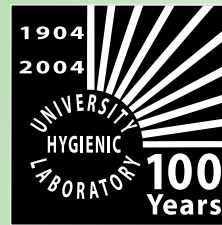


CLIA Corner

The University of Iowa Hygienic Laboratory

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CLIA Certification and Billing Process

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- *Billing and renewal process for each type of certificate.*

Initial Application Process for All CLIA Certificate Types

The first step in applying for a CLIA certificate is completing the Centers for Medicare and Medicaid Services (CMS) -116 application form. This form can be downloaded from the CMS website located at: www.cms.hhs.gov/clia. Select the link "How to Apply for a CLIA Certificate, Including International Laboratories." From this page, scroll to **Related Links Inside CMS** and click on "CMS-116 Form and Instructions" to access a printable version. When applying for a new certificate, allow six to eight weeks for the entire application process.

Follow the instructions to complete the form and provide ALL the information for the specific type of certificate you are requesting. The application must include your facility's federal tax identification number (EIN), phone number, mailing address (if applicable), and name and qualifying credentials (if applicable) of the designated laboratory director. **Important:** The individual listed as the laboratory director MUST sign and date page 4 of the CMS-116 form. If the application is missing any of the above information, it will not be processed.

The completed application is to be mailed to the state agency for the state where the laboratory is located. For the list of state agency addresses, go to the CMS website, click on link for "State Agencies and Regional Office Contacts."

The state agency enters the application information into the CMS database within 15 days of receipt. Once entered, the system automatically prints the appropriate user-fee coupon and mails it to the facility's mailing address. The laboratory must then remit payment. Payments must be sent to the address provided on the back of the fee coupon and NOT to the state agency.

After payment has been posted to the facility's account, the system automatically prints the appropriate certificate. The user-fee coupons and certificates are printed and mailed once per week from the CMS Central Office in Baltimore. Allow a minimum of two to three weeks for receipt of user-fee coupons or certificates from the printing date. NOTE: When submitting your application, do NOT send payment for the certificate and fees. The user-fee coupons (bills) are generated every two months for a total of three billings. If payment is not received within six months from the entry date of the application, the application is automatically terminated.

Certificate of Waiver (CoW)

A certificate of waiver allows a facility to perform only tests and test systems that are classified by the FDA as "waived." The ONLY requirements for facilities performing waived testing is to follow manufacturer's

instructions/requirements and have a current CLIA certificate. Therefore, the laboratory should have a copy of the current manufacturer's instruction for all waived tests and test systems. There are no personnel requirements or qualifications for the laboratory director or the testing personnel with this type of certificate. Facilities with a certificate of waiver are not subject to routine on-site surveys.

Initial Billing Process: After the state agency receives and enters the initial application into the CMS database, the system assigns a CLIA identification number and automatically generates a user-fee coupon. Upon receipt of payment, the certificate is issued and expires two (2) years from the date the application is entered into the CMS database.

Renewal Process: The CMS database will automatically generate a user-fee coupon six (6) months prior to the expiration date on the current certificate. The system is set up to send up to three bills (i.e. a fee coupon every two months). If payment is not received after the third bill, the certificate is automatically terminated. All payments are posted upon receipt, but the new certificate will not be issued until two to three weeks prior to the expiration date of the current certificate. The biennial fee for a certificate of waiver is \$150.

Certificate of Provider Performed Microscopy Procedures (PPMP)

A PPMP certificate allows a facility to perform any waived testing and, in addition, a limited number of microscopic procedures. The director of a PPMP certificate must be a licensed physician, midlevel practitioner, or dentist. With this certificate type, all personnel are qualified to perform waived testing, but **only** a licensed physician, midlevel practitioner, or dentist is qualified to perform the microscopic procedures. A facility with a PPMP certificate must meet the same CLIA regulations as a certificate of compliance laboratory (i.e. quality control, quality assessment, personnel competencies, etc.) However, facilities holding a PPMP certificate are not subject to routine on-site surveys. **IMPORTANT:** When submitting the application for a PPMP certificate, the facility must provide documentation of the laboratory director's qualifications.

Initial Billing and Renewal Processes: The billing and renewal processes for a PPMP certificate is the same process as the certificate of waiver; the only difference is the biennial fee is \$200.

