—The Joint Commission's policies with respect to whether surveys are announced or unannounced, to assure that surveys are unannounced.
—The Joint Commission's agreement to provide us with a copy of the most current accreditation survey together with any other information related to the survey as we may require (including corrective action plans).

IV. Response to Public Comments and Notice Upon Completion of Evaluation

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Upon completion of our evaluation, including evaluation of comments received as a result of this notice, we will publish a final notice in the **Federal Register** announcing the result of our evaluation.

V. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

VI. Regulatory Impact Statement

In accordance with the provisions of Executive Order 12866 (September 1993, Regulatory Planning and Review, the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354)), the Office of Management and Budget did not review this proposed notice.

In accordance with Executive Order 13132, we have determined that this proposed notice would not have a significant effect on the rights of States, local or tribal governments.

Authority: Section 1865 of the Social Security Act (42 U.S.C. 1395bb).

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: May 1, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E8–10776 Filed 5–22–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[CMS–2224–N]

RIN 0938–ZA98

Medicare, Medicaid, and CLIA Programs; Continuing Approval of AABB (Formerly the American Association of Blood Banks as a CLIA Accreditation Organization

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

ACTION: Notice.

SUMMARY: In this notice, we reapprove and grant AABB (formerly known as the American Association of Blood Banks) deeming authority as an accrediting organization for clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program. This deeming authority is granted to AABB for the Blood Bank and Transfusion Service (BB/TS) accreditation program and the Immunohematology Reference Laboratory (IRL) Program.

DATES: *Effective Date:* This notice is effective from May 23, 2008 to May 23, 2014.

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), Public Law 100–578. CLIA replaced in its entirety, section 353(e)(2) of the Public Health Service Act, as enacted by the Clinical Laboratory Improvement Act of 1967. We issued a final rule implementing the accreditation provisions of CLIA on July 31, 1992 (57 FR 33992). Under the CLIA program, CMS may grant deeming authority to an accreditation organization that accredits 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 in subpart E (Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program) specify the requirements an accreditation 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 at the frequency determined by CMS.
- Apply standards and criteria that are equal to, or more stringent than, those condition-level requirements established by CMS.
- Assure that laboratories accredited by the accreditation organization 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 changes in its standards.
- If we withdraw our approval, notify the accredited laboratories of the withdrawal within 10 days of the withdrawal.

CLIA requires that we perform an annual evaluation of approved accreditation organizations by inspecting a representative sample of laboratories accredited by an approved accreditation organization as well as by any other means that we determine to be appropriate.

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. 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 complies with the applicable CLIA requirements and grant AABB approval as an accreditation organization under subpart E, as for the period stated in the ''Effective Date'' section of this notice for the following specialty and subspecialty areas:

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

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

III. Evaluation of AABB Request for Approval as an Accreditation Organization Under CLIA

The following describes the process used to determine that requirements of the AABB accreditation program are equal to or more stringent than the CLIA condition level requirements, and that AABB has met the requirements of subpart E of 42 CFR part 493.

AABB formally reapplied to us for approval as an accreditation organization under CLIA for the following specialties and subspecialties:

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

We evaluated the AABB application to determine compliance with our implementing and enforcement regulations, and the deeming/exemption requirements of the CLIA rules.

We verified that the AABB BB/TS and IRL accreditation program requirements and methods require 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

AABB submitted the specialties and subspecialties that it would accredit; a comparison of its accreditation requirements to CLIA condition level requirements; a description of its inspection process and its 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 procedures for removing or withdrawing laboratory accreditation; its current list of accredited laboratories; and its announced or unannounced inspection process.

AABB has additional requirements pertaining to waived testing. AABB will routinely inspect laboratories that perform waived tests that are normally associated with blood centers and transfusion services. These laboratories will be inspected to verify that tests are performed according to manufacturer's instructions. In addition, AABB requires that there be appropriately qualified personnel—that is a director, a supervisor, and testing personnel for waived testing. Section 493.15 of the CLIA regulations requires only that a laboratory follow manufacturer's instructions and does not require routine inspections of waived testing. Thus the requirements of AABB are more stringent than the requirements of the CLIA regulations.

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

AABB's requirements are equal to the CLIA requirements at § 493.801 through § 493.865. Both CLIA regulations and AABB standards require accredited laboratories to participate in a CMS-approved proficiency testing (PT) program for any of the tests listed in subpart I. Additionally, AABB administers a non-regulated PT program to challenge the ability of the labs in the IRL program to resolve complex serological problems.

Subpart J—Facility Administration for Nonwaived Testing

AABB requirements are equal to or more stringent than the CLIA requirements at § 493.1100 through § 493.1105. The following specific AABB requirements are more stringent than the requirements of the CLIA regulations:

- AABB's record-keeping requirements are more extensive and detailed than the CLIA requirements. For example, AABB requires laboratories to retain quality assessment records for 5 years, while the CLIA regulations require laboratories to retain those records for only 2 years.
- The IRL standards require laboratories to maintain an extensive inventory of rare reagents for resolving complex serological problems.

Subpart K— Quality System for Nonwaived Testing

The quality control requirements of AABB have been evaluated against the requirements of the CLIA regulations. AABB, like CLIA, uses a quality system approach in its requirements for laboratories. AABB inspectors use detailed checklists to ensure that compliance with specific CLIA requirements is met. AABB requirements are equal to the CLIA requirements at § 493.1200 through § 493.1299.

