

State by State CLIA Requirements

Helpful documents for applicants:

[CMS CLIA Waiver Step by Step Guide](#)

[CLIA State Agency Contacts](#)

[CLIA Certificate Fee Schedule](#)

[CLIA Application](#)

[The current fee for a waived CLIA certificate is \\$180.](#)

Alabama

Chapter 420-5-8. Independent Clinical Laboratories

“(2) Application.

(a) Application. An application for license or renewal of license shall be made on forms provided by the State Board of Health and shall contain such information as the Board may require.

(b) Fee. Each application for license shall be accompanied by a fee as mandated by statute. No fee shall be refunded. Fees shall be paid by cash, check or money order made payable to the Alabama Department of Public Health.”

Application: https://www.alabamapublichealth.gov/providerstandards/assets/icl_initial.pdf

In addition to the information requested within the application, the following must also be submitted:

1. A completed license application and \$240 application fee. Application fees are not refundable.
2. Organizational documents such as: Articles of Incorporation, LLC Agreement, Partnership Agreement, or Statement of Sole Proprietorship under which the facility will operate. A copy of the registration to conduct business in Alabama must accompany this application if the entity was established in a state other than Alabama.
3. Qualifications and licensure information regarding the medical director.

Following review of the application, a copy of the application will be forwarded to the Division of Health Care Facilities, Laboratory Unit. A staff member from the Division of Health Care Facilities Laboratory Unit may contact you regarding an on-site licensure visit to determine if the facility meets minimum requirements for a state license.

Due to workload volume, application review takes a minimum of thirty days. An onsite survey (if required) could add considerable time to completion of the licensure process.

Alaska

Application: <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms116.pdf>

The application should be signed and dated by the laboratory director. Once the application is processed, the laboratory will receive a CLIA bill in the mail. The lower portion of the bill should be mailed in with the laboratory's payment. Application review typically takes one month.

Checks should be made out to “CLIA Laboratory Program” and mailed to:

CLIA Laboratory Program

P.O. Box 3056

Portland, OR 97208-3056

Please do not mail checks to the Alaska State Agency.

Arkansas

Application: <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms116.pdf>

Requests for New Provider Applications (CMS116) or Change of Ownership (CHOW) Applications should be submitted via mail, email or fax to the ADH Health Facility Services office, listed below. Completed applications for New Providers or Change of Ownership should be submitted to Health Facility Services via mail (5800 W. 10th St., Suite 400 Little Rock, AR 72204), email (adh.hfs@arkansas.gov) or fax (501-661-2165). Application review typically takes one month.

California

Title 17. Public Health. Division 1. State Department of Health Services. Chapter 2. Laboratories

“(a) All persons performing, supervising, consulting on, or directing clinical laboratory tests or examinations in California shall meet the requirements for performing, supervising, consulting on, or directing laboratory tests or examinations as set forth in Chapter 3 for the type and complexity of tests performed and irrespective of whether the clinical laboratory is operated under a CLIA certificate or under a state license or registration.”

“(b) An application for licensure to direct a clinical laboratory or to perform clinical laboratory tests or examinations under Chapter 3 shall be considered complete when the following is provided to the department:

- (1) Name and address of the applicant, including city, state and zip code; and
- (2) Social security number of the applicant (Pursuant to the authority found in Section 1224 of the Business and Professions Code and in Section 100275 of the Health and Safety Code, and as required by Section 17520 of the Family Code, it is mandatory to provide the social security number. The social security number will be used for purposes of identification.); and
- (3) Gender and birthdate; and
- (4) License for which the applicant is applying; and
- (5) Whether the applicant has or has not been convicted of any felonies or misdemeanors other than minor traffic violations; and
- (6) Documentation of the applicant's education including:
 - (A) Name, address, major course of study, dates of attendance, number of credits, and degree/completion date for all colleges and universities attended by the applicant; and
 - (B) Official transcripts from the registrar of all accredited colleges or universities attended by the applicant showing all courses, course credits, degrees conferred and date of conference; and
 - (C) Official transcripts from non-United States colleges or universities which are not in English shall be returned to the applicant to obtain translation from a translation service approved in the United States for legal or government documents.
- (7) Documentation of the applicant's training including:
 - (A) Name and address of training program, dates of training, specialty and subspecialty areas of training, length of time in each specialty and subspecialty area of training; and
 - (B) Signed documentation from the training program director that this training has been successfully completed; and
- (8) Documentation of the applicant's experience, appropriate to the specific license for which the applicant is applying, including the following:
 - (A) Facility name, address, dates of employment, number of hours per week employed, the specialties and subspecialties in which clinical laboratory tests or examinations were performed and a description of clinical laboratory tests or examinations performed; and
 - (B) Signed documentation of such experience from the director of the laboratory; and
- (9) Evidence of satisfactory performance on a licensing examination pursuant to Section 1029; and
- (10) Signature of the applicant, telephone number and date of application; and
- (11) Payment of license application fee pursuant to Business and Professions Code Section 1300.”

Clinical Laboratories are required to submit their CLIA Application for Certification ([CMS-116](#)), [Form LAB 182](#) Attestation of each Owner, [Form LAB 183](#) Attestation of each Laboratory Director. These completed

forms can be uploaded to the application portal, which can be accessed [here](#).

State payment of \$113 is due at the time of submission, and federal payment is collected later. The certificate will be mailed after all payments have been collected.

Connecticut

Regs. Conn. State Agencies § 19a-36-D22

Application: <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms116.pdf>

“(a) In applying for licensure, the applicant shall set forth the name and location of the laboratory, a complete statement of its ownership including the names and addresses of all owners and the agent for service of process and the agent’s address, the name of the director, a list of laboratory tests and examinations for which licensure is sought and such other information as to ownership, quarters, facilities, personnel and proposed operations as the department may require. Application for renewal of licensure shall delineate changes made in the preceding licensure period. When applying for renewal of licensure under this section, the applicant shall simultaneously apply for renewal of any additional registration required by sections 19a-36-A25 through 19a-36- A33 of the regulations of Connecticut State Agencies, and such renewal, when granted, shall be considered to be in force for the issuance of such certificates of approval as are required by section 19a-36-A33 of the regulations of Connecticut State Agencies. The applicant shall, as part of each application, agree to abide by such standards of operation as are made a part thereof.

(b) The following clinical laboratories are exempt from licensure:

- (1) laboratories owned and operated by the United States or any agency of the federal government;
- (2) laboratories that perform tests or examinations for research purposes only;
- (3) laboratories that perform tests or examinations for forensic purposes only; and
- (4) laboratories that perform tests or examinations that are exempt for CLIA purposes.”

Hawaii

Haw. Admin. Rules (HAR) § 11-110.1-23 Clinical Laboratory Personnel License

“(a) No person shall serve as a clinical laboratory director, medical technologist (clinical laboratory scientist), clinical laboratory specialist, cytotechnologist, or medical laboratory technician without a current and valid clinical laboratory personnel license issued by the department.

(b) Application forms for licensure may be obtained by request from the state laboratories division, department of health.

(c) The clinical laboratory personnel licenses are:

- (1) Clinical laboratory director;
- (2) Medical technologist (clinical laboratory scientist);
- (3) Clinical laboratory specialist;
- (4) Cytotechnologist; and
- (5) Medical laboratory technician (clinical laboratory technician).

(d) Every applicant for a clinical laboratory personnel license shall provide documents verifying education, training, and employment experience requested on the application form.

(e) The specific education, training, and experience requirements for clinical laboratory personnel licenses may be waived by the director if the applicant presents evidence to the satisfaction of the director that the applicant’s combination of education, training, and experience is substantially equivalent to the specific clinical licensure requirements.

(f) All applications for original licensure shall be approved or denied no later than sixty calendar days following the date that the application is complete with all required documents verifying education, training, experience and full payment of all required fees. All applications for license renewal or restoration shall be

approved or denied no later than sixty calendar days following receipt of a completed renewal or restoration application and the full payment of all required fees.

(g) All clinical laboratory personnel licenses shall expire on January 31 of each odd-numbered year.

(h) All valid clinical laboratory personnel licenses in effect immediately prior to the effective date of this subchapter shall remain in effect until their renewal dates.”

Application: <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms116.pdf>

To apply for a CLIA certificate of waiver, applicants must complete Form CMS116 and Form [1513](#). Application forms should be mailed to State of Hawaii Department of Health Office of Health Care Assurance.

Notices to pay CLIA fees for an initial CLIA certificate are mailed about 2 weeks after the CLIA application is accepted by Hawaii Department of Health’s office. Once paid, the biennial CLIA certificate is in effect for 2 years, starting from the date the application is accepted by our office. All forms can be found [here](#).

Idaho

16.02.06 Quality Assurance for Idaho Clinical Laboratories

“01. Registration Timeframes. (7-1-21)T

a. Every person responsible for the operation of a laboratory that performs tests on material derived from the human body must register such facility with the Department within thirty (30) days after first accepting specimens for testing. (7-1-21)T

b. Existing laboratories must submit a completed laboratory registration form every two (2) years and indicate any changes in laboratory operations. (7-1-21)T

02. Registration Form. Each laboratory must submit its registration information on the Department-approved form. These forms are available upon request from the Department. Each completed registration form must include the following information: (7-1-21)T

a. Name and location of the laboratory; (7-1-21)T

b. Name of the laboratory director; (7-1-21)T

c. Types of laboratory tests performed in the laboratory; and (7-1-21)T

d. Other information requested by the Department that it deems necessary to evaluate the performance of the laboratory. (7-1-21)T”

Application: <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms116.pdf>

Any Idaho laboratory performing tests on humans for the purpose of diagnosis, treatment, or assessment of health must have a license from the Centers for Medicare and Medicaid Services (CMS) as part of the Clinical Laboratory Improvement Amendment (CLIA) program. The CLIA form may be mailed to Lab Improvement, 2220 Old Penitentiary Road, Boise, Idaho 83712, emailed to LabImprovement@dhw.idaho.gov, or faxed to 208-334-4067. The CLIA Certificate of Waiver cost \$180.

Indiana

Application: <http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads//cms116.pdf>

Any person or facility that performs laboratory tests on human specimens for the purpose of diagnosis and/or treatment is required by federal law to have a CLIA certificate. Currently, the Indiana Department of Health (IDOH) does not license laboratories or laboratory personnel. IDOH does have Communicable Disease and Universal Precautions rules that must be followed. These rules can be found under Indiana Administrative Code 410 Article 1.

Iowa

Application: <http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads//cms116.pdf>

Iowa does not have additional State licensure or certification requirements for laboratories. Completed CMS116 forms can be mailed to Iowa CLIA Laboratory Program, State Hygienic Laboratory, UI Research Park, 2490 Crosspark Road, Coralville, IA or faxed to 319.335.4174

Kansas

Application: <http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads//cms116.pdf>

Applications may be submitted by email to kdhe.clia2@ks.gov or faxed to 785-559-5207.

Kentucky

Title XXVI. Occupations and Professions. Chapter 333. Medical Laboratories

“Application for a medical laboratory license shall be made under oath by the director of the medical laboratory. The license shall be issued only for the performance of those medical laboratory procedures which the particular laboratory, by virtue of the educational and experience background of its laboratory personnel and the nature of its equipment and facilities, is competent to perform. A license shall not be issued unless the cabinet determines that the medical laboratory is adequately staffed and equipped to operate in conformity with the requirements of this chapter and the regulations promulgated hereunder.”

Application: <http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads//cms116.pdf>

Louisiana

Title 46. Professional and Occupational Standards. Part XLV. Medical Professions. Subpart 2. Licensure and Certification

“A. General Requirements. Application for licensure or certification under this Chapter shall be made on a form supplied by the committee. Such form, and any supporting documentation required to be submitted therewith, shall provide information sufficient to assure the applicant satisfies the minimum qualifications for the category of licensure or certification applied for.

