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4120-01-U-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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 (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**).

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:* This is an extension package. The Clinical Laboratory Improvement Amendments of 1988 (CLIA) section 353 of the Public Health Service Act requires the Department of Health and Human Services (HHS) to establish certification requirements for any entity, with certain exceptions contained in the regulation, that performs testing on human beings to meet performance requirements based on test complexity and risk factors related to erroneous test results in order to be certified by HHS.

This information collection reflects a series of records required to be maintained by laboratories participating in the CLIA program and are based upon the publication of a final quality assessment rule on January 24, 2003, and the publication of the final fee, histocompatibility, personnel, and alternative sanction rule on December 28, 2023 (88 FR 89976). Included in the revisions were amendments to the histocompatibility and personnel regulations under CLIA to address obsolete regulations and update the regulations to incorporate technological changes, and that are reflected in this extension package.

The previous iteration was a revision of the information collection. Based on notice of final rulemaking, CMS-3326-F (88 FR 89976) published on December 28, 2023, we revised the ICR by adding additional sections.

The final rule addressed recommendations provided by the Centers for Disease Control and Prevention (CDC)'s Clinical Laboratory Improvement Advisory Committee (CLIAC). CMS and CDC incorporated changes in the rulemaking to remove specific regulations already covered in the general requirements and laboratory director responsibilities. The additional

requirements included sections 493.1278, 493.1359, 493.1405-1411; 493.1423, 493.1443-1445, 493.1461-1463; 493.1483; 493.1489-1491. These sections included histocompatibility (493.1278) and personnel (493.1359, 493.1405-1411; 493.1423, 493.1443-1445, 493.1461-1463; 493.1483; 493.1489-1491) which required 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 Penny Keller at 410-786-2035).

2. *Type of Information Collection Request:* Extension 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:* This is an extension package. The Clinical Laboratory Improvement Amendments of 1988 (CLIA) established a new section 353 of the Public Health Service Act (PHSA) which requires the Department of Health and Human Services (HHS) to establish certification requirements, with certain exceptions, for any laboratory that performs testing on human specimens. Laboratories must meet performance requirements based on test complexity in order to be certified by HHS. CLIA also provides for the recognition of private accreditation organizations and State licensure programs whose standards are determined to be equal to or more stringent than the HHS requirements.

Final regulations were published on February 28, 1992, at 42 CFR part 493 which implemented the certificate, laboratory standards and inspection requirement sections of CLIA. There have been several subsequent rules that have modified these regulations.

On July 31, 1992, final regulations implementing the provisions of 353 PHSA concerning the recognition of private accreditation organizations and State licensure programs for CLIA

purposes were published as Subpart E of part 493. These regulations establish that we may approve a private, nonprofit organization as an accreditation organization for clinical laboratories under the CLIA program if the organization's requirements for its accredited laboratories are equal to or more stringent than the applicable CLIA program requirements of part 493. These regulations also provide for the CLIA exemption of laboratories in a State that applies licensure requirements that are equal to or more stringent than those of CLIA.

On May 14, 1998, revisions to Subpart E were published as part of other CLIA final rulemaking. The revisions to Subpart E eliminated duplicative information by restructuring and consolidating requirements for accreditation organizations and State licensure programs seeking approval under CLIA. The revised Subpart better reflects the information required and process involved in obtaining approval. This restructuring did not change the requirements, but only redesignated them into a more customer-oriented document, making them easier for users to understand. In this process we used new section numbers, but retained all the requirements for Subpart E.

The last iteration required accreditation organizations and State licensure programs to revise and update policies and procedures applicable to new or amended requirements in the final rule, CMS-3326-F, to remain complaint with the regulations at 493.553-557. The accreditation organizations or State licensure programs are required to meet or exceed the CLIA regulations. The final rule, CMS-3326-F, was published on December 28, 2023 (88 FR 89976). *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 Penny Keller at 410-786-2035.)

William N. Parham, III,

Director,

Division of Information Collections and Regulatory Impacts,

Office of Strategic Operations and Regulatory Affairs.

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