

SUPPORTING STATEMENT
FOR
CLIA BUDGET WORKLOAD REPORTS
AND SUPPORTING REGULATIONS IN 42 CFR 493.1-.2001
(CMS-102 and CMS-105)

A. BACKGROUND

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. Final regulations with comments were published February 28, 1992 and became effective September 1, 1992. These regulations are based on the complexity of testing performed.

There are various categories of certificates being issued to laboratories. A laboratory which is inspected and certified by a CMS approved accreditation body will be eligible for a Certificate of Accreditation. Certificates of Waiver exempts from routine inspections and Federal standards those laboratories performing only simple laboratory examinations and procedures, which the Secretary has found through regulation to have an insignificant risk of an erroneous result or have no reasonable risk of harm to the patient if the test is performed incorrectly. Provider performed microscopy (PPM) certificates allow laboratories to perform PPM procedures and waived testing under the requirements and criteria listed in 42 CFR 493.19, and these PPM laboratories are also not subjected to routine inspections. Laboratories not issued either an accreditation certificate, PPM, or a waiver certificate, must apply for a Federal certificate of compliance. These laboratories will be inspected biennially by State survey agencies, or in the case of Federal and State laboratories, inspections will be performed by Federal surveyors.

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.

B. JUSTIFICATION

1. Need and Legal Basis

Legislative authority for this activity is found in Section 353 of the Public Health Service Act along with Section 1864 of the Social Security Act, as follows:

“Section 353(g) Inspections.--

(1) In General--The Secretary may, on an announced or unannounced basis, enter and inspect, during regular hours of operation, laboratories which have been issued a certificate under this section....”

(2) Compliance With Requirements and Standards.--The Secretary shall conduct inspections of laboratories under paragraph (1) to determine their compliance with the requirements of subsection (d) and the standards issued under subsection (f)”

“Section 1864(a)-(b).--

(a) The Secretary shall make an agreement with any State which is able and willing to do so under which the services of the State health agency or other appropriate State agency (or the appropriate local agencies) will be utilized by him/her for the purpose of determining ... whether a laboratory meets the requirements of paragraphs (14) and (15) of section 1861(s)....

(b) The Secretary shall pay any such State, in advance or by way of reimbursement, as may be provided in the agreement with (and may make adjustments in such payments of account of overpayments or underpayments previously made), for the reasonable cost of performing the functions specified in subsection (a)....”

2. Information Users

The information collected on these forms consists of source data used by CMS Headquarters and CMS Location Offices in determining the appropriate level of Federal reimbursement for surveys conducted in laboratories participating in the CLIA program, in developing annual operating budgets and apportionments for the CLIA program, in administering State awards from initial award through closeout, and in evaluating CLIA program performance.

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS PROGRAM BUDGET/EXPENDITURE REPORT – CMS-102

The CLIA 102 is a multi-purpose form designed to capture and record all budget and expenditure data.

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS PROGRAM PLANNED WORKLOAD REPORT – CMS-105

This form captures the annual projected CLIA workload that the State survey agency will accomplish. It is also used by the CMS Locations to approve the annual projected CLIA workload. The information is required as part of the 1864 agreement with the State.

3. Improved Information Technology

The CMS 102 and 105 reports are developed and submitted electronically via the SC-CLIA Budget System.

4. Duplication of Similar Information

These forms are not duplicative of other CMS forms currently used for the Medicare/Medicaid program. These forms collect information specific to the CLIA program, which is not collected on other CMS forms.

5. Small Businesses

These forms do not impact small businesses. They are used for State agencies only.

6. Less Frequent Collection

In order to comply with the law, this information cannot be submitted on a less frequent basis.

7. Special Circumstances

There are no special circumstances.

8. Federal Register Notice/Outside Consultation

The 60-day Federal Register notice published on November 28, 2023 (88 FR

83133). There were no public comments received.
The 30-day Federal Register notice published on February 23, 2024 (89 FR 13720). There were no public comments received.

9. Payment/Gift to Respondent

There is no payment or gift involved.

10. Confidentiality

We make no pledges of confidentiality.

11. Sensitive Questions

There are no questions of a sensitive nature on these forms.