B. Applicant for Licensure as CLS-G, CLS-S, CLS-T, or Cytotechnologist. Each application for licensure as a CLS-G, CLS-S, CLS-T, or cytotechnologist shall be accompanied by all of the following:

1. a recent photograph for identification;
2. the appropriate fee;
3. a copy of the registration or certification card indicating successful completion of an approved nationally recognized certification examination;
4. for non-U.S. citizen applicants, proof of lawful entry into the country; and
5. if the requested licensure or certification is based on reciprocity as provided in § 3513, a statement from the licensing authority of the other state attesting to the licensure status of the applicant in the other state. Such statement shall be issued directly to the committee from the licensing authority of the other state.

C. Application for Licensure as a Laboratory Assistant. Each application for licensure as a laboratory assistant shall be accompanied by all of the following:

1. a recent photograph for identification;
2. the appropriate fee;
3. evidence of completion of a satisfactory training program;
4. copy of a high school diploma or equivalent; and
5. if moderate complexity testing is to be performed, documentation of competency in the area of testing to be performed.

D. Application for Certification as a Phlebotomist. Each application for certification as a phlebotomist shall be accompanied by all of the following:

1. a recent photograph for identification;
2. the appropriate fee; and
3. evidence of completion of a satisfactory training program and successful completion of a board-approved or administered certifying examination or successful completion of an approved nationally recognized certification examination.

E. Multiple Licensure. An applicant may be licensed or certified in each category for which he or she is qualified.”

Application: <http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads//cms116.pdf>

In addition to a completed CMS116 form, applications should also submit a [Listing of Tests Performed in the Facility](#). Once the information is complete the applicant may submit via email to alexa.little@la.gov or mail to CLIA Laboratory Program, P O BOX 3767, Baton Rouge, LA 70821.

Massachusetts

Title 130. Division of Medical Assistance. Chapter 401. Independent Clinical Laboratory Services

“An independent clinical laboratory must be enrolled in MassHealth on the date of service in order to be eligible for payment.

(A) In-state Providers. To be eligible to enroll as a MassHealth provider, an independent clinical laboratory must be

- (1) located and doing business in the Commonwealth of Massachusetts;
- (2) certified as an independent clinical laboratory by the Centers for Medicare & Medicaid (CMS), based on the criteria set forth in the Clinical Laboratory Improvement Amendments (CLIA) of 1988; and
- (3) licensed as a clinical laboratory by the Massachusetts Department of Public Health.”

Clinical Laboratory License Application: <https://www.mass.gov/how-to/apply-for-a-massachusetts-clinical-laboratory-license>

The Massachusetts State Department of Public Health requires laboratories to possess a Clinical Laboratory License in addition to the CLIA Certificate of Waiver for performing CLIA-waived tests. The fee for a full license is \$300 for each specialty area. The fee for a limited license is \$300 per applicant. Form CMS116 and [Laboratory Tests Performed On-Site List](#) must be submitted in the application materials which should be sent to CLIALab@mass.gov.

Minnesota

Application: <http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads//cms116.pdf>

Mississippi

Application: <http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads//cms116.pdf>

Send CLIA applications to the following:

Mississippi State Department of Health
Licensure and Certification – CLIA
P.O. Box 1700
Jackson, MS 39215-1700

Telephone: 601-364-1100 or 601-364-1115
Fax: 601-364-5053

Applications are accepted by e-mail. E-mail submission results in the fastest processing.

Email: CLIA-MSDH@msdh.ms.gov

Missouri

Application: <http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads//cms116.pdf>

Send CLIA applications to the following:

Mail: DHSS - Bureau of Diagnostic Services

CLIA Program

PO Box 570

Jefferson City, MO 65102

E-mail: CLIA@health.mo.gov

Fax: 573-751-6158

Montana

Application: <http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads//cms116.pdf>

Return the completed CMS-116 form to the Montana CLIA Program via fax (406-444-3456), email (mtssad@mt.gov), or mail (Certification Bureau-CLIA Program, 2nd floor DPHHS - QAD, PO BOX 202953, Helena, MT 59620-2953). A bill will be automatically generated and mailed within two to three weeks after the application has been entered into the computer by the Montana CLIA program.

Nebraska

Title 471. Nebraska Medical Assistance Program Services. Chapter 18. Physicians' Services

“18-001.02 Independent Clinical Laboratories: In addition to the provider agreement, independent clinical laboratories must meet the following requirements:

1. When state or applicable local law requires licensing of independent clinical laboratories, the laboratory must be licensed under the law; and
2. The laboratory must meet the health or safety requirements of the Department of Health and Human Services (HHS).

