Applications (RFA)/Program Announcements (PA)'' soliciting proposals for individual research projects of $500,000 or more in total (direct and indirect) costs per year require the applicant to include a plan describing how the final research data will be shared/released or explain why data sharing is not possible. Details on data sharing and release, including information on the timeliness of the data and the name of the project data steward, should be included in a brief paragraph immediately following the Research Plan Section of the PHS 398 form. References to data sharing and release may also be appropriate in other sections of the application (*e.g.* background and significance, or human subjects requirements). The content of the data sharing and release plan will vary, depending on the data being collected and how the investigator is planning to share the data. The data sharing and release plan will not count towards the application page limit and will not factor into the determining scientific merit or the priority scoring. Investigators should seek guidance from their institutions on issues related to institutional policies, and local IRB rules, as well as local, state and federal laws and regulations, including the Privacy Rule.

Further detail on the requirements for addressing data sharing in applications for NCIPC funding may be obtained by contacting NCIPC program staff or by visiting the NCIPC Internet Web site at: *http://www.cdc.gov/ncipc/osp/sharing_policy.htm.*

*VI.3. Reporting*

You must provide CDC with an original, plus two hard copies of the following reports:

1. Interim progress report, (use form PHS 2590, OMB Number 0925–0001, rev. 5/2001 as posted on the CDC Web site) no less than 90 days before the end of the budget period. The progress report will serve as your non-competing continuation application, and must contain the following elements:

a. Current Budget Period Activities Objectives.

b. Current Budget Period Financial Progress.

c. New Budget Period Program Proposed Activity Objectives.

d. Detailed Line-Item Budget and Justification.

e. Measures of Effectiveness.

f. Additional Requested Information.

2. Financial status report, no more than 90 days after the end of the budget period.

3. Final financial and performance reports, no more than 90 days after the end of the project period.

These reports must be mailed to the Grants Management Specialist listed in the ''Agency Contacts'' section of this announcement.

## VII. Agency Contacts

We encourage inquiries concerning this announcement.

For general questions, contact:

Technical Information Management Section, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770–488–2700.

For scientific/research issues, contact: Charlene Baker, PhD, Centers for Disease Control and Prevention, 4770 Buford Highway, NE, MS K–60, Atlanta, GA 30341, Telephone: 770–488–1737, E-mail: *asu6@cdc.gov.*

For questions about peer review, contact: Gwendolyn Cattledge, PhD, Scientific Review Administrator, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE., Mailstop K–02, Telephone: 770–488–1430, E-mail: *gxc8@cdc.gov.*

For financial, grants management, or budget assistance, contact: James Masone, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, E-mail: *JMasone@cdc.gov.*

## VIII. Other Information

This and other CDC funding opportunity announcements can be found on the CDC Web site, Internet address: *http://www.cdc.gov*. Click on ''Funding'' then ''Grants and Cooperative Agreements.''

Dated: December 23, 2004.

**William P. Nichols,**

*Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.*

[FR Doc. 04–28619 Filed 12–29–04; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

### Advisory Council for the Elimination of Tuberculosis Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following council meeting.

*Name:* Advisory Council for the Elimination of Tuberculosis (ACET).

*Times and Dates:* 8:30 a.m.–5 p.m., February 16, 2005; 8:30 a.m.–12 p.m., February 17, 2005.

*Place:* Corporate Square, Building 8, 1st Floor Conference Room, Atlanta, Georgia 30333. Telephone (404) 639–8008.

*Status:* Open to the public, limited only by the space available. The meeting room accommodates approximately 100 people.

*Purpose:* This council advises and makes recommendations to the Secretary, Department of Health and Human Services; the Assistant Secretary for Health; and the Director, CDC, regarding the elimination of tuberculosis (TB). Specifically, the Council makes recommendations regarding policies, strategies, objectives, and priorities; addresses the development and application of new technologies; and reviews the extent to which progress has been made toward eliminating TB.

*Matters to be Discussed:* Agenda items include issues pertaining to Global TB epidemiology and public health response, nucleic acid amplification testing (NAAT), and other TB related topics.