Subpart M—Personnel for Nonwaived Testing

AABB uses the criteria identified in the CLIA regulations at §§ 493.1441, 493.1447, 493.1453, 493.1459, and 493.1487 (applicable to laboratories performing high-complexity testing). A qualified individual must fulfill the responsibilities of each required position in the laboratory. The laboratory director and laboratory personnel must meet educational and experience requirements. Although certain duties of the laboratory director may be delegated to qualified individuals, the laboratory director remains ultimately responsible.

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 perform onsite inspections every 2 years.

Subpart R—Enforcement Procedures

AABB meets the requirements of subpart R to the extent that it applies to 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 appeal 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 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 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 CMS or our agents, 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 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 1 year, to allow 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.

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 Clinical Laboratory Improvement Amendments of 1988 (CLIA) program, codified in 42 CFR part 493, subpart E, are currently approved by OMB under OMB approval number 0938–0686.

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

Dated: April 11, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E8–10769 Filed 5–22–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–7009–N]

Medicare Program; Announcement of Meeting of the Advisory Panel on Medicare Education, June 26, 2008

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

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces a meeting of Advisory Panel on Medicare Education (the Panel). The Panel advises and makes recommendations to the Secretary of Health and Human Services and the Administrator of the Centers for Medicare & Medicaid Services on the effectiveness of consumer education strategies concerning the Medicare program. This meeting is open to the public.

DATES: *Meeting Date:* June 26, 2008 from 9 a.m. to 3:30 p.m., d.s.t.

Deadline for Meeting Registration, Presentations and Comments: June 19, 2008, 12 noon, d.s.t.

Deadline for Requesting Special Accommodations: June 12, 2008, 12 noon, d.s.t.

ADDRESSES: *Meeting Location:* Four Points Hotel, 1201 K Street, NW., Washington, DC 20005, (202) 349–2205.

Meeting Registration, Presentations, and Written Comments: Lynne Johnson, Designated Federal Official, Division of Forum and Conference Development, Office of External Affairs, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mailstop S1–05–06, Baltimore, MD 21244–1850 or contact Ms. Johnson via e-mail at *Lynne.Johnson@cms.hhs.gov.*

Registration: The meeting is open to the public, but attendance is limited to the space available. Persons wishing to attend this meeting must register by contacting Lynne Johnson at the address listed in the **ADDRESSES** section of this notice or by telephone at (410) 786–0090, by the date listed in the **DATES** section of this notice.

FOR FURTHER INFORMATION CONTACT: Lynne Johnson, (410) 786–0090. Please refer to the CMS Advisory Committees' Information Line (1–877–449–5659 toll free)/(410–786–9379 local) or the Internet (*http://www.cms.hhs.gov/FACA/04_APME.asp*) for additional information and updates on committee activities. Press inquiries are handled through the CMS Press Office at (202) 690–6145.

SUPPLEMENTARY INFORMATION: Section 9(a)(2) of the Federal Advisory Committee Act authorizes the Secretary of Health and Human Services (the Secretary) to establish an advisory panel if the Secretary determines that the panel is ''in the public interest in connection with the performance of duties imposed * * * by law.'' Such duties are imposed by section 1804 of the Social Security Act (the Act), requiring the Secretary to provide informational materials to Medicare beneficiaries about the Medicare program, and section 1851(d) of the Act, requiring the Secretary to provide for ''activities * * * to broadly disseminate information to [M]edicare beneficiaries * * * on the coverage options provided under [Medicare Advantage] in order to promote an active, informed selection among such options.''

The Panel is also authorized by 1114(f) of the Act (42 U.S.C. 1311(f)) and section 222 of the Public Health Service Act (42 U.S.C. 217a). The Secretary signed the charter establishing this Panel on January 21, 1999 and approved the renewal of the charter on November 14, 2006. The establishment of the charter and the renewal of the charter were announced in the February 17, 1999 **Federal Register** (64 FR 7899), and the March 23, 2007 **Federal Register** (72 FR 13796), respectively. The Panel advises and makes recommendations to the Secretary and the Administrator of the Centers for Medicare & Medicaid Services (CMS) on opportunities to enhance the effectiveness of consumer education strategies concerning the Medicare program. The Secretary delegates authority to the Administrator.

The goals of the Panel are as follows:

- To provide recommendations on the development and implementation of a national Medicare education program that describes the options for selecting a health plan and prescription drug plan under Medicare.
- To enhance the Federal government's effectiveness in informing the Medicare consumer, including the appropriate use of public-private partnerships.
- To provide recommendations on how to expand outreach to vulnerable and underserved communities, including racial and ethnic minorities, in the context of a national Medicare education program.
- To assemble an information base of best practices for helping consumers evaluate health plan options and build a community infrastructure for information, counseling, and assistance.

The current members of the Panel are: Anita B. Boles, Executive Director, Society for the Arts in Healthcare; Gwendolyn T. Bronson, SHINE/SHIP Counselor, Massachusetts SHINE Program; Dr. Yanira Cruz, President and Chief Executive Officer, National Hispanic Council on Aging; Clayton Fong, President and Chief Executive Officer, National Asian Pacific Center on Aging; Nan Kirsten-Forte, Executive Vice President, Consumer Services, WebMD; Dr. Jessie C. Gruman, President and Chief Executive Officer, Center for the Advancement of Health; Dr. David Lansky, PhD., President and Chief