For a Nebraska independent lab to be an approved provider under NMAP, the Division of Medicaid and Long-Term Care must receive a copy of Form CMS-1539, “Medicaid/Medicare Certification and Transmittal,” (see 471-00-66) which displays current Medicare certification from the CMS Regional Office. The CMS Regional Office updates certification information and sends the information to the Division according to the federal time frame which is currently in effect for independent clinical laboratory surveys. For an out-of-state independent clinical lab to be an approved provider under NMAP, the Division must request verification of certification from the CMS Regional Office. The Division approves or denies enrollment based on the certification information received from the CMS Regional Office.”

Application: <http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads//cms116.pdf>

To be initially certified as a CLIA lab in Nebraska, you must complete the following forms:

1 CLIA Application for Certification form (CMS-116)

2 CLIA Ownership Information Form

3 List of Tests Performed

These forms can be found here: <https://dhhs.ne.gov/licensure/Pages/CLIA-Clinical-Labs.aspx>

Submit these documents with original signatures to:

DHHS Public Health – Licensure Unit/CLIA
Po Box 94669
301 Centennial Mall South
Lincoln, NE 68509-4669

New Mexico

Application: <http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads//cms116.pdf>

North Carolina

Application: <http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads//cms116.pdf>

Send CLIA applications to the following:

Mailing Address: Division of Health Service Regulation/CLIA Certification, 2713 Mail Service Center,
Raleigh, NC 27699-2713

Fax: 919-733-0176

North Dakota

Title 96. Board of Clinical Laboratory Practice. Article 96-02. Clinical Laboratory Personnel Licensure.

“The following requirements apply to all applicants seeking initial licensure by the board:

1. A completed application form.
2. Payment of the appropriate application fee as set by the board.
3. Evidence of the required education.
4. The applicant has passed a national certifying examination approved by the board.
5. The applicant must meet one or more of the following conditions:
 - a. The applicant has passed a national certifying examination approved by the board within two years of the date of application for initial licensure.
 - b. The applicant has practiced by performing clinical laboratory testing as defined in subsection 5 of North Dakota Century Code section 43-48-01 for a total of three hundred hours within three years of the date of application for initial licensure. Proof of practice by performing clinical laboratory testing must be provided by the applicant and may be evaluated by the board for sufficiency.
 - c. The applicant has obtained thirty continuing education hours within two years of the date of application for initial licensure. The continuing education hours obtained must satisfy the requirements for continuing education established in section 96-02-04-01.
6. All applications must be signed or attested to electronically.”

1. Initial fee for licensing

a. Application for license received on or after May first of the even-numbered year and before January first of the odd-numbered year:

- | | |
|------------------------------------|----------|
| (1) Medical technologist | \$100.00 |
| (2) Clinical laboratory scientist | \$100.00 |
| (3) Clinical laboratory specialist | \$100.00 |
| (4) Clinical laboratory technician | \$80.00 |
| (5) Medical laboratory technician | \$80.00 |

b. Application for license received on or after January first of the odd-numbered year and before July first of the odd-numbered year:

- | | |
|-----------------------------------|---------|
| (1) Medical technologist | \$75.00 |
| (2) Clinical laboratory scientist | \$75.00 |

(3) Clinical laboratory specialist \$75.00

(4) Clinical laboratory technician \$60.00

(5) Medical laboratory technician \$60.00

c. Application for license received on or after July first of the odd-numbered year and on or before December thirty-first of the odd-numbered year:

(1) Medical technologist \$50.00

(2) Clinical laboratory scientist \$50.00

(3) Clinical laboratory specialist \$50.00

(4) Clinical laboratory technician \$40.00

(5) Medical laboratory technician \$40.00

d. Application for license received on or after January first of the even-numbered year and before May first of the even-numbered year:

(1) Medical technologist \$25.00

(2) Clinical laboratory scientist \$25.00

(3) Clinical laboratory specialist \$25.00

(4) Clinical laboratory technician \$20.00

(5) Medical laboratory technician \$20.00

Return the completed CMS-116 form and [Laboratory Tests Performed](#) to:

North Dakota Department of Health

Division of Health Facilities

600 E Boulevard Ave., Dept. 301

Bismarck, ND 58505-0200

clialab@nd.gov

Fax: 701-328-2352

Oklahoma

Application: <http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads//cms116.pdf>

Oregon

Chapter 333. Oregon Health Authority, Public Health Division. Division 24. Clinical Laboratories.