Agenda items are subject to change as priorities dictate.

*Contact Person for More Information:* Paulette Ford-Knights, National Center for HIV, STD, and TB Prevention, 1600 Clifton Road, NE., M/S E–07, Atlanta, Georgia 30333, telephone (404) 639–8008.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: December 20, 2004.

**B. Kathy Skipper,**

*Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 04–28615 Filed 12–29–04; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

**[CMS–2490–N]**

### CLIA Program; Continued Approval of the American Association of Blood Banks for Deeming Authority

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

**ACTION:** Notice.

**SUMMARY:** This notice announces the re-approval of the American Association of Blood Banks (AABB) as an accrediting organization for clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program. The initial exemption

was published in the **Federal Register** on July 21, 1995. We have determined 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 us or our designee.

**EFFECTIVE DATE:** This notice is effective for the period July 21, 2001 through July 21, 2007.

**FOR FURTHER INFORMATION CONTACT:** Daralyn Hassan, (410) 786–9360.

**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 replaced in its entirety section 353(e)(2) of the Public Health Service Act, as enacted by the Clinical Laboratories Improvement Act of 1967. We issued a final rule (57 FR 33992) implementing the accreditation provisions of CLIA on July 31, 1992. Under the CLIA program, we may approve a private, nonprofit organization as an approved accreditation organization to accredit clinical laboratories 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).

The regulations listed in subpart E of part 493 (Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program) specify the requirements an organization must meet to be an approved accreditation organization. We approve an accreditation organization for a period not to exceed 6 years.

In general, the approved accreditation organization must:

- 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.
- Provide reasonable assurance that its accredited laboratories continually meet these standards and criteria.
- 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 change in its standards.
- If we withdraw our approval, notify the accredited laboratories of the withdrawal within 10 days of the withdrawal.

CLIA requires CMS 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 Approval of AABB as an Accrediting Organization

In this notice, we approve AABB as an organization that may continue to accredit laboratories for purposes of establishing their compliance with CLIA requirements. We have examined the AABB application and all subsequent submissions to determine equivalency with our requirements under subpart E of part 493 that an accreditation organization must meet to be approved under CLIA. We have determined that AABB complied with the applicable CLIA requirements and grant AABB approval as an accreditation organization under subpart E, through July 21, 2007, for the following specialties and subspecialty areas:

- Immunohematology.
- General immunology.
- Hematology.
- Routine chemistry.
- Toxicology.

As a result of this determination, any laboratory that is accredited by the AABB during the effective time period for an approved specialty or subspecialty listed above is deemed to meet the CLIA requirements for laboratories found in part 493 of our regulations for that specialty or subspecialty 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 us, or by any other validly authorized agent.

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

The AABB formally applied to us for approval as an accreditation organization under CLIA for the specialties of immunohematology, hematology, general immunology, and the subspecialties of routine chemistry and toxicology. We evaluated the AABB application to determine compliance with our implementing and enforcement regulations, and the deeming/exemption requirements of the CLIA rules.

We evaluated the application to verify assurance of the AABB's compliance with the following subparts of part 493:

- Subpart H, Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing.
- Subpart J, Facility Administration for Nonwaived Testing.
- Subpart K, Quality System for Nonwaived Testing.
- Subpart M, Personnel for Nonwaived Testing.
- Subpart Q, Inspections.
- Subpart R, Enforcement Procedures.

The AABB meets the requirements for subparts H, J, K, M, Q, and R.

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 part 493 as explained below:

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

The AABB submitted a list of all 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; its data management and analysis system; a listing of the size, composition, education and experience of its inspection teams; its investigative and complaint response procedures; its notification agreements with CMS; its removal or withdrawal of laboratory accreditation procedures; its current list of accredited laboratories; and its announced or unannounced inspection process.

