How to Apply for a CLIA Certificate of Waiver

Clinical Laboratory Improvement Amendments (CLIA) Background

Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988 establishing quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. A laboratory is defined as any facility which performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, treatment of disease, or impairment of, or assessment of health. The Centers for Medicare and Medicaid Services (CMS) is charged with the implementation of CLIA, including laboratory registration, fee collection, surveys, surveyor guidelines and training, enforcement, approvals of PT providers, accrediting organizations and exempt states. The FDA is responsible for test categorization.
Section 1 - General Information

> This person should be identified as the principle party responsible for overseeing testing programs, ensuring that facility personnel administering testing are fully trained, and documentation is maintained to the meet CLIA standards. States deemed as “State Licensure” or “Exempt” may require additional accreditation within their individual states to qualify (e.g. medical director with licensed medical degree, etc.). Refer to state listing for the states that may apply.

> Name of Director

The following are the types of CLIA Certificates that may be obtained. All types of certificates permit testing with approved CLIA waived tests.

- **Certificate of Registration (COW):** Issued to lab to conduct nonwaived (moderate and/or high complexity) testing until lab is determined to be in compliance with CLIA regulations.

- **Certificate of Accreditation (COA):** Issued to lab that performs nonwaived (moderate and/or high complexity) testing, and is based on an accreditation by organization approved by CMS (Centers for Medicare/Medicaid Services).

- **Certificate of Compliance (COC):** Issued to lab that performs nonwaived (moderate and/or high complexity) testing once the State Dept. of Health determines lab is compliant with CLIA requirements.

Section 2 - Type of Certificate

> Check box indicated.

The following are the types of CLIA Certificates that may be obtained. All types of certificates permit testing with approved CLIA waived tests.

- Certificate of Waiver (COW): Issued to lab that performs only waived tests.

- Certificate for Provider Performed Microscopy (PPM) procedures: Issued to lab in which physician, midlevel practitioner or dentist performs specific microscopy procedures categorized as moderate complexity.

- Certificate of Registration: Issued to lab to conduct nonwaived (moderate and/or high complexity) testing until lab is determined to be in compliance with CLIA regulations.
Section 3 - Type of Laboratory

Facility Identification

> This should be checked off from the description that best describes the type of facility and services provided.

Section 4 - Hours of Laboratory Testing

Hours of Operation

> Indicate when testing services will be available at the test site. This may or may not mirror site location’s operating hours.

Section 5 - Multiple Sites

Multiple Locations

> Most applications will respond “NO” to this question. Check off as indicated if applicable and immediately go to Section 6.

For applications that have multiple location sites, contact your local CMS office to ensure that the regulatory exceptions for this provision are met prior to completing this form. Additionally, Section 5 will require that each location’s testing hours are identified.
Section 6 - Waived Testing

**Annual Test Volume**

> This number represents the total estimate number of tests that will be performed at the testing facility annually. Under CLIA Application of Waiver submission, the fee charged for a two-year certificate is $150.00, regardless of the volume of CLIA waived tests conducted within a facility. Whereas, CLIA Certificates for Moderate Complexity and High Complexity are fee rendered by this number indicated as well as the type of testing performed as identified under Section 7.

**Skip Section 7 & 8**

**IF YOU ARE ONLY CONDUCTING WAIVED TESTING**

Section 9 - Type of Control

**Facility Overseer**

> Indicate which code closely identifies with your organization. This would be understood by how you are identified currently with the IRS for tax filing purposes.

Section 10 - Director Affiliation with Other Laboratories

**Other Affiliations**

> Many identified Directors may have affiliations with other facilities and/or programs within each state. This section must be completed if the Director identified for this application has been registered to other site locations and/or organizations.
Section 10 - Director Affiliation with Other Laboratories

**Contractual Obligation**

The Laboratory Director must sign and complete the application. By signing this application, the Director agrees to permit the Secretary, or any Federal officer or employee designated by the Secretary, to inspect the laboratory, operations and all records at any reasonable time to determine applicants eligibility or continued eligibility for a CLIA certificate and continued compliance with CLIA requirements are met.

**Mail**

Completed Application

Once the application is completed, it should be mailed directly to the local CMS office in your state. No check or money order should be sent at this time. The application is then entered into a national database. Within the next two (2) weeks, a bill with a detachable coupon will be mailed to the attention of the Director. Fees for a Certificate of Waiver for two years will be $150.00. Detach the coupon and send along with payment to the address provided. Be sure to reference the assigned CLIA certificate number on your check should the coupon be lost or separated from payment.
CLIA Certificate of Waiver

> Processing for a new certificate may take up to two months, however calling your local office may or may not yield information on the progress of your application. Your CLIA certificate number is established on your original invoice. Only once your payment is credited may you begin testing within your facility. The CLIA certificate will arrive approximately two (2) weeks following credited payment.

Renewal

> Anticipate ten months prior to renewal date of your CLIA Certificate, a coupon voucher to arrive

For additional information, contact your local CMS office.

State Survey Agencies (CLIA Contact List)
CLIA Important Information

State Exemption

> Any laboratory located in a state that has a CMS approved laboratory program is exempt from CLIA certification. Currently, there are two states with approved programs: Washington and New York. New York has a partial exemption; therefore, if your laboratory is located in that state, contact the New York State Agency concerning your need for a CLIA certificate.

Additions or Changes to Issued Certificates

> During the two-year certificate period, information supplied on the original certificate application may change (e.g., lab director, add-on site location, etc). It is important that this information be communicated in a prompt manner to the local State Reporting office. The local states maintain the database for each issued certificate within the state. For questions concerning changes to the current certificate status, it is best to contact your local CMS office for clarification. Most often a simple letter is all that is required. This will be kept on file at the state office. A new certificate will not be issued reflecting these changes. Only upon renewal application will the changed information be indicated.

Facility Inspections

> The local state offices of CMS inspect facilities from time to time to monitor and ensure that each is operating under the CLIA guidelines. While these inspections are not punitive in nature, inspectors will check to see that Manufacturers' Guidelines are followed within each facility. Additionally, reported complaints in the field will prompt a mandatory inspection of any facility. A report will be written for both random and mandated inspections that will advise any inconsistencies and recommendations to bring a facility up to compliance. Timelines for compliance adherence will be established. What can this mean potentially to a CLIA waived testing site? If a second follow-up inspection reveals that conformance has not been established, the local CMS office can cease CLIA testing operations for a given time to that facility or site until conformance has been satisfactorily met. Similarly, if additional complaints are filed against the facility, CLIA certification can be permanently revoked and punitive action can take place dependent on the nature of the complaint.