

**Supporting Statement for the Laboratory Personnel Report (CLIA)
(CMS-209) and Supporting Regulations in
42 CFR 493.1 – 403.201**

A. 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 CLIA 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 are conducted on a biennial basis.

For this submission, we are making minor revisions to the collection instrument.

B. 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 19,183 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 inspection 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 CLIA inspection, 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 uses the information submitted on the CMS-209 to verify compliance with the CLIA personnel requirements.

2. Information Users

The CMS-209 form is used by the laboratory 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 on the qualifications for moderate or high complexity testing 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 available for completion electronically. Currently, most surveyors only require a signature from the current laboratory director for this collection.

4. Duplication of Efforts

There is no duplication of this information on another information collection.

5. Small Business

These requirements do not significantly affect small businesses. To reduce impact to small businesses, the form was designed to only collect the information necessary to establish compliance with the CLIA regulations.

6. Less Frequent Collection

Under CLIA, laboratories are required to be surveyed once every 2 years. This collection is essential for the CLIA survey process and cannot be collected less frequently.

7. Special Circumstances

There are no special circumstances associated with this collection.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published on

The 30-day Federal Register notice published on

No other outside consultation was sought.

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 inspections 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 19,183 the following computations are appropriate.

Private Sector

17,809 (laboratories) (biennial review)/2 = 8,904.5 laboratories per year
X 0.50 hours per response = 4,452 annual burden hours

State, Local or Tribal Government

1,297 (laboratories) (biennial review)/2 = 649 laboratories per year

X 0.50 hours per response = 325 annual burden hours

Federal Government

77 (laboratories) (biennial review)/2 = 38.5 laboratories per year

X 0.50 hours per response = 19 annual burden hours

Total

19,183 (laboratories) (biennial review)/2 = 9,591.5 laboratories per year

X 0.50 hours per response = 4,796 annual burden hours

We estimate these information collection requirements (ICR) will cost \$14.50 (0.5 hrs x \$29.00 per hour) for each form collected.

Private Sector

4,452 annual burden hours X \$14.50 = \$64,554.00

State, Local or Tribal Government

325 annual burden hours X \$14.50 = \$4,712.50

Federal Government

19 annual burden hours X \$14.50 = \$275.50

Total

4796 annual burden hours X \$14.50 = \$69,542.00

We projected the hourly wage of laboratory staff completing the CMS-209 form to be \$29.00. Based on the type of information requested on the form, we assumed that a mid-level clerical/technical staffer would be completing the form with final sign-off and approval from the laboratory director. According to the U.S. Department of Labor – Wage and Hour Division (<https://www.dol.gov/whd/minimumwage.htm>), the minimum hourly wage for U.S. workers in 2017 is \$7.25. Assuming some technical knowledge of laboratory practices, we believe that the hourly wage of a laboratory staffer completing this form would be double the minimum hourly wage for U.S. workers and would include a 100% fringe.

13. Capital Costs

There is no capital cost associated with this collection.

14. Cost to Federal Government

The following are estimated annual Federal costs for this information collection.

Printing and distribution	\$ 3,000
Review and data entry	+ <u>63,444.56*</u>

\$66,44.56

*Based on .25 hr. x 8,904.5 laboratories x \$28.50/hr = \$63,444.56

We estimated that the Federal costs involved in collecting the CMS-116 information for administering the CLIA program would be based on an employee earning an average of \$28.50 per hour. The tasks involved range from printing and distributing the form, and then reviewing and entering the data into the CLIA data system. We estimate that these tasks would be completed by a Federal employee at the GS-11 grade level. According to the 2017 GS Salary Table, as shown on opm.gov's web site (https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/17Tables/html/GS_h.aspx), the salary for a GS-11 employee ranges from \$25.07 through \$32.59 and we selected the mid-range hourly wage of \$28.50.

15. Changes to Burden

The changes in burden are the result of an increase in the numbers of respondents in the CLIA program (i.e. 132 additional laboratory facilities that have a CLIA certificate of compliance). There are no program changes. The respondents increased from 19,051 to 19,183. The burden hours increased from 4,763 to 4796.

16. Publication/Tabulation Dates

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

17. Expiration Date

CMS will display the expiration date on the collection instrument.

18. Certification Statement

There are no exceptions to the certification statement.