The AABB has additional requirements pertaining to waived testing. The AABB will routinely inspect laboratories that perform waived tests that are normally associated with blood centers and transfusion services. These laboratories will be inspected for good manufacturing practices and to verify that tests are performed according to manufacturer's instructions. In addition, for waived testing, the AABB requires that there be appropriately qualified personnel that is, director, supervisor, and testing personnel. Section 493.15 of the CL1A regulations

requires only that a laboratory follow manufacturer's instructions and does not require routine inspections of waived testing. Thus, the requirements of the AABB are more stringent than the requirements of the CLIA regulations.

We have determined that the AABB has complied with the requirements under subpart E of part 493 and that the requirements of the AABB are equal to or more stringent than the condition-level requirements in subparts H, J, K, M, Q, and R of part 493.

**Subpart H—Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing**

The AABB has revised its requirements to be equal to or more stringent than the CLIA requirements at § 493.801 through § 493.865.

**Subpart J—Facility Administration for Nonwaived Testing**

The AABB has revised its requirements to be equal to or more stringent than the CLIA requirements at § 493.1100 through § 493.1105. For example, the AABB requires laboratories to retain quality assessment records for five years, while the CLIA regulations require laboratories to retain these records for only two years.

**Subpart K—Quality System for Nonwaived Testing**

The quality control (QC) requirements of the AABB have been evaluated against the requirements of the CLIA regulations. The AABB has modified its survey process and made revisions to its standards encompassing general QC as well as specialty and subspecialty QC requirements in order to reflect the new QC requirements in the CLIA regulations. As such, we have determined that the AABB's requirements are equal to or more stringent than the requirements in the CLIA regulations. The specific requirements that are more stringent than the requirements of the CLIA regulations are the following:

- The requirement that laboratories meet the AABB's QC requirements for all waived testing they perform.
- The requirement for compliance with standards for parentage testing.
- The AABB's requirement that laboratories that perform provider-performed microscopy procedures must meet the same certification requirements as all other laboratories that perform moderate complexity testing.

**Subpart M—Personnel for Nonwaived Testing**

The AABB has revised its requirements to equal the CLIA requirements at § 493.1403 through § 493.1495 for laboratories that perform moderate and high complexity testing. The AABB personnel standards provide that the laboratory must meet CLIA requirements for personnel qualifications. The CLIA requirements for personnel responsibilities are encompassed in the revisions made to the AABB standards.

**Subpart Q—Inspections**

We have determined that the AABB's requirements for inspections are equal to or more stringent than the requirements of § 493.1771 through § 493.1780 of this subpart.

**Subpart R—Enforcement Procedures**

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

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

**IV. Federal Validation Inspection and Continuing Oversight**

The Federal validation inspections of AABB accredited laboratories 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 us or our agent, or the State survey agency, will be our principal means for verifying that the laboratories accredited by AABB 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 CMS may rescind the approval of an accreditation organization, such as that of the AABB, for cause, before the end of the effective date of approval. If we determine that the AABB failed to adopt requirements that are equal to, or more stringent than, the CLIA requirements, or that systemic problems exist in its inspection process, we may give it a probationary period, not to exceed one year, to allow the AABB to adopt comparable requirements.

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

In accordance with the provisions of Executive Order 12866, the Office of Management and Budget did not review this notice because our publication of this notice is not a regulatory action under that Executive Order.

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

Dated: November 16, 2004.

**Mark B. McClellan,**

*Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. 04–28152 Filed 12–29–04; 8:45 am]

**BILLING CODE 3410–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

**[CMS–9024–N]**

### Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—July 2004 Through September 2004

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

**ACTION:** Notice.

**SUMMARY:** This notice lists CMS manual instructions, substantive and interpretive regulations, and other **Federal Register** notices that were published from July 2004 through September 2004, relating to the Medicare and Medicaid programs. This notice provides information on national coverage determinations (NCDs) affecting specific medical and health care services under Medicare. Additionally, this notice identifies certain devices with investigational device exemption (IDE) numbers approved by the Food and Drug Administration (FDA) that potentially may be covered under Medicare. Finally, this notice also includes listings of all approval numbers from the Office of Management and Budget for collections of information in CMS regulations.

Section 1871(c) of the Social Security Act requires that we publish a list of