accredited laboratories are equal to or more stringent than the applicable CLIA program requirements established at part 493 of our regulations. Under § 493.501(d)(4) of our regulations, the approval period may not exceed 6 years.

In general, the accreditation organization must meet the following requirements that are set forth in part 493:

- Use inspectors qualified to evaluate laboratory performance and agree to inspect laboratories with the frequency determined by HHS.
- Apply standards and criteria that are equal to or more stringent than those CLIA condition-level requirements for laboratories established by HHS when taken as a whole.
- Provide reasonable assurance that its standards and criteria are continually met by its accredited laboratories.
- Provide HHS with the name of any laboratory that has had its accreditation denied, suspended, withdrawn, limited or revoked. HHS must receive this notification within 30 days of any adverse action against a laboratory.
- Notify HHS at least 30 days before the effective date of any proposed change in its standards.
- If HHS withdraws its approval for the organization to accredit laboratories, notify its accredited laboratories of the withdrawal within 10 days of the withdrawal.

Along with requiring us to publish criteria for approving an accreditation organization and for withdrawing the approval, CLIA requires HHS to annually evaluate the performance of the approved accreditation organization for compliance with the CLIA requirements by inspecting a sufficient number of laboratories accredited by the approved accreditation organization as well as by any other means that HHS determines appropriate. Under section 353(o) of the PHSA, HHS may, by agreement, use the services or facilities of any other Federal, State, or local public agency, or any private, nonprofit organization to conduct inspections of laboratories performing clinical testing on human specimens in the United States and its territories for the purpose of determining compliance with CLIA requirements.

II. Notice of Approval of AOA as an Accrediting Organization

This notice announces our decision to approve AOA as an organization that may accredit a laboratory for purposes of establishing its compliance with CLIA requirements for all specialty/subspecialty areas. We are approving AOA as an accreditation organization for the period July 21, 1995 through July 21, 1997.

AOA accredits laboratories for a 2-year period beginning with the date of the certification. Any laboratory that is accredited by AOA during this time period is deemed to meet the CLIA requirements found in part 493 of our regulations 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 that we perform, or any other Federal, State, or local public agency or nonprofit private organization performs, which acts in conformance with an agreement with HHS.

III. Evaluation of the AOA Request for Approval as an Accreditation Organization under CLIA

AOA formally applied to us for approval as an accreditation organization under CLIA for all specialties and subspecialties. We evaluated the AOA application to determine equivalency with our implementing and enforcement regulations, and the deeming/exemption requirements of the CLIA rules at 42 CFR part 493.

We also verified the organization's assurance that it requires the laboratories it accredits to be, and that the organization is, in compliance with the following subparts of 42 CFR part 493 as explained below:

Subpart E—Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program

AOA submitted a list of the specialties and subspecialties that it would accredit; a comparison of individual accreditation and condition-level requirements; a description of its

inspection process, Proficiency Testing (PT) monitoring process, and its data management and analysis system; a list of the size, composition, education, and experience of its inspection teams; a description of its investigative and complaint response procedures; a description of its notification agreements with HCFA; a list of its procedures for removing or withdrawing laboratory accreditation; a current list of accredited laboratories; and an explanation of its announced or unannounced inspection process. We determined that AOA complies with the general requirements for an accreditation organization under § 493.501, the applicable parts of § 493.506 for approval of a private, nonprofit accreditation organization, and the CLIA requirements for approval as an accreditation organization under various subparts of part 493.

Subpart H—Participation in Proficiency Testing for Laboratories Performing Tests of Moderate or High Complexity, or Both

AOA revised its requirements to be equivalent to the CLIA requirements at §§ 493.801 through 493.865 on an overall basis.

Subpart J—Patient Test Management for Moderate or High Complexity Testing, or Both

AOA revised its requirements to be equivalent to the CLIA requirements at §§ 493.1101 through 493.1111 on an overall basis.

Subpart K—Quality Control for Tests of Moderate or High Complexity, or Both

AOA revised its requirements to be equivalent to the CLIA requirements at §§ 493.1201 through 493.1285 on an overall basis.

Subpart M—Personnel for Moderate and High Complexity Testing

AOA revised its requirements to be equivalent to the CLIA requirements at §§ 493.1401 through 493.1495 on an overall basis.

