

**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 inspections 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 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 inspection 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. There are approximately 17,500 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 re-inspection of a laboratory, 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 inspected.

The surveyor will provide the laboratory with the CMS-209 form prior to or during the CLIA inspection. The laboratory completes the CMS-209 by recording the personnel data needed to support their compliance with the personnel requirements of CLIA. The CLIA 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.). CLIA surveyors use the information collected on the CMS-209 to verify compliance with the CLIA personnel requirements and to help to complete the personnel section of the CMS-1557 [SURVEY REPORT FORM (CLIA) OMB Ctrl No. 0938-0544].

3. Improved Information Technology

The signature of the owner/director is required on this form. Since the laboratory director of a laboratory often changes, the current laboratory director's signature is needed to attest to the accuracy of their laboratory's compliance with the CLIA personnel requirements. Currently, the CMS-209 form is available on the Internet at <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS209.pdf> and is in a 'fillable' format so that the applicant can more easily download and complete the form.

4. Duplication of Similar Information

This form does not duplicate any information currently collected. It contains information essential to the operation of the CLIA program.

5. Small Businesses

This application form does not significantly affect small businesses. We believe that the number of small business entities is similar to the number of low volume A CLIA certificate of compliance facilities. As of December 2020, there are 6,012 low volume A CLIA certificate of compliance facilities. 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 inspected once every 2 years. This collection is essential for the CLIA inspection 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 April 2, 2021 (86 FR17392). There were no public comments received.

The 30-day Federal Register notice published on June 17, 2021 (87 FR 32270).

No other outside consultation was sought.

9. Payment/Gift to Respondents

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

10. Confidentiality

We make no pledges of confidentiality.

11. Sensitive Questions

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

12. Burden Estimate (Total 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 inspection 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 19,163 the following computations are appropriate.

Hourly Burden computation

19,163 (laboratories) (biennial review)/2 = 9,581.5 laboratories per year X 0.50 hours per response = 4,791 annual burden hours

Wage Burden computation for laboratory

We projected the hourly wage of laboratory staff completing the CMS-209 form to be \$52.68. Based on the type of information requested on the form, we assumed that a mid-level Clinical Laboratory Technologists/Technicians would be completing the form with the final sign-off and approval from the laboratory director. According to the U.S. Bureau of Labor Statistics the mean hourly wage for U.S. Clinical Laboratory Technologists and Technicians in May 2019 (<https://www.bls.gov/oes/current/oes292010.htm>), was \$26.34. We believe the mean hourly wage of a laboratory technologist or technician would be appropriate and would include a 100% fringe.

The cost would be \$252,390 (4,791 annual hours X \$52.68).

13. Capital Costs (Maintenance of Capital Costs)

There is no capital cost associated with this collection.

14. Cost to Federal Government

There is no cost estimate to the Federal Government.

15. Program or Burden Changes

There was a decrease in the responses from 9,593 to 9,582. The burden hours decreased slightly from 4,796 to 4,791. The changes in burden are the result of an increase in the hourly wage of laboratory staff completing the CMS-209 form to \$52.68 from \$35.92. There are no program changes. The wage burden increased from \$86,136.16 to \$252,390.

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.