DEPARTM

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-102 and 105]

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 **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

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 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 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:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* CLIA Budget Workload Reports; *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, and semi-annually; *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.)

William N. Parham, III,

Director,

Division of Information Collections and Regulatory Impacts,

Office of Strategic Operations and Regulatory Affairs.

4120-01-U-P

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