Subpart P—Quality Assurance for Moderate or High Complexity Testing or Both

AOA revised its requirements to be equivalent to the CLIA requirements at §§ 493.1701 through 493.1721 on an overall basis.

Subpart Q—Inspections

AOA made revisions to its inspection process and will perform on-site inspections of the laboratory on a biennial basis so that it meets the applicable CLIA requirements at § 493.1777. Therefore, we have determined that AOA's requirements meet the requirements of subpart Q.

Subpart R—Enforcement Procedures for Laboratories

AOA meets the requirements of subpart R to the extent it applies to accreditation organizations. AOA policy stipulates the action it takes when a laboratory it accredits does not comply with its essential standards. When appropriate, AOA will deny, revoke, or limit a laboratory's accreditation and report the action to us within 30 days of initiating the action against the laboratory. AOA also provides an appeals process for a laboratory that has had its accreditation denied or revoked.

Some specific actions AOA takes in response to noncompliance or violation of essential standards include the following:

- If an AOA-accredited laboratory is identified as having intentionally referred a PT specimen to another laboratory, AOA revokes the laboratory's accreditation for 1 year.
- If an AOA-accredited laboratory is unsuccessful in PT participation for a Federally required analyte, subspecialty, and/or specialty, AOA terminates a laboratory's accreditation for that particular analyte, subspecialty and/or specialty. To regain accreditation, the laboratory must provide appropriate training and seek technical assistance to correct the problem(s) related to PT failure, and successfully participate in two consecutive PT events.
- If AOA determines that a serious risk of harm (for example, immediate jeopardy to patient health or safety) exists in an AOA-accredited laboratory, the laboratory must cease testing and immediately correct the problem that poses the risk. Failure to do so will result in a recommendation to the AOA Bureau of Healthcare Facilities Accreditation committee to deny that facility's accreditation. In addition, AOA will notify us within 10 days of its determination that the laboratory is no longer an AOA-accredited laboratory.

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

IV. Federal Validation Inspections and Continuing Oversight

We may conduct Federal validation inspections of AOA-accredited laboratories, as specified in § 493.507, on a representative sample basis or in response to substantial allegations of noncompliance (called complaints). The outcome of those validation inspections, performed either by us, the State survey agency, or our agent, is 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 at § 493.511 provide that we may remove the approval of an accreditation organization, such as that of AOA before the end of the effective date of approval. If validation inspection outcomes and the comparability or validation review produce findings described at § 493.509(a), we conduct a review of an accreditation organization's program. We also conduct a review when the validation review findings, irrespective of the rate of disparity (as defined in § 493.2), indicate systemic problems in the organization's 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 we determine that AOA has failed in practice to enforce its standards, or systemic problems exist in its inspection process, we may give it a probationary period, not to exceed 1 year, to allow AOA to conform its inspection or enforcement procedures to the CLIA requirements. Based on an evaluation of any of the items stipulated at § 493.511(d), we make a determination as to whether or not AOA retains its approved status as an accreditation organization under CLIA. If we deny approved status, AOA may revise its program to address the rationale for the denial, demonstrate that it can reasonably assure that its accredited laboratories meet CLIA condition-level requirements, and resubmit its application for approval as an accreditation organization in its entirety. If, however, AOA requests reconsideration of an adverse determination in accordance with subpart D of part 488 of our regulations, it may not submit a new application until we issue a final reconsideration determination.

Should circumstances result in AOA having its accreditation approval withdrawn, we will publish a notice in the **Federal Register** explaining the basis for removing its accreditation approval.

VI. Other

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

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

Dated: May 22, 1995.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

[FR Doc. 95–17979 Filed 7–20–95; 8:45 am]

BILLING CODE 4120–01–P

[HSQ–228–N]

CLIA Program; Approval of the American Association of Blood Banks

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: This notice announces the approval of the American Association of Blood Banks (AABB) as an accrediting organization for clinical laboratories under the Clinical Laboratory Improvement Amendments (CLIA) program. We have found that the accreditation process of this organization provides reasonable assurance that a laboratory accredited by it meets the conditions required by Federal law and regulations. Consequently, laboratories that are voluntarily accredited by the AABB and continue to meet the AABB requirements will be deemed to 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 Federal requirements. They are, however, subject to validation and complaint investigation surveys conducted by HHS or its designee.

