



WEST VIRGINIA SECRETARY OF STATE

MAC WARNER

ADMINISTRATIVE LAW DIVISION

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Office of West Virginia
Secretary Of State

**NOTICE OF FINAL FILING AND ADOPTION OF A LEGISLATIVE RULE AUTHORIZED
BY THE WEST VIRGINIA LEGISLATURE**

AGENCY: Health TITLE-SERIES: 64-57
RULE TYPE: Legislative Amendment to Existing Rule: Yes Repeal of existing rule: No
RULE NAME: CLINICAL LABORATORY PRACTITIONER
LICENSURE AND CERTIFICATION

CITE STATUTORY AUTHORITY: 16-1-4, 16-1-11, and 16-5J-10

The above rule has been authorized by the West Virginia Legislature.

Authorization is cited in (house or senate bill number) 4126

Section 64-5-1(g) Passed On 3/3/2022 12:00:00 AM

This rule is filed with the Secretary of State. This rule becomes effective on the following date:

May 1, 2022

This rule shall terminate and have no further force or effect from the following date:

August 01, 2027

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENT IS TRUE AND CORRECT.

Yes

April L Robertson -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.

TITLE 64
LEGISLATIVE RULE
BUREAU FOR PUBLIC HEALTH

SERIES 57
CLINICAL LABORATORY PRACTITIONER LICENSURE AND CERTIFICATION

§64-57-1. General.

1.1. Scope. -- This legislative rule sets forth standards and procedures for the licensing of clinical laboratory practitioners and establishes penalties for the use of unlicensed persons to perform the work of clinical laboratory practitioners by health care facilities.

1.2. Authority. -- W. Va. Code §16-1-4, §16-1-11, and §16-5J-10.

1.3. Filing Date. -- April 4, 2022.

1.4. Effective Date. -- May 1, 2022.

1.5 Sunset Provision. -- This rule shall terminate and have no further force or effect on August 1, 2027.

1.6. Applicability. -- Except as otherwise provided in this rule, this rule applies to:

1.6.a. Clinical laboratory practitioners who perform non-waived clinical laboratory tests as defined by 42 CFR 493.17 of the Clinical Laboratory Improvement Amendments of 1988 (CLIA); and

1.6.b. Clinical laboratory consultants, directors, supervisors, or testing personnel who perform non-waived testing or manipulate and report data obtained from laboratories in West Virginia.

1.6.c. This rule does not apply to:

1.6.c.1. Any individual who performs only laboratory tests published in the Federal Register as waived under CLIA by the Centers for Disease Control and Prevention under the provisions of 42 CFR 493.17;

1.6.c.2. Any physician, dentist, nurse practitioner, nurse midwife, or physician assistant, licensed within this state working within the scope of his or her professional license, who performs only provider-performed microscopy procedures as found at 42 CFR 493.19 (a) - (e);

1.6.c.3. Any respiratory care provider licensed within the state providing diagnostic testing within the scope of his or her professional license who performs moderate complexity testing as defined by CLIA, pursuant to 42 CFR 493.17;

1.6.c.4. An individual who performs laboratory tests only on himself or herself or members of his or her family;

1.6.c.5. An individual employed as a clinical laboratory practitioner in an agency or organization exempt from licensure in accordance with W. Va. Code §16-5j-7;

1.6.c.6. A medical doctor, doctor of osteopathy, or podiatrist licensed to practice that profession in West Virginia;

1.6.c.7. A doctor of philosophy performing laboratory testing within the scope of his or her degree and board certification;

1.6.c.8. An individual performing laboratory testing for a CLIA-exempt laboratory;

1.6.c.9. An individual solely performing forensic laboratory testing; or

1.6.c.10. An individual solely performing drug testing for a laboratory certified by the Substance Abuse and Mental Health Services Administration;

1.7. Enforcement. -- This rule is enforced by the secretary of the West Virginia Department of Health And Human Resources.

§64-57-2. Definitions.

2.1. Certifying agency – means one of the following institutions:

2.1.a. American Society for Clinical Pathology (ASCP);

2.1.b. American Medical Technologists (AMT);

2.1.c. American Association of Bioanalysts (AAB);

2.1.d. American Board of Bioanalysts (ABB);

2.1.e. American Board of Clinical Chemistry (ABCC);

2.1.f. American Board of Forensic Toxicology (ABFT);

2.1.g. American Board of Medical Genetics and Genomics (ABMGG);

2.1.h. American Board of Medical Laboratory Immunology (ABMLI);

2.1.i. American Board of Medical Microbiology (ABMM);

2.1.j. American College of Histocompatibility and Immunogenetics; and

2.1.k. National Registry of Certified Chemists (NRCC).

