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, 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 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–1561/1561A Health Insurance Benefit Agreement

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; *Title of Information Collection:* Health Insurance Benefit Agreement; *Use:* The CMS–1561 form applies to specific types of health care providers and opioid treatment programs and the CMS–1561A form applies to rural health clinics (RHCs). The CMS–1561 and CMS–1561A forms are health insurance benefits agreements that are essential for the Centers for Medicare and Medicaid Services (CMS) to ensure that applicants to the Medicare program have made a binding commitment to comply with all applicable Federal requirements. The CMS–1561/1561A forms are essential in that they allow CMS to ensure that applicants are in compliance with the requirements. Applicants will be required to sign the completed form and provide operational information to CMS to assure that they continue to meet the requirements after approval. The collection is made only once, when the provider or RHC submits their application for participation in Medicare by signing the completed CMS–1561 or CMS–1561A form (as applicable). *Form Number:* CMS–1561/1561A (OMB control number: 0938–0832); *Frequency:* Once only; *Affected Public:* Private sector—(Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 2,050; Total *Annual Responses:* 2,050; *Total Annual Hours:* 2,050. (For policy questions regarding this collection contact Caroline Gallaher at 410–786–8705).

Dated: September 25, 2023

William N. Parham, III,

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

[FR Doc. 2023–21334 Filed 9–28–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3383–N2]

Clinical Laboratory Improvement Amendments of 1988 Exemption of Laboratories Licensed by the State of Washington; Exemption Period Extension

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

ACTION: Notice; exemption period extension.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) announce the extension of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) exemption period for the State of Washington. The exemption period is extended for 6 months, that is until April 2, 2024.

DATES: The exemption granted by this notice is effective from October 2, 2023 to April 2, 2024.

FOR FURTHER INFORMATION CONTACT: Mary Hasan, (410) 786–6480.

SUPPLEMENTARY INFORMATION: In the ''Medicare, Medicaid, and CLIA Programs; Clinical Laboratory Improvement Amendments of 1988 Exemption of Laboratories Licensed by the State of Washington'' notice that appeared in the September 30, 2019 **Federal Register** (84 FR 51591), we announced that laboratories located in and licensed by the State of Washington that possess a valid license under the Medical Test Site law, Chapter 70.42 of the Revised Code of Washington, are exempt from the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) for a period of 4 years. This period expires on October 2, 2023. Pending re-approval of Washington State's CLIA exemption period, we are extending Washington State's current CLIA exemption period for 6 months, that is until April 2, 2024.

The Administrator of CMS, Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Chyana Woodard, who is the **Federal Register** Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Chyana Woodard,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2023–21460 Filed 9–28–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–3900]

Graft-Versus-Host Diseases: Developing Drugs, Biological Products, and Certain Devices for Prevention or Treatment; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.