“(1) It shall be unlawful:

(a) For any Owner or Director of a clinical laboratory to operate or maintain a clinical laboratory without a license or without a temporary permit issued under this rule or to perform or permit the performance of any laboratory specialty for which the laboratory is not licensed, unless the laboratory has been issued a valid certificate from the federal government under the Clinical Laboratory Improvement Amendments of 1988.

(a) The application for a license for a clinical laboratory shall be made on forms provided by the Division and shall be executed by the Owner or one of the Owners or by an officer of the firm or corporation owning the clinical laboratory, or in the case of a county or municipality, by the public official responsible for operation of the laboratory, or in the case of an institution, by the administrator of the institution. The application shall contain the names of the Owner, the Director or Directors of the clinical laboratory, the location and physical description of the clinical laboratory, the laboratory specialties for which a license is requested, and such other information as the Division may require:

(A) Not-for-profit, or state, or local government laboratories that engage in limited public health testing may file a single application, provided they have the same owner and director. They may perform a combined total of fifteen test methods listed in the waived, physician performed microscopy and moderate complexity category.

(B) Laboratories that are located at the same site and are under the same director may file a single application.

Laboratories must pay an annual or biennial, non-refundable license fee prior to issuance of a license or permit. Numbers in the fee category indicate the number of tests performed annually; count tests on patient/client specimens only. Count the number of tests in each profile. Do not count waived tests, physician-performed microscopy by physicians and clinicians, standards, controls, calculated tests, or proficiency testing samples.

Effective July 1, 2000, the annual fees are:

Waived — Accredited and Non-Accredited — \$75;

Physician Performed Microscopy (PPM) — Accredited and Non-Accredited — \$100;”

Rhode Island

Title 23. Health and Safety. Chapter 16.2. Laboratories

[RI Clinical Laboratory Application](#). Fee calculation is available within the application.

Return the completed application to
Rhode Island Department of Health
3 Capitol Hill, Room 306
Providence, RI 02908-5097

South Carolina

Application packets are mailed upon request. Requests may be made by phone at (803)545-4205 or by fax at (803) 545-4563. Applications (CMS Form-116) are also available on the CLIA Web site. (Note: The application packet requested from SC DHEC CLIA PROGRAM contains required documents that cannot be obtained from the CLIA Web site.)

South Dakota

CLIA applications are obtained from the South Dakota Department of Health, Office of Licensure and Certification, 615 East 4th Street, Pierre, SD 57501. Telephone (605) 773-3356, Division of Laboratory Standards and Performance, Health Standards and Quality Bureau, Centers for Medicare/Medicaid Services, 7500 Security Boulevard S-2-11-07, Baltimore, MD 21244-1850. Telephone (410)-786-3531, or online at www.phppo.cdc.gov/clia/default.asp.

Tennessee

Tenn. Comp. R. & Regs. 1200-06-01-.07
Alternatively cited as TN ADC 1200-6-1-.07

[Medical Laboratory Personnel Application Guidelines for Completing an Online Application](#)

Tennessee Medical Laboratory License Fee is \$60

Texas

Laboratories are not state licensed. The Secretary of the DHHS directs state health agencies or other appropriate agencies to determine if health care entities meet federal standards. This helping function is termed “CLIA certification”. On behalf of the CMS CLIA program, HHSC uses [Form 3225, Application for Certification – Supplement to CMS 116](#) to process CLIA certificate applications. The Texas Health and Human Services Commission (HHSC), on behalf of the CMS CLIA program, uses Form 3225 to process CLIA certificate applications. Applicants must forward a completed Form 3225 to their appropriate CLIA State

Agency regional office for HHSC to accept and process their CLIA application. HHSC will not process Form 3225 applications until the CLIA State Agency regional office receives and approves all requested information.

