DEPARTM

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-102 and CMS-105]

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**).

CMS-102 and CMS-105	CLIA Budget Workload Reports and Supporting Regulations in 42 CFR 493.1-.2001

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 with change of a previously approved collection; *Title of Information Collection:* CLIA Budget Workload Reports and Supporting Regulations in 42 CFR 493.1-.2001; *Use*: The Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578 were enacted on October 31, 1988. Provisions of this law mandated by Congress require entities (with few exceptions) that test human specimens be subject to Federal regulation and have in effect a certificate issued by the Department of Health and Human Services. CLIA mandates that fees must be paid by each laboratory to obtain or renew a certificate and for the cost of compliance determination if applicable. The certificate issuance fees will be set by CMS at levels sufficient to recover the full costs of administering the operational provisions of CLIA, including approval and monitoring of proficiency testing programs and accrediting bodies and implementing Federal requirements. Fees will also be collected by CMS to cover the costs of inspecting non-accredited laboratories and validating accrediting laboratories based on the lab's volume and scope of testing. Currently, CMS contracts with 50 State agencies to conduct surveys of all participating health care facilities. As part of their contract, CMS reimburses the State agencies for the reasonable cost of conducting surveys. This information collection gathers the information necessary to reimburse State agencies for a reasonable cost. *Form Number*: CMS-102 and CMS-105 (OMB control number: 0938-0599); *Frequency:* Yearly/Quarterly; *Affected Public*: State, Local or Tribal Governments; *Number of Respondents:*50; *Total Annual Responses*: 50; *Total Annual Hours:* 34. (For policy questions regarding this collection contact Eric Powell at 312-886-0791).

Dated: November 22, 2023.

William N. Parham, III

Director,

Paperwork Reduction Staff,

Office of Strategic Operations and Regulatory Affairs.

4120-01-U-P

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