Supporting Regulations in 42 CFR 433.68 through 433.74; *Use:* States may elect to submit a waiver to CMS for the broad based and/or uniformity requirements for any health care related tax program which does not conform to the broad based and uniformity requirements. It is also the responsibility of each State to demonstrate that their tax program(s) do not violate the hold harmless provision. For a waiver to be approved and a determination that the hold harmless provision is not violated, States must submit written documentation which satisfies the regulatory requirements. Without this information, the amount of FFP (Federal financial participation) payable to a State cannot be correctly determined. *Form Number:* CMS–R–148 (OMB control number: 0938–0618); *Frequency:* Quarterly and occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 50; *Total Annual Responses:* 40; *Total Annual Hours:* 3,200. (For policy questions regarding this collection contact Stuart Goldstein at 410–786–0694.)

5. *Title of Information Collection:* Pharmacy Benefit Manager Transparency for Qualified Health Plans; *Type of Information Collection Request:* Revision of a currently approved collection; *Use:* Implementation of section 1150A of the Social Security Act, as added by section 6005 of the Patient Protection and Affordable Care Act (ACA), requires, among other entities, Qualified Health Plans (QHPs) and pharmacy benefit managers (PBMs) that serve QHP issuers to report information on prescription drug benefits to the U.S. Department of Health and Human Services (HHS). PBMs are third-party administrators of prescription programs for a variety of types of health plans, including QHPs. CMS finalized regulations for this reporting at 45 CFR 156.295 and 184.50.

Under these requirements a QHP issuer is required to report issuer and plan level prescription drug data to CMS only when the QHP issuer does not contract with a PBM to administer the prescription drug benefit for their QHPs. Section 1150A(a)(1) of the Social Security Act authorizes CMS to collect the same prescription drug and rebate information from Prescription Drug Plan sponsors of a prescription drug plan and Medicare Advantage organizations offering a Medicare Advantage Prescription Drug Plan under part D of title XVIII. Since 2012, CMS has collected these data from Part D sponsors as part of the Medicare Part D Direct and Indirect Remuneration (DIR) reporting requirement, and detailed drug information for each National Drug Code (NDC) from the Prescription Drug Event (PDE) data that plans are required to submit.

CMS is formally requesting an extension of this ICR in connection with submission from QHP issuers that do not contract with a PBM and PBMs (hereinafter referred to as ''submitters''). The information required from submitters and the process of submission has changed since the previous OMB approval. The submitters are now required to complete a web form that reports the allocation methodology that is selected by the submitters to allocate data, where necessary. Submitters are required to maintain internal documentation of the allocation methodologies chosen, as CMS may need to follow up with the submitters to better understand the methodology. The associated burden estimates for this collection reflect the time and effort for submitters to provide prescription drug benefit information to CMS using the Health Information Oversight System (HIOS) module. *Form Number:* CMS–10725 (OMB control number: 0938–1394); *Frequency:* Annually; *Affected Public:* Private Sector, Business or other For-Profits; *Number of Respondents:* 278; *Number of Responses:* 278; *Total Annual Hours:* 1,285. (For questions regarding this collection, contact LeAnn Brodhead at (301) 492–4493.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024–08828 Filed 4–24–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3449–N]

Announcement of the Re-Approval of AABB (Association for the Advancement of Blood and Biotherapies) as an Accreditation Organization Under the Clinical Laboratory Improvement Amendments of 1988

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

ACTION: Notice.

SUMMARY: This notice announces the application of the Association for the Advancement of Blood and Biotherapies (AABB) for re-approval as an accreditation 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) program, the Immunohematology Reference Laboratory (IRL) program, the Molecular Testing (MT) program, and the Cellular Therapy (CT) program. We have determined that AABB meets or exceeds the applicable CLIA requirements. We are announcing the re-approval and grant AABB deeming authority for a period of 6 years.

DATES: The approval is effective from April 25, 2024 to April 25, 2030.

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 Re-Approval of AABB as an Accreditation Organization

In this notice, we approve the Association for the Advancement of Blood and Biotherapies (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, Parasitology, and Virology.
- Diagnostic Immunology, including Syphilis Serology and General Immunology.
- Chemistry, including Routine Chemistry.
- Hematology.

• Immunohematology, including ABO Group & Rh Group, Antibody Detection, Antibody Identification, and Compatibility Testing.

We have examined the initial AABB application and all subsequent submissions to determine its accreditation program's equivalency with the requirements for re-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 re-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 specialties and subspecialties, 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 CMS or its agent(s).

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

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

• Microbiology, including Bacteriology, Mycology, Parasitology, and Virology.
• Diagnostic Immunology, including Syphilis Serology and General Immunology.
• Chemistry, including Routine Chemistry.
• Hematology.
• Immunohematology, including ABO Group & Rh Group, Antibody Detection, Antibody Identification, and 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 a description of 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's 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 with respect to inspection, monitoring proficiency testing (PT) performance, investigating complaints, and making PT information available. AABB also 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 re-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

AABB's requirements are equal to or more stringent than the CLIA requirements at §§ 493.801 through 493.865. Like CLIA, all AABB's accredited laboratories are required to participate in an HHS-approved PT program for tests listed in part 493 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 AABB 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 AABB requirements are equal to the CLIA requirements at §§ 493.1200 through 493.1299.

E. Subpart M—Personnel for Nonwaived Testing

We have determined that 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—Inspection

We have determined that 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 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

In accordance with § 493.563, 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 Re-Approval as an Accrediting Organization

CLIA regulation at § 493.575 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 re-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 re-approval, we will publish a notice in the **Federal Register** explaining the basis for removing its re-approval.

VI. Collection of Information Requirements

The information collection requirements associated with the accreditation process for clinical laboratories under the CLIA program are currently OMB-approved under OMB control number 0938–0686 and expire May 31, 2025. Additionally, this notice does not impose any new or revised information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, it does not need to be reviewed by the Office of Management and Budget (OMB) under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq).

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), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Trenesha Fultz-Mimms, who is the **Federal Register** Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Trenesha Fultz-Mimms,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2024–08809 Filed 4–24–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–5473]

Promotional Labeling and Advertising Considerations for Prescription Biological Reference Products, Biosimilar Products, and Interchangeable Biosimilar Products: Questions and Answers; Revised Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a revised draft guidance for industry entitled ''Promotional Labeling and Advertising Considerations for Prescription Biological Reference Products, Biosimilar Products, and Interchangeable Biosimilar Products: Questions and Answers.'' FDA is issuing this revised draft guidance to address questions that manufacturers, packers, distributors, and their representatives (firms) may have when developing FDA-regulated promotional labeling and advertisements (promotional communications) for prescription reference products, biosimilar products, and interchangeable biosimilar products licensed under the Public Health Service Act (PHS Act). In conjunction with the enactment of the Biosimilar User Fee Amendments of 2022 (BsUFA III), FDA agreed to publish a draft guidance on promotional labeling and advertising considerations for interchangeable biosimilar products, as described in the document titled ''Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2023 through 2027.'' The revised draft guidance is consistent with this commitment and replaces the draft guidance for industry entitled ''Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products: Questions and Answers'' issued on February 4, 2020.

DATES: Submit either electronic or written comments on the draft guidance by June 24, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–D–5473 for ''Promotional Labeling and Advertising Considerations for Prescription Biological Reference Products, Biosimilar Products, and Interchangeable Biosimilar Products: Questions and Answers.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two