Do not send payment for CLIA fees to HHSC. Follow the instructions on the user fee coupon generated by CMS to make a payment.

When submitting a check, always include the CLIA ID number.

Fees for certificates are billed biennially. The amount is based on certificate type (for Certificates of Waiver and PPM) and the annual volume of testing and number of laboratory specialties performed (for Certificates of Compliance and Accreditation).

West Virginia

W. Va. Code St. R. § 64-57-5

§ 64-57-5. Licensure Requirements, Duration, Renewal.

5.1. General. -- Applicants for licensure under this rule shall submit an application form available online at <https://dhhr.wv.gov/ols/regulatory/Pages/Licensure.aspx> and the following materials:

5.1.a. Documentation of the applicant's qualifying education and certification or documentation of other substitute qualification as permitted by this section;

5.1.b. The applicant's job description or education program description for which certification is sought by the applicant; and

5.1.c. The annual licensure fee of \$25 per person as authorized by W. Va. Code § 16-5J-10 and any other special circumstance fees as required by this section.

5.1.d. Applicants seeking license renewal shall provide evidence of the completion of the continuing education requirements contained in subsection 5.9.

Wisconsin

Application: <http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms116.pdf>

Wyoming

WY Rules and Regulations 048.0013.1-6

Formerly cited as WY ADC HLTH CL

Complete a CLIA Application, in its entirety and mail to: Healthcare Licensing and Surveys, Hathaway Building, Suite 510, 2300 Capitol Avenue, Cheyenne, WY 82002

All clinical laboratories in Wyoming Shall have a valid license issued by the state agency. In order to receive a license, a laboratory shall have a director certified by the state agency, and meet the appropriate inspection and proficiency testing requirements as specified in Chapters III, IV, and V following.

The owner(s) or director-owner shall request, in writing, an application for license from the state agency.

(d) The license application shall be accompanied by the appropriate license fee.

(i) The fee shall be one hundred dollars (\$100.00) for each category of tests.

(ii) Test categories are: microbiology, serology, chemistry, hematology, biophysics, cytology, and pathology.

(iii) The license fee for any laboratory shall not exceed five hundred dollars (\$500.00)

(a) The license application shall require: (i) The name, address, and phone number of the laboratory; (ii) The name and address of the owner; (iii) The name and Certificate of Qualification; number of the director; (iv) A list of the laboratory tests performed; (v) A list of personnel that perform the laboratory tests; (vi) Documentation of participation in the appropriate proficiency testing program. (vii) For reference laboratories,

CLIA license number, Medicare provider number, documentation of accreditation from JCAHO or CAP, and a copy of the most recent inspection report.

(b) The license shall be issued: (i) To the owner if he is the director of the laboratory or; (ii) Jointly to the owner and director of the laboratory or; (iii) Jointly to co-owners and directors of the laboratory.

(c) The license shall specify the owner, the laboratory director, laboratory classification, location of the laboratory, and the laboratory procedures or categories of procedures authorized.

(d) The license shall be valid for the calendar year in which it was issued.

(e) A license shall automatically be voided if there is a change in the laboratory director.

(f) A license shall automatically be voided thirty (30) days following a change in ownership or location.

(g) Application for a new license may be made prior to any change in the laboratory director, ownership, or location of the laboratory or within the thirty (30) day expiration period noted in (f) above.

(h) A laboratory shall notify the state agency, in writing, if the laboratory intends to offer a new test or tests for which it has not been licensed, during the license year. The state agency shall have thirty (30) days beginning with receipt of the notice to amend the existing license, reissue a license, or make no change in the existing license. During the thirty (30) day period, the state agency may, depending on the nature of the test(s) being considered, determine by inspection, check testing or both, that the laboratory can satisfactorily perform the new test(s).

(i) The state agency shall renew a license on a yearly basis provided: (i) The appropriate fee is submitted with a completed renewal form; (ii) The laboratory director has a valid Certificate of Qualification; (iii) The laboratory has met the appropriate inspection and proficiency testing requirements.