12. Burden Estimate (Total Hours & Wages)

The burden estimates are based on the projected national average hourly cost of the CLIA program in FY 2023. CLIA is a self-supporting, user fee financed program. This rate is used because it is more specific to projected CLIA costs than general labor categories and associated rates, particularly where a variety of positions are used to prepare reports. The burden estimate is based on current uses of this and similar forms for the Medicare/Medicaid program.

There are 50 State Agencies that are required to provide the requested information. All information needed to complete the forms is easily accessible.

CLINICAL LABORATORY IMPROVEMENTS AMENDMENTS PROGRAM
BUDGET/EXPENDITURE REPORT – CMS-102

This is a multi purpose form prepared by the State agencies to request funds and report expenditures.

Annual Budget Request

(200 hours) 50 State Agencies x 4 hrs. x \$108.78 = \$1,756

(200 hours) 50 State Agencies x 4 hrs. x \$101.71 = \$21,756(Supplemental)

Quarterly Expenditure Report

(800 hours) 50 State Agencies x 4 qtrs. x 4 hrs. x \$108.78= \$87,024

Burden for CMS-102 = 1,200 hours

Total cost is \$130,536

CLINICAL LABORATORY IMPROVEMENTS AMENDMENTS PROGRAM PLANNED WORKLOAD REPORT – CMS-105

This form is prepared and signed by a State official and indicates either their planned workload or accomplished workload. This report must accompany every budget request and expenditure report. Workload estimates can be computer generated and modified as needed in approximately 2 hours.

(400 hours) 50 State Agencies x 4 qtrs. x 2 hrs. x \$108.78 = \$43,512
(100 hours) 50 State Agencies x 2 hrs. x \$108.78 = \$10,878 (Budget request)
Burden for CMS-105 = 500 hours

Total cost is \$54,390.

The total for both the CMS-102 and the CMS-105 is 1,700 hours.
The total cost for both forms is \$184,926.

13. Capital Costs (Maintenance of Capital Costs)

There are no capital costs associated with this collection.

14. Costs to Federal Government

Congress mandated that the CLIA program would be a self-supporting program. All costs associated with this collection of information will be absorbed by CLIA.

The State agencies have copies of the forms and because of the low number of reports to be submitted, make copies as needed.

Processing the information - for Federal estimate of costs we assume a GS-13/6 . employee will process these forms.

CLINICAL LABORATORY IMPROVEMENTS AMENDMENTS PROGRAM BUDGET/EXPENDITURE REPORT – CMS-102

This is a multi purpose form prepared by the State agencies to request funds and report expenditures. The CMS Location analyzes the request and forwards to CMS Headquarters for processing. The total time spent by both the Location and Headquarters offices is 4 hours for the budget request and 4 hours for the quarterly expenditure report.

Annual Budget Request

(200 hours) 50 State Agencies x 4 hrs. x \$62.83 = \$12,566

(200 hours) 50 State Agencies x 4 hrs. x \$62.83 = \$12,566

Quarterly Expenditure Report

(800 hours) 50 State Agencies x 4 qtrs. x 4 hrs. x \$62.83 = \$50,264

CLINICAL LABORATORY IMPROVEMENTS AMENDMENTS PROGRAM PLANNED WORKLOAD REPORT – CMS-105

This form is prepared and signed by a State official and indicates either their planned workload or accomplished workload. This report must accompany every budget request and expenditure report. The total time spent by the CMS Location and CMS Headquarters to review and analyze the workload report is approximately 2 hours per State per quarter.

(100 hours) 50 State Agencies x 2 hrs. x \$62.83 = \$6,283 (Budget request)

(200 hours) 50 State Agencies x 2 qtrs. x 2 hrs. x \$62.83 = \$12,566

TOTAL ANNUAL FEDERAL COSTS = \$94,245

15. Program/Burden Changes



The burden estimate has remained at 1,700 hours to account for the time it takes to prepare the requested reports; however, the hourly cost has increased due to inflation. The burden costs have increased from \$161,315, to \$184,926.

16. Publication and Tabulation Dates

There are no publication and tabulation dates.

17. Expiration Date

CMS will display the expiration date on the collection instruments.

18. Certification Statement

There are no exceptions to the certification statement.