Supporting Statement
Clinical Laboratory Improvement Amendments (CLIA) Application Form (CMS -116)
and Supporting Regulations

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. This section requires the Department of Health and Human Services (HHS) to establish certification requirements for any entity that performs testing on human beings for health assessment to meet certain requirements (i.e., quality control) based on test complexity in order to be certified by HHS. Regulations implementing CLIA are found at 42 CFR Part 493.

If a laboratory conducts relatively simple tests that are categorized as waived or as provider performed microscopy test procedures (PPM), it must obtain a certificate of waiver or certificate of PPM. If the laboratory conducts any tests outside these two categories, it must apply for a certificate of compliance or certificate of accreditation and initially obtain a registration certificate. Upon payment of the appropriate fees (which is dependent on testing specialties and annual testing volume) laboratories are issued the applicable certificate. Certificates are valid for a period of up to two years.

Laboratories requesting a certificate of waiver or certificate of PPM are not subject to biennial surveys to determine compliance with CLIA requirements. Laboratories requesting a certificate of compliance or certificate of accreditation are initially issued a registration certificate. The registration certificate permits a facility to perform testing until compliance with CLIA requirements is determined through an inspection or proof of accreditation by an approved accreditation organization is received. The certificate of compliance or certificate of accreditation is issued (or reissued) subsequent to determination of compliance with the CLIA requirements or verification of accreditation by an approved accreditation organization and receipt of payment for the certificate.

The information that the laboratory submits to enroll in the CLIA program is the CMS Laboratory Application form, CMS-116. In this revision (2017), the majority of changes were minor changes to the form and accompanying instructions to facilitate the completion and data entry of the form. However, we added the collection of identifying the non-waived testing to be performed to section VIII of the CMS-116 form. We anticipate that the change to section VIII will take an average of 15 additional minutes to complete. Additionally, the CMS-116 form will continue to be available on the CMS Website and be ‘fillable’, enabling a laboratory to complete the form accurately and submit to State agencies timely.

B. Justification

1. Need and Legal Basis

Legislative authority for this activity is found in Section 353 of the Public Health Service Act. Section 353 (b) specifies that the laboratory must submit an application in such form and manner as the Secretary shall prescribe that describes the characteristics of the laboratory and examinations and procedures performed by the laboratory.

Information requested on these forms is essential for administering the CLIA program, including responding to inquiries regarding certification status and information regarding the size and scope of laboratory operations across the country. Obtaining certain information (e.g., location of multiple sites, hours of laboratory operation) on the application form also allows for the use of fewer resources and a more efficient method of preparing, scheduling and conducting surveys to assess compliance.

2. Information Users

The information collected is used by CMS to identify entities performing laboratory testing, to assess fees and to issue the appropriate certificate so that the entities comply with CLIA. The hours of operation and the type of laboratory are needed to help schedule the biennial inspection for certificate of compliance laboratories and for conducting compliant inspections for all CLIA certified laboratories. This information is also forwarded to the database used by carriers, intermediaries and the Medicaid program to ensure appropriate Medicare/Medicaid reimbursement.

3. Improved Information Technology

Since the signature of the owner/director is required on this form, this information collection does not lend itself to electronic transmission. However, the CMS-116 form is available on the Internet at https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS116.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. It is the only standardized mechanism available to record data on entities applying for CLIA certification.

5. Small Businesses

This application form does impact small businesses that operate as laboratories regulated under CLIA. The forms have been designed to collect only that information considered essential to operate the CLIA program. In order to minimize the burden on the laboratory, particularly those in physician offices, we only require completion of the CMS-116 upon initial entry to the program and when significant changes occur in the laboratory operation (for example changing the type of certificate).

6. Less Frequent Collection

If this information is not collected, there would be no mechanism for identifying what entities must comply with CLIA requirements or for determining the applicable fee(s) to be assessed. This information is collected when a laboratory initially applies for a CLIA certificate, when a laboratory reports the changes required by the CLIA regulations (e.g., ownership, name, location, director) and during each biennial inspection of CLIA certificate of compliance laboratories.

7. Special Circumstances

There are no special circumstances associated with this information collection.

8. Federal Register Notice/Outside Consultation

The 60-day Federal Register notice was published on June 22, 2017 (82 FR 28488). There were no public comments received.

The 30-day Federal Register notice published on August 25, 2017 (82 FR 40584). There were no public comments received.

9. Payment/Gift To Respondent

There are not payments or gifts 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 this form.

12. Burden Estimate (Total Hours & Wages)

The information contained on the CMS-116 is basic information concerning the operation of the laboratory that is needed to assess the appropriate user fee, issue the appropriate certificate and if applicable conduct the survey. We anticipate it will take an average of 60 minutes (one hour) to complete the form, depending on the size of the laboratory and the type of certificate requested.

During each year, about 16,000 laboratories register in the CLIA program for the first time and there are currently a total of 257,000 laboratories registered in the CLIA program. The number of laboratories registering each year was based on the average number of new laboratories registered in the last few years. Since CLIA (42 CFR 493.43) states that a laboratory must notify CMS when there are any changes to a lab's CLIA certificate, the usual means of notification is the completion of a CMS-116. We estimate 25,350 laboratories submit status changes and laboratory director personnel changes (annually).
There are 19,300 laboratories subject to biennial compliance surveys (9,650 annually).

16,000 new registrants + 25,350 laboratories reporting changes + 9,650 compliance surveys = 51,000 laboratories utilizing the CMS-116 each year

Hourly Burden computation
1 hour (average time) x 51,000 laboratories= 51,000 hours (annual)

Wage Burden computation for laboratory
1 hour (average time) x $29.00 (hourly wage of laboratory staff completing form) = $29.00

$29.00 x 51,000 laboratories = $1,479,000(annual)

We projected the hourly wage of laboratory staff completing the CMS-116 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 (Maintenance of Capital Costs)

There are no capital costs associated with this information collection.

14. Cost to Federal Government

Congress provided the Secretary with the authority to establish a user fee system in order that the cost of administering the CLIA program be borne by the laboratories, thus making the CLIA Program self-supporting.

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

Printing and distribution	$ 5,000
Review and data entry	+ $479,655*
	$484,655

*****Based on .**33** hr. x **51,000** laboratories x $**28.50**/hr = **$479,655**

*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. Program or Burden Changes

There are minor revisions to the form that serve to shorten forms completion for the laboratory community and to enhance the data reporting of laboratory demographics and trends. To be consistent with information currently collected for waived testing in Section VI and PPM testing in Section VII, we added the collection of identifying the non-waived testing to be performed to section VIII of the CMS-116 form. We anticipate that the change to section VIII will take an average of 15 additional minutes to complete. The burden increase is due to an increase in the number of new laboratories participating in the CLIA program (from 15,000 to 16,000), an increase in the number of laboratories reporting changes (from 9,700 to 25,350), an increase in the number of laboratories subject to biennial compliance surveys (from 9,500 to 9,650) and to the addition of 15 extra minutes for completing the form. The number of laboratories using the form has increased from 34,200 to 51,000. The burden hours have increased from 25,650 to 51,000.

16. Publication and Tabulation Dates

The information collected is used to produce summary reports on CLIA certification activity by certificate type (number of waived laboratories, number of PPM laboratories, etc.). These reports are presented at meetings and are also

available via the Internet. Specific information for listings of laboratories by name address and facility type (hospital based, physician office, skilled nursing facility, etc.) may also be provided to the public (at cost) upon written request.

17. Expiration Date

CMS will display the expiration date.