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Centers for Medicare & Medicaid Services

[Document Identifier: CMS-R-26 and CMS-R-185]

Agency Information Collection Activities: Proposed Collection; 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 (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 **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

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, please access the CMS PRA web site 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-R-26 Clinical Laboratory Improvement Amendments (CLIA) Regulations

CMS-R-185 Granting and Withdrawal of Deeming Authority to Private Nonprofit Accreditation Organizations and CLIA Exemption Under State Laboratory Programs

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*: Revision of a currently approved collection; *Title of Information Collection*: Clinical Laboratory Improvement Amendments (CLIA) Regulations; *Use:* The information is necessary to determine an entity's compliance with the Congressionally-mandated program with respect to the regulation of laboratory testing (CLIA). In addition, laboratories participating in the Medicare program must comply with CLIA requirements as required by section 6141 of OBRA 89. Medicaid, under the authority of section 1902(a)(9)(C) of the Social Security Act, pays for services furnished only by laboratories that meet Medicare (CLIA) requirements.

This is a revision of the information collection. Based on the notice of proposed rulemaking, published in the ***Federal Register*** on July 26, 2022 (87 FR 44896), we are revising the information collection request by adding sections. The additional requirements include sections 493.1278, 493.1359, 493.1405-1411; 493.1423, 493.1443-1445, 493.1461-1463; 493.1483; 493.1489-1491. These sections include histocompatibility (493.1278) and personnel (493.1359, 493.1405-1411; 493.1423, 493.1443-1445, 493.1461-1463; 493.1483; 493.1489-1491) require laboratories to revise and update policies and procedures applicable to new or amended requirements. *Form Number*: CMS-R-26 (OMB Control Number: 0938-0612); *Frequency*: Monthly, occasionally; *Affected Public*: Business or other for-profits and Not-for-profit institutions, State, Local or Tribal Governments, and the Federal government; *Number of Respondents*: 49,626; *Total Annual Responses:* 88,259,802; *Total Annual Hours:* 14,514,802. (For policy questions regarding this collection contact Jelani Sanaa at 410-786-6782).

2. *Type of Information Collection Request:* Revision of currently approved collection;

Title of Information Collection: Granting and Withdrawal of Deeming Authority to Private Nonprofit Accreditation Organizations and CLIA Exemption Under State Laboratory Programs; *Use:* The information required is necessary to determine whether a private accreditation organization/State licensure program standards and accreditation /licensure process is at least equal to or more stringent than those of the Clinical Laboratory Improvement Amendments of 1988 (CLIA). If an accreditation organization is approved, the laboratories that it accredits are "deemed" to meet the CLIA requirements based on this accreditation. Similarly, if a State licensure program is determined to have requirements that are equal to or more stringent than those of CLIA, its laboratories are considered to be exempt from CLIA certification and requirements. The information collected will be used by HHS to: determine comparability/equivalency of the accreditation organization standards and policies or State licensure program standards and policies to those of the CLIA program; to ensure the continued comparability/equivalency of the standards; and to fulfill certain statutory reporting requirements.

We are revising the information collection request by adding and amending collection requirements for 493.553-557. The proposed rule published in the ***Federal Register*** on July 26, 2022 (87 FR 44896). These require laboratories to revise and update policies and procedures applicable to new or amended requirements. *Form Number:* CMS-R-185 (OMB control number: 0938-0686); *Frequency:* Occasionally; *Affected Public:* Private Sector - Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 9; *Total Annual Responses:* 9; *Total Annual Hours:* 5,359. (For policy questions regarding this collection contact Arlene Lopez at 410-786-6782.)

Dated: July 06, 2023.

William N. Parham, III,

Director, Paperwork Reduction Staff,

Office of Strategic Operations and Regulatory Affairs.

4120-01-U-P

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