Supporting Statement for the Laboratory Personnel Report (CLIA)
(CMS-209) and Supporting Regulations in
42 CFR 493.1357, 493.1363, 493.1405, 493.1406, 493.1411, 493.1417, 493.1423, 493.1443, 493.1449, 493.1455, 493.1461, 493.1462, 493.1469, 493.1483, 493.1489 and 493.1491
CMS-209, OMB 0938-0151

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 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 approval of accreditation bodies and State licensure bodies, 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 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 will be 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 CMS its findings on facility compliance with the individual standards on which CMS determines compliance, the laboratory completes the Laboratory Personnel Report (CLIA) (CMS-209) form.

The CMS-209 requires an estimated range from 5 minutes to 45 minutes to complete. This is based on information available in the Regulatory Impact Analysis of HSQ-176-FC. There are approximately 21,000 laboratories in the CLIA database that require a State survey for determining CLIA compliance. An average time of 30 minutes for form completion was calculated. Without this form, the surveyor would need access to each individual personnel file and would then need to possibly examine the entire file to obtain qualifying data. Often personnel files may be in a locked area and may not be available to the surveyor in a timely manner resulting in deficiencies and possibly reinspections for laboratories, thus increasing the cost of the survey process. In cases of multiple site laboratories, this process could become even more time consuming as the personnel files may not be at the site being surveyed.

The surveyor will provide the laboratory with the CMS-209 form. While the surveyor performs other aspects of the survey, the laboratory will complete the CMS-209 by recording the personnel data needed to support their compliance with the personnel requirements of CLIA. The surveyor will then use this information in choosing a sample of personnel to verify compliance with the personnel requirements. Information on personnel qualifications of all technical personnel is needed to ensure the sample is representative of the entire laboratory.

2. Information Users

The CMS-209 form is used to report the names and positions of personnel serving as director, technical consultant, clinical consultant, technical supervisor, general supervisor, cytology general supervisor, cytotechnologist, and testing personnel in the laboratory. Information as to shift worked, qualifications for moderate or high complexity testing as well as full or part time employment is also collected. Personnel information is not required for non-technical staff (i.e., clerical, billing phlebotomists, etc.) This information is used to assess whether the laboratory personnel are qualified for the testing performed.

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 current laboratory director. If CMS had the capability of accepting electronic signature(s), this collection would still not be made electronically available.

4. Duplication of Efforts

Some personnel information is collected on the application; however, additional information is needed to determine compliance with the personnel requirements. The application requires the qualifications of personnel by the number in each portion. The Laboratory Personnel Report Form identifies each individual by name to permit the

surveyor to verify qualification information.

The Laboratory Personnel Report Form (CMS-209) for which clearance is requested is the only source of the information requested. Having this information available to the surveyor at the time of survey will greatly expedite the inspection process.

5. Small Business

These requirements do not significantly affect small businesses. The form was designed to collect only the information 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

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

A 60-day Federal Register notice for an extension of this currently OMB approved collection published on November 29, 2011 (76 FR 73648), 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 Estimate (Hours and Wages)

This form contains the information necessary for laboratories to demonstrate their compliance with the CLIA personnel qualification regulations. We anticipate the time requirement for completion of this form to range between 5 and 45 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 = $65,690.63

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 $2,950 and is based on printing 20,000 forms.

15. Changes to Burden

There are no program-related changes. Based on agency estimates, the total number of respondents, annual responses, and annual burden hours have been adjusted (decreased). The annual cost to the Federal Government has also been adjusted to account for an increased cost for printing form CMS-209.

16. Publication/Tabulation Dates

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

17. Expiration Date

CMS prefers not to display the expiration date. As can be seen from item 14, we print a considerable number of these forms and use them on continuing basis; to have to toss a goodly number because of the expiration date would be wasteful.

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.