EFFECTIVE DATE: This notice is effective for the period July 21, 1995 through July 21, 1997.

FOR FURTHER INFORMATION CONTACT: Tracey Mummert, (410) 597–5906.

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 of the Public Health Service Act (PHSA), as enacted by the Clinical Laboratories Improvement Act of 1967, and made every laboratory in the United States and its territories that tests human specimens for health reasons subject to the requirements established by HHS and Federal regulation whether or not it participates in the Medicare or Medicaid program. New section 353 requires HHS to establish requirements for any laboratory that performs tests on human specimens and certify, through issuance of a certificate, that those laboratories meet the requirements established by HHS.

Section 6141 of the Omnibus Budget Reconciliation Act of 1989, Public Law 101–239, amended the Social Security Act (the Act) to require that laboratories participating in the Medicare program meet the certificate requirements of section 353 of the PHSA. Subject to specified exceptions, laboratories must have a current unrevoked and unsuspended certificate to be eligible for reimbursement in the Medicare or Medicaid programs, or both. Laboratories that are accredited by an accreditation organization approved under section 353(e) of the PHSA will automatically be eligible for Medicare and Medicaid participation as long as they meet applicable State requirements.

On February 28, 1992, we published several final rules in the **Federal Register** (57 FR 7002–7243) that implemented the amendments to section 353 of the PHSA. Specifically, regulations were established at 42 CFR part 493 that:

- Require laboratories to pay fees for issuance of registration certificates, certificates of waiver, certificates of accreditation, or other applicable certificates and to fund activities to determine compliance with our performance requirements.
- Specify the performance requirements that apply to laboratories subject to CLIA and list requirements for laboratories performing certain limited testing to be eligible for a certificate of waiver.
- Set rules for the enforcement of CLIA requirements on laboratories that are found not to meet Federal requirements.

On July 31, 1992, we issued final rules (57 FR 33992), under authority in section 353(e)(2) of the PHSA, that permit us to approve a private, nonprofit organization as an accreditation organization for clinical laboratories under the CLIA program if that organization's requirements for its accredited laboratories are equal to, or more stringent than, the applicable CLIA program requirements established at part 493 of our regulations. Therefore, a laboratory accredited by an approved organization that meets and continues to meet all of the accreditation organization's requirements is deemed to meet CLIA condition level requirements. Subpart E of part 493 specifies the requirements an accreditation organization must meet in order to be approved. We may approve an accreditation organization under § 493.501(d) of our regulations for a period not to exceed 6 years.

In general, the accreditation organization must:

- Use inspectors qualified to evaluate laboratory performance and agree to inspect laboratories with the frequency determined by HHS;
- Apply standards and criteria that are equal to, or more stringent than, those condition level requirements established by HHS when taken as a whole;
- Provide reasonable assurance that these standards and criteria are continually met by its accredited laboratories;
- Provide HHS, within 30 days, with the name of any laboratory that has had its accreditation denied, suspended, withdrawn, limited, or revoked;
- Notify HHS at least 30 days prior to changing its standards; and
- If HHS withdraws its approval, notify its accredited laboratories of the withdrawal within 10 days of the withdrawal.

Along with requiring the promulgation of criteria for approving an accreditation body and for withdrawing such approval, CLIA requires HHS to annually evaluate the performance of an approved accreditation body for compliance with the CLIA requirements by inspecting a sufficient number of laboratories accredited by the organization as well as by any other means that HCFA determines appropriate. Under section 353(o) of the PHSA, the Secretary may, by agreement, use the services or facilities of any other Federal, State or local public agency, or any private, nonprofit organization to conduct inspections of laboratories performing clinical testing on human specimens in the United States and its territories for the purpose of determining compliance with CLIA requirements.

II. Notice of Approval of AABB as an Accrediting Organization

In this notice, we approve the AABB as an organization that may accredit laboratories for purposes of establishing their compliance with CLIA requirements for the following specialty/subspecialty areas:

- Immunohematology
- Diagnostic Immunology
- Hematology
- Histocompatibility
- Routine Chemistry
- Toxicology

As a result of this determination, any laboratory that is accredited by AABB during the effective time period for an approved specialty/subspecialty is deemed to meet the CLIA requirements