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General Conditions

CDC reserves the right to cancel, suspend, and/or modify the Challenge, or any part of it, for any reason, at CDC's sole discretion.

Participation in this Challenge constitutes an applicants' full and unconditional agreement to abide by the Challenge's Official Rules found at <https://www.Challenge.gov>.

Authority: 15 U.S.C. 3719.

Noah Aleshire,

Chief Regulatory Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10291, CMS-10529, CMS-10722, CMS-R-148, and CMS-10725]

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

AGENCY: Centers for Medicare & Medicaid Services, 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 (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 a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate 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 on the collection(s) of information must be received by the OMB desk officer by *May 28, 2024*.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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 (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-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 that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* State Collection and Reporting of Dental Provider and Benefit Package Information on the Insure Kids Now! Website and Hotline; *Use:* On the Insure Kids Now (IKN) website, the Secretary is required to post a current and accurate list of dentists and providers that provide dental services to children enrolled in the state plan (or waiver) under Medicaid or the state child health plan (or waiver) under

CHIP. States collect the information pertaining to their Medicaid and CHIP dental benefits. *Form Number:* CMS-10291 (OMB control number: 0938-1065); *Frequency:* Yearly and quarterly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 51; *Total Annual Responses:* 255; *Total Annual Hours:* 11,781. (For policy questions regarding this collection contact Andrew Snyder at 410-786-1274.)

2. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Quarterly Medicaid and CHIP Budget and Expenditure Reporting for the Medical Assistance Program, Administration and CHIP; *Use:* The Medicaid and CHIP Financial System is a financial reporting system that produces budget estimate statements for Forms CMS-37 and CMS-21B. The Medicaid and CHIP Budget and Expenditure System is a financial reporting system that produces expenditure statements for Forms CMS-64 and CMS-21. All forms are to be filed on a quarterly basis and need to be certified by the states. *Form Number:* CMS-10529 (OMB control number: 0938-1265); *Frequency:* Quarterly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 672; *Total Annual Hours:* 18,144. (For policy questions regarding this collection contact Robert Lane at 410-786-2015.)

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Annual State Report on CMS Value Based Purchasing Arrangements (VBP) Supplemental Rebate Agreements; *Use:* The reported data is being collected to safeguard against unnecessary utilization of such care and services and to assure that state payments to providers of Medicaid services are consistent with efficiency, economy, and quality of care. CMS will collect this data to ensure that VBP programs adopted by states continue to meet these standards. *Form Number:* CMS-10722 (OMB control number: 0938-1385); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 51; *Total Annual Responses:* 51; *Total Annual Hours:* 306. (For policy questions regarding this collection contact Abraham Weinschneider at 410-786-5688.)

4. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Limitations on Provider Related Donations and Health Care Related Taxes, Medicaid and

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.

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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.