2007 Supporting Statement for the Clinical Laboratory Improvement Amendments
(CLIA) Application Form (CMS -116) and Supporting Regulations Contained in
42 CFR 493.1-.2001

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 (PPMP), it must obtain a certificate of waiver or certificate of PPMP. If the laboratory conducts any tests outside of 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 PPMP 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 (2007), a number of changes were made to the form and accompanying instructions to facilitate the completion and data entry of the form. Specifically, the enumeration of individuals involved in laboratory testing was eliminated, and the reporting of hours of laboratory operations was streamlined. Some fields were expanded to reflect changes in laboratory demographics (added prison and assisted living facility to location of laboratory testing) and to collect complete information on the number of tests performed in laboratories (added PPMP test totals). Also, the CMS-116 form will 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. 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

This information collection does not lend itself to electronic

transmission. However, the CMS-116 form is available on the Internet at www.cms.hhs.gov/cclia 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.

7. Special Circumstances

There are no special circumstances associated with this information collection.

8. Federal Register Notice/Outside Consultation

A 60-day Federal Register notice was published on June 8, 2007, attached. No comments were received.

There has been no further, outside consultation.

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 continue to take between thirty minutes to two hours to complete depending on the size of the laboratory and type of certificate requested.

During the year, about 3,000 new labs register in the CLIA program for the first time. Currently, there are about 187,000 labs in the program. Since CLIA (493.43) states that a lab must notify CMS when there are any changes to the labs CLIA certificate, the usual means of notification is the completion of a CMS-116. We estimate 8% of labs notify us of these changes each year.

Hourly Burden computation:

1.25 hrs (average time) x 17,960 laboratories = 22,450 hours

Calculation is as follows: (187,000 total laboratories x .08% = 14,900 labs + 3,000 new labs = 17,960 labs x 1.25 hours = 22,450 hours)

TOTAL HOURLY BURDEN 22,450 hours

Wage Burden computation for laboratory:

1.25 (average time) x $14.50 (hourly wage of lab staff completing form) = $18.13

$18.13 x 17,960 = $325,614.80

TOTAL WAGE BURDEN $325,614.80

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	$233,480*
	$238,480

*Based on .50 hr. x 17,960 laboratories x $26/hr

15. Program or Burden Changes

There are no program changes, however, the minor revisions to the form serve to shorten forms completion for the laboratory community and to enhance the data reporting of laboratory demographics and trends. The slight burden increase is due to new labs participating in the CLIA program.

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 PPMP 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

We do not seek approval for non-display of the expiration date for the OMB approval of the information collection.

18. Certification Statement

There are no exceptions to the certification statement.

C. Collection of Information Employing Statistical Methods

There are no statistical methods employed in this information collection.