

Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters for Discussion: The meeting will include the initial review, discussion, and evaluation of applications received in response to “Nutrition and Obesity Policy Research and Evaluation Network (NOPREN) Coordinating Center, (SIP)14–026, and Nutrition and Obesity Policy Research and Evaluation Network (NOPREN) Collaborating Center, SIP14–027, Panel M, initial review.”

Contact Person for More Information: M. Chris Langub, Ph.D., Scientific Review Officer, CDC, 4770 Buford Highway NE., Mailstop F–80, Atlanta, Georgia 30341, Telephone: (770) 488–3585, EEO6@cdc.gov.

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 the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

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

[FR Doc. 2014–11978 Filed 5–22–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review

The meeting announced below concerns Miner Safety and Health Training Program—Western United States (U60) RFA–OH–14–004, initial review.

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 aforementioned meeting:

Time and Date: 1:00 p.m.–4:00 p.m., June 16, 2014 (Closed).

Place: Teleconference.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters for Discussion: The meeting will include the initial review, discussion, and evaluation of applications received in

response to “Miner Safety and Health Training Program—Western United States (U60) RFA–OH–14–004,” initial review.

Contact Person for More Information: George Bockosh, M.S., Scientific Review Officer, CDC/NIOSH, 1600 Clifton Road, Mailstop E–74, Atlanta, Georgia 30333, Telephone: (412) 386–6465.

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 the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

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

[FR Doc. 2014–11969 Filed 5–22–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3291–N]

Announcement of the Re-Approval of AABB (Formerly Known as the American Association of Blood Banks) 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 AABB for approval as an accreditation organization for clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program. We have determined that AABB meets or exceeds the applicable CLIA requirements. In this notice, we announce the approval and grant AABB deeming authority for a period of 6 years. This deeming authority is granted to AABB for the Blood Bank and Transfusion Service (BB/TS) program, the Immunohematology Reference Laboratory (IRL) program, the Molecular Testing (MT) program, and the Cellular Therapy (CT) program.

DATES: *Effective Date:* This notice is effective from May 23, 2014 to May 25, 2020.

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 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) specifies the requirements an accreditation organization must meet to be approved by CMS as an accreditation organization under CLIA.

II. Notice of Approval of AABB as an Accreditation Organization

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

- Microbiology, including Bacteriology, Mycology, and Virology.
- Diagnostic Immunology, including Syphilis Serology, General Immunology.
- Chemistry, including Routine Chemistry, Urinalysis, Toxicology.
- Hematology.
- Immunohematology, including ABO Group & Rh Group, Antibody Detection, Antibody Identification, Compatibility Testing.

We have examined the initial AABB 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 AABB meets or exceeds the applicable CLIA requirements. We have also determined that AABB 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 R. Therefore, we grant AABB approval as an accreditation organization under subpart E of part 493, for the period stated in the **DATES** section of this notice for the submitted specialty and subspecialty areas under CLIA. As a result of this determination, any laboratory that is accredited by AABB

during the time period stated in the **DATES** section of this notice will be deemed to meet the CLIA requirements for the listed 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 AABB Request for Approval as an Accreditation Organization Under CLIA

The following describes the process used to determine that the AABB accreditation program meets the necessary requirements to be approved by CMS as an accreditation program with deeming authority under the CLIA program. AABB formally applied to CMS for approval as an accreditation organization under CLIA for the following specialties and subspecialties:

- Microbiology, including Bacteriology, Mycology, Virology.
- Diagnostic Immunology, including Syphilis Serology, General Immunology.
- Chemistry, including Routine Chemistry, Urinalysis, Toxicology.
- Hematology.
- Immunohematology, including ABO Group & Rh Group, Antibody Detection, Antibody Identification, Compatibility Testing.

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

AABB 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 AABB policies and procedures for oversight of laboratories performing laboratory testing for the submitted 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. AABB 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 programs 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 AABB's requirements are equal to the CLIA requirements at § 493.801 through § 493.865. Like CLIA, all of AABB's accredited laboratories are required to participate in an HHS-approved PT program for tests listed in subpart I. Additionally, AABB administers a non-regulated PT program to challenge the ability of the laboratories in the IRL program to resolve complex serological problems. Laboratories in the MT program are required to participate in a graded PT program or a sample exchange program.

C. Subpart J—Facility Administration for Nonwaived Testing

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

G. Subpart R—Enforcement Procedures

We have determined that the AABB meets the requirements of subpart R to the extent that such requirements are utilized by accreditation organizations. 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, AABB will deny, suspend, or revoke accreditation in a laboratory accredited by AABB and report that action to us within 30 days. AABB also provides an appeals process for laboratories that have had accreditation denied, suspended, or revoked.

We have determined that AABB'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 AABB 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 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 we may rescind the approval of an accreditation organization, such as that of AABB, for cause, before the end of the effective date of approval. If we determine that AABB 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 1 year, in which AABB would be allowed to address any identified issues. Should AABB be unable to address the identified issues within that timeframe, CMS may, in accordance with the applicable regulations, revoke AABB's deeming authority under CLIA.

Should circumstances result in our withdrawal of AABB'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: May 12, 2014.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2014-11918 Filed 5-22-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10525]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by *July 22, 2014*.

ADDRESSES: When commenting, please reference the document identifier or OMB control number (OCN). To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786-1326.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-10525 Health Plan Monitoring System Level I and Level II Data Entry for the Program of All-Inclusive Care for the Elderly

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a

60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Existing collection in use without an OMB control number); *Title of Information Collection:* Health Plan Monitoring System Level I and Level II Data Entry for the Program of All-Inclusive Care for the Elderly; *Use:* This information collection would require Program of All-Inclusive Care for the Elderly (PACE) organizations to enter Level I and Level II data into the CMS's Health Plan Monitoring System. The collected information will be used to develop a quality improvement strategy for PACE. *Form Number:* CMS-10525 (OMB control number: 0938-New); *Frequency:* Quarterly and occasionally; *Affected Public:* Private sector—Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 100; *Total Annual Responses:* 7,000; *Total Annual Hours:* 1,575. (For policy questions regarding this collection contact Tamika Gladney at 410-786-0648).

Dated: May 20, 2014.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2014-11947 Filed 5-22-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10520]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing