Supporting Statement for the Form CMS-1557
and Supporting Regulations in
42 CFR 493.1 - 493.2001
OMB 0938-0544

Background

The Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, was enacted on October 31, 1988. CLIA established a new section 353 of the Public Health Service Act to replace the existing section 353. Section 353 requires the Department of Health and Human Services (HHS) to establish certification requirements for any laboratory that performs tests on human specimens, and to certify through the issuance of a certificate that those laboratories meet the requirements established by HHS. Also, the legislation contains certificate requirements and specifies circumstances that permit certificates of waiver to be issued. The law also includes requirements for inspections, sanctions, judicial review, fees and disclosure of information to the public.

Section 6141 of the Omnibus Budget Reconciliation Act of 1989 (OBRA '89), Public Law 101-239, requires that laboratories participating in the Medicare program comply with CLIA requirements. Subject to specified exceptions, laboratories must have a current unrevoked and unsuspended certificate to operate and to be eligible for reimbursement in the Medicare or Medicaid programs or both.

Final CLIA regulations (with comment) were published in the *Federal Register* on February 28, 1992. Compliance surveys of laboratories began September of 1992. The law provides for inspections on an announced or unannounced basis during regular hours of operation. In conducting such inspections, all records and information having a bearing on whether the laboratory is being operated in accordance with the law can be requested by the surveyor. These inspections are conducted on a biennial basis.

A. Justification

1. Need and Legal Basis

The information collected on this survey form is used in the administrative pursuit of the Congressionally-mandated program with regard to regulation of laboratories participating in CLIA.

Legislative regulatory authority for this activity is Public Law 100-578.

To determine compliance, the Secretary has authorized States [in Section 1864(a) of the Social Security Act] through contracts to conduct surveys of laboratories under CLIA. In order for the State survey agency to report to the Centers for Medicare & Medicaid Services (CMS) its findings on facility compliance with the individual standards on which CMS determines compliance, the surveyor completes the Survey Report Form (CLIA) (CMS-1557). The Survey Worksheet provides space to document the surveyor's

notes.

To facilitate validation of information submitted by the laboratory to CMS, the CMS-1557 follows the format of the CLIA application (CMS-116, OMB Number: 0938-0581) where possible. This form will require an estimated range from 5 minutes to 60 minutes to complete. This is based on information available in the Regulatory Impact Analysis of HSQ-176-FC. There are approximately 20,486 laboratories in the CLIA data base that require a State survey for CLIA compliance. An average time of 30 minutes for form completion was calculated.

Portions of the form will be filled out prior to the onsite survey (e.g., general information, survey status, State license number, State/county/State region code, Medicare provider number, personnel, specialties/subspecialties, accredited program, annual test volume) and verified onsite. As necessary, the surveyor will enter the addition or deletion of specialty/subspecialty testing and the appropriate effective date. The surveyor can record pertinent proficiency testing information (i.e., program, score, unsuccessful participation for an analyte, etc.) in the column provided.

2. Information Users

CMS Form-1557 is used to report surveyor findings during a CLIA survey. For each type of survey conducted (i.e., initial certification, recertification, validation, complaint, addition/deletion of specialty/subspecialty, transfusion fatality investigation, or revisit inspections), the Survey Report Form (CLIA) incorporates requirements as specified by the CLIA regulations.

3. Use of Information Technology

The form is available electronically on the CMS Internet at http://www.cms.hhs.gov/forms/. This collection is not currently available for completion electronically. This collection requires a signature from the laboratory surveyor. If CMS had the capability of accepting electronic signature(s), this collection would still not be made electronically available.

4. Duplication of Efforts

Information (general, specialty/subspecialty, accredited program, and annual test volume) collected on the application is validated by the inspection process. The number of people qualified under each applicable regulatory section, addition/deletion of specialty/subspecialty and effective dates, and proficiency testing data is not collected on any other CLIA survey report form.

5. Small Business

These requirements do not significantly affect small businesses. The form was designed to collect information only necessary to establish compliance with CLIA.

6. Less Frequent Collection

Under CLIA, laboratories are required to be surveyed once every 2 years. If this information would be collected less frequently, the CLIA survey findings would be negatively impacted.

7. Special Circumstances for Information Collection

These requirements comply with all general information collection guidelines in 5 CFR 1320.6. There are no special circumstances associated with this collection.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published on February 7, 2012 (77 FR 6124). The publication of this notice was used to solicit outside consultation. No other outside consultation was sought. No comments were received.

9. Payments or Gifts to Respondents

There are no payments or gifts to respondents associated with this collection.

10. Confidentiality

We do not pledge confidentiality.

11. Sensitive Questions

There are no questions of a sensitive nature associated with these forms.

12. Burden Estimates

This form contains information necessary for the surveyor to determine compliance with CLIA. We anticipate the time requirement for completion of this form to range between 5 and 60 minutes. The average length of time to report this information is 30 minutes. Since CLIA surveys are biennial (i.e., a CLIA survey occurs once every two years), the annual frequency is 0.5 times a year per laboratory respondent. Based on the number of laboratory respondents as 20,486, the following computations are appropriate.

Private Sector
19,111 (laboratories) (biennial review)/2 = 9,555.5 laboratories per year
X 0.50 hours per response = 4,777.75 annual burden hours

State, Local or Tribal Government
1,290 (laboratories) (biennial review)/2 = 645 laboratories per year
X 0.50 hours per response = 322.50 annual burden hours

Federal Government
85 (laboratories) (biennial review)/2 = 42.5 laboratories per year
X 0.50 hours per response = 21.25 annual burden hours

Total
20,486 (laboratories) (biennial review)/2 = 10,243 laboratories per year
X 0.50 hours per response = 5,121.50 annual burden hours

13. Capital Costs

There is no capital cost associated with this collection.

14. Cost to Federal Government

We estimate these information collection requirements (ICR) will cost $13.75 (0.5 hrs x $27.50 per hour) for each form collected.

Private Sector
4,777.75 annual burden hours X $13.75 = $65,694.06

State, Local or Tribal Government
322.50 annual burden hours X $13.75 = $4,434.38

Federal Government
21.25 annual burden hours X $13.75 = $292.19

Total
5,121.50 annual burden hours X $13.75 = $70,420.63

The cost estimate for the forms themselves is approximately $800 and is based on printing 20,000 forms.

15. Changes in Burden/Program Changes

Changes in burden are the result of a decrease in the numbers of respondents in the CLIA program (i.e., 514 less laboratory facilities have a CLIA certificate of compliance). There are no program changes.

Also, the 2009 Supporting Statement set out three respondent types but only one ICR specific to Private Sector respondents. This package corrects the 2009 package by setting out the three respondent types as three distinct ICRs: (1) Private Sector respondents, (2) Federal respondents, and (3) State, Local, or Tribal Government respondents.

16. Publication and Tabulation Dates

There are no publication and tabulation dates associated with this collection.

17. Expiration Date

CMS would like an exemption from displaying the expiration date as these forms are used on a continuing basis. To include an expiration date would result in having to discard a potentially large number of forms.

18. Certification Statement

There are no exceptions to the certification statement.

B. Collections of Information Employing Statistical Methods

There are no statistical methods employed in this information collection.