Certificate of Accreditation

A certificate of accreditation allows a laboratory to perform waived testing and, in addition, perform moderate- and high-complexity testing. With this type of certificate, there are more stringent requirements for laboratory director, clinical consultant, technical supervisor, technical consultant, general supervisor and testing personnel. (For specific laboratory personnel qualifications, see Subpart M of the CLIA regulations.) When initially applying for a certificate of accreditation, the facility must indicate on the application which accrediting organization will be conducting the on-site surveys (i.e. Joint Commission, College of American Pathologists, COLA, American Association of Blood Banks, American Osteopathic Association, or American Society for Histocompatibility and Immunogenetics). In addition, the facility must provide documentation of the laboratory director's qualifications and evidence of accreditation from the accrediting organization (e.g. a letter from the accrediting agency confirming enrollment).

Initial Billing Process: As with the other types of certificate applications, upon receipt the state agency enters the information into the CMS database. The system assigns a CLIA identification number and automatically generates a user-fee coupon for a registration certificate. This one-time fee is \$100. Upon receipt of payment, the certificate of registration is printed and mailed. The certificate of registration is good for two years during which the accrediting organization will conduct an on-site survey. After the on-site survey is conducted, the accrediting

agency enters the survey information into the CMS database. This automatically triggers the database to print a fee coupon for the certificate of accreditation and validation user fees. The fee schedule is based on the laboratory's annual test volume and the number of specialties performed (e.g. chemistry, hematology, microbiology, etc.). Laboratories with a certificate of accreditation also pay a fee for validation surveys. The cost is 5 percent of the compliance (inspection) fee, and is based on the fee schedule set for each individual state. Upon receipt of payment, the certificate of accreditation is printed and mailed. The certificate expires two years from the effective date on the CLIA certificate.

Renewal Process: The accrediting organization will conduct an on-site survey during the two year cycle of the CLIA certificate; after which they enter the survey report into the CMS database. Six (6) months prior to the expiration date on the current CLIA certificate, the system automatically generates a fee coupon for the certificate and validation user fees. These two fees are assessed biennially. All payments are posted upon receipt; however, the new certificate will not be issued until two to three weeks prior to the expiration date of the current certificate.

Certificate of Compliance

A certificate of compliance allows a laboratory to perform waived testing, and, in addition, perform moderate- and high-complexity testing. The difference between this certificate and a certificate of accreditation is that the state agency performs the on-site surveys. Again, there are more stringent requirements for laboratory director, clinical consultant, technical supervisor, technical consultant, general supervisor and testing personnel. For an initial certificate of compliance, the laboratory must submit documentation of the laboratory director's qualifications along with the application. **IMPORTANT:** The application will NOT be processed without the laboratory director's credentials.

Initial Billing Process: Upon receipt of the application, the state agency enters the information into the CMS database. As with other applications, entry is made within 15 days of receipt. The CMS database assigns a CLIA identification number and automatically generates a user-fee coupon, which includes both the registration fee and the compliance (inspection) fee. The registration fee is a one-time fee of \$100. The compliance fee is based on the laboratory's annual test volume and number of specialties performed. The compliance fees vary from state to state. (Contact the state agency in which the laboratory is located for the fee schedule.) Upon receipt of the payment, a certificate of registration is printed and mailed to the facility. The certificate of registration is good for two years during which a survey will be conducted by the state agency. Once the survey is conducted and entered into the CMS database, an effective date for the certificate of compliance is assigned based on receipt of an acceptable plan of correction and other documentation, as applicable, and the system automatically prints and mails a user-fee coupon for the certificate. The fee schedule is based on the laboratory's annual test volume and number of specialties performed. Again, upon receipt of payment, the certificate of compliance is printed and mailed. The certificate is good for two years from the effective date.

Renewal (recertification) Process: Twelve (12) months prior to the expiration date of the current certificate, the CMS database generates a fee coupon for the compliance (inspection) fee. Upon receipt of the payment, the facility is eligible for a recertification survey. A recertification survey is conducted six to nine months prior to the expiration date of the CLIA certificate. After the on-site survey and the determination of the laboratory's compliance with the regulations, the survey report is entered into the CMS database. The system automatically generates the fee coupon for renewal of the certificate. The fees may fluctuate biennially due to changes in the laboratory's annual test volumes and type of tests performed. All payments are posted upon receipt; however, the new certificate will not be issued until two to three weeks prior to the expiration date of the current certificate.

***If you have any questions or comments, please contact us at
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