SUPPORTING STATEMENT
FOR
CLIA BUDGET WORKLOAD REPORTS
AND SUPPORTING REGULATIONS IN 42 CFR 493.1-.2001

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 l, 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

B. JUSTIFICATION

1. Need and Legal Basis

Legislative authority for this activity is found in Section 353 of the Public Health Service Act. The subsection identifying the mandate for laboratories to be surveyed is found at Section 353(g).

"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. In conducting such inspections the Secretary shall have access to all facilities, equipment, materials, records, and information that the Secretary determines have a bearing on whether the laboratory is being operated in accordance with this section. . ."

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

Legislative authority for this activity is also found in Section 1864 of the Social Security Act. The subsection identifying the authority for State agencies to conduct surveys and be reimbursed by DHHS, CMS is found at 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 an agency therein is a hospital or skilled nursing facility, or whether an agency therein is a home health agency, or whether an agency is a hospice program or a home intravenous drug therapy provider, or whether a facility therein is a rural health clinic as defined in section 1861(aa)(2) or a comprehensive outpatient rehabilitation facility as defined in section 1861(cc)(2), or whether a laboratory meets the requirements of paragraphs (14) and (15) of section 1861(s), or whether a clinic, rehabilitation agency or public health agency meets the requirements of subparagraph (A) or (B), as the case may be, of section

1861(p) (4), or whether an ambulatory surgical center meets the standards specified under section 1832(a) (2) (F) (I).

(3). In the extent that the Secretary finds it appropriate, an institution or agency which such a State (or local) agency certifies is a hospital, skilled nursing facility, rural health clinic, comprehensive outpatient rehabilitation facility, home health agency, hospice program, or home intravenous drug therapy provider (as those terms as defined in section 1861) may be treated as such by the Secretary. . .

(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), and for the Federal Hospital Insurance Trust Fund's fair share of the cost attributable to the planning and other efforts directed toward coordination of activities in carrying out its agreement and other activities related to the provisions of services similar to those for which payment may be made under part A, or related to the facilities and personnel required for the provision of such services, or related to improving the quality of such services."

The information collected on these forms will assist CMS in determining the Federal reimbursement for surveys conducted in laboratories participating in the CLIA program.

2. Information Users

The information on these forms will be used by CMS in determining the amount of Federal reimbursement for surveys conducted. Use of the information includes program evaluation, audit, budget formulation and budget approval.

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 regional office to approve the annual projected CLIA workload. The information is required as part of the 1864 agreement with the State.

3. Improved Information Technology

Respondents are encouraged to take advantage of any technological resources available to them.

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

A 60-day Federal Register notice was published on July 27, 2007.

These forms have been used by the State agencies for the past several years and we have not experienced any adverse reactions or unfavorable comments from the States.

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 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
(2,000 hours) 50 State Agencies x 40 hrs. x $52.31 = $104,620
(400 hours) 50 State Agencies x 8 hrs. x $52.31 = $20,924 (Supplemental)
Quarterly Expenditure Report
(1,600 hours) 50 State Agencies x 4 qtrs. x 8 hrs. x $52.31 = $83,696
Burden for CMS-102 = 4,000 hours

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 $52.31 = $20,924
(100 hours) 50 State Agencies x 2 hrs. x $52.31 = $ 5,231 (Budget request)
Burden for CMS-105 = 500 hours
The total for both the CMS-102 and the CMS-105 is 4,500 hours.

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-12/5 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 regional office analyzes the request and forwards to central office for processing. The total time spent by both the regional office and central office is 20 hours for the budget request and 8 hours for the quarterly expenditure report.

Annual Budget Request
50 State Agencies x 20 hrs. x $25.74 = $25,740
50 State Agencies x 8 hrs. x $25.74 = $10,296

Quarterly Expenditure Report
50 State Agencies x 4 qtrs. x 8 hrs. x $25.74 = $41,184

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 Regional Office and Central Office to review and analyze the workload report is approximately 2 hours per State per quarter.

50 State Agencies x 2 hrs. x $25.74 = $2,574 (Budget request)
50 State Agencies x 4 qtrs. x 2 hrs. x $25.74 = $10,296

TOTAL ANNUAL FEDERAL COSTS = $90,090

15. Program/Burden Changes

There are no program or burden changes.

16. Publication and Tabulation Dates

There are no publication and tabulation dates.

17. Expiration Date

CMS is not requesting an exception to the expiration date.

18. Certification Statement

There are no exceptions to the certification statement.