law enforcement, officer and public safety, humanitarian, and public health interests. DHS shall consult with CDC concerning how these types of case-by-case, individualized exceptions shall be made to help ensure consistency with current CDC guidance and public health assessments.

This Amended Order and Extension is not a rule subject to notice and comment under the Administrative Procedure Act (APA). In the event this order qualifies as a rule subject to notice and comment, a delay in effective date is not required because the foregoing discussion shows that there is good cause to dispense with prior public notice and the opportunity to comment on this order and a delay in effective date.[33] Given the public health emergency caused by COVID–19, it would be impracticable and contrary to the public health—and, by extension, the public interest—to delay the issuing and effective date of this Order. In addition, because this Order concerns ongoing discussions with Canada and Mexico on how to best control COVID–19 transmission over our shared borders, it directly ''involve[s] . . . a . . . foreign affairs function of the United States.'' 5 U.S.C. 553(a)(1). Notice and comment and a delay in effective date would not be required for that reason as well.

* * * * *

This Amended Order and Extension goes into effect at 12:00 a.m. Eastern Daylight Time (EDT) on May 21, 2020 and shall remain in effect until I determine that the danger of further introduction of COVID–19 into the United States has ceased to be a serious danger to the public health, and the continuation of the Order is no longer necessary to protect the public health. Upon making this determination, I will publish a notice in the **Federal Register** terminating this Order and its Extensions. CDC shall reassess the Order every 30 days to determine whether current conditions warrant continued implementation, modification, or termination of the Order. I may further amend or extend the Order as needed to protect the public health.

* * * * *

Authority

The authority for these orders is Sections 362 and 365 of the Public Health Service Act (42 U.S.C. 265, 268) and 42 CFR 71.40.

[33] *See* 5 U.S.C. 553(b)(B) and (d)(3).

Dated: May 19, 2020.

Robert K. McGowan,

Chief of Staff, Centers for Disease Control and Prevention.

[FR Doc. 2020–11179 Filed 5–20–20; 4:15 pm]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3398–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 4 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: The approval announced in this notice is effective from May 26, 2020 to May 27, 2024.

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 (Pub. L. 100–578, enacted on October 31, 1988) (CLIA). 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 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 us 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 its compliance with CLIA requirements for the following specialty and subspecialty areas under CLIA:

- Microbiology, including Bacteriology, Mycology, Parasitology and Virology.
- Diagnostic Immunology, including Syphilis Serology, General Immunology.
- Chemistry, including Routine Chemistry.
- 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. The accredited laboratory, however, is subject to validation and complaint investigation surveys performed by us, 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 us and that, as such, we may approve AABB as an accreditation program with deeming authority under the CLIA program. AABB formally applied to us for approval as an accreditation organization under CLIA for the following specialties and subspecialties:

- Microbiology, including Bacteriology, Mycology, Parasitology, Virology.
- Diagnostic Immunology, including Syphilis Serology, General Immunology.
- Chemistry, including Routine Chemistry.
- 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. 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

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

The AABB's requirements are equal to the CLIA requirements at § 493.1100 through § 493.1105.

D. Subpart K—Quality System for Nonwaived Testing

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

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 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 us 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, we 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 document does not impose information collection requirements, that is, reporting, record keeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget (OMB) under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). The requirements associated with the accreditation process for clinical laboratories under the CLIA program, codified in 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.

The Administrator of the Centers for Medicare & Medicaid Services (CMS),

Seema Verma, having reviewed and approved this document, authorizes Evell J. Barco Holland, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: April 21, 2020.

Evell J. Barco Holland,

Federal Register Liaison, Department of Health and Human Services.

[FR Doc. 2020–11235 Filed 5–22–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–317]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid 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 the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and 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 27, 2020.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. 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' website address at website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

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: William N. Parham at (410) 786–4669.

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–317 State Medicaid Eligibility Quality Control (MEQC) Sample Plans

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:* Reinstatement without change of a previously approved collection of information; *Title of Information Collection:* State Medicaid Eligibility Quality Control Sampling Plan; *Use:* The Medicaid Eligibility Quality Control (MEQC) program provides states and the District of Columbia a unique opportunity to improve the quality and accuracy of their Medicaid and Children's Health Insurance Program (CHIP) eligibility determinations. The MEQC program is intended to complement the Payment Error Rate Measurement (PERM) program by ensuring state operations make accurate and timely eligibility determinations so that Medicaid and CHIP services are appropriately provided to eligible individuals. Current regulations require that states review equal numbers of active cases and negative case actions (*i.e.,* denials and terminations) through random sampling. Active case reviews are conducted to determine whether or not the sampled cases meet all current criteria and requirements for Medicaid or CHIP eligibility. Negative case reviews are conducted to determine if Medicaid and CHIP denials and terminations were appropriate and undertaken in accordance with due process. *Form Number:* CMS–317 (OMB control number: 0938–0146); *Frequency:* Occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 10; *Total Annual Responses:* 20; *Total Annual Hours:* 520. (For policy questions regarding this collection contact Camiel Rowe at 410–786–0069.)

Dated: May 19, 2020.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2020–11161 Filed 5–22–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3397–PN]

Medicare and Medicaid Programs; Application From The Joint Commission (TJC) for Continued CMS-Approval of Its Ambulatory Surgical Center (ASC) Accreditation Program

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