2.2. CLIA. -- Clinical Laboratory Improvement Amendments of 1988, Section 353 of the Public Health Service Act, 42 CFR Part 493, last amended September 2, 2020.

2.3. Clinical Laboratory. -- Any facility or place, however named, for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information

for the diagnosis, prevention or treatment of any disease, or the impairment of, or the assessment of the health of human beings.

2.4. Clinical Laboratory Consultant. -- A person who meets the qualifications for:

2.4.a. Moderate complexity testing technical consultant found at 42 CFR 493.1411;

2.4.b. Moderate complexity testing clinical consultant found at 42 CFR 493.1417; or

2.4.c. High complexity testing clinical consultant found at 42 CFR 493.1455.

2.5. Clinical Laboratory Director. -- A person who:

2.5.a. Provides overall management and direction of a clinical laboratory; and

2.5.b. Meets the qualifications for:

2.5.b.1. Moderate complexity testing laboratory director found at 42 CFR 493.1405; or

2.5.b.2. High complexity testing laboratory director found at 42 CFR 493.1443.

2.6. Clinical Laboratory Practitioner. -- Includes medical laboratory technicians, point of care technicians, cytotechnologists, histologists, medical laboratory scientists, pathologist assistants, and trainees.

2.7. Clinical Laboratory Practitioner Trainee. -- A person who is in a training program designed for his or her qualification as a clinical laboratory practitioner or who has successfully completed such a training program and has applied for, but not yet received a clinical laboratory practitioner license.

2.8. Clinical Laboratory Supervisor. -- A person who meets the qualifications for:

2.8.a. A high complexity testing technical supervisor found at 42 CFR 493.1449;

2.8.b. A high complexity testing general supervisor found at 42 CFR 493.1461; or

2.8.c. A high complexity testing cytology general supervisor found at 42 CFR 493.1469.

2.9. Cytotechnologist. -- A type of laboratory technologist whose job tasks include specimen processing, test performance, and reporting of cytological examinations supervised by a pathologist or other physician recognized as a specialist in diagnostic cytology.

2.10. Department. -- The West Virginia Department of Health and Human Resources.

2.11. Grossing. -- The pathological inspection, description, measurement, sectioning, and evaluation of tissue specimens for the purpose of diagnosis or treatment of disease or the assessment of health.

2.12. Histologist (CLP-HT) -- A laboratory technologist or technician with the education, skills, and training to perform high complexity pathology specimen grossing, inking, and mapping, and associated special staining procedures or tissue analysis under the direct supervision of a pathologist or pathologist assistant.

2.13. Medical Laboratory Technician (CLP-MLT). -- A person whose job tasks include specimen processing, laboratory test performance, or laboratory test reporting in a clinical laboratory which tasks require limited exercise of independent judgment and are performed under the supervision of a clinical laboratory director or a clinical laboratory supervisor.

2.14. Medical Laboratory Scientist (CLP-MLS). -- A person who performs a broad range of laboratory tests in a clinical laboratory. Job tasks may include specimen processing, laboratory test performance, or laboratory test reporting and other tasks requiring the broad exercise of judgment and responsibility with little or no direct technical supervision.

2.15. Laboratory Test. -- The biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of human beings.

2.16. National Accrediting Agency for Clinical Laboratory Science (NAACLS) -- The accrediting organization for laboratory science-related educational programs, recognized by the Council for Higher Education Accreditation.

2.17. Pathologist Assistant (CLP-PA) -- A type of advanced practice laboratory technologist who processes a variety of pathology specimens, including comprehensive macroscopic examination and evaluation (grossing) of surgical pathological specimens, under the supervision of a pathologist.

2.18. Point of Care Technician (CLP-POCT). -- A type of laboratory technician whose job tasks include specimen processing, laboratory test performance, and laboratory test reporting directly to a physician to review and evaluate the results obtained. These technicians shall perform only tests that have been categorized as moderately complex under CLIA under the personal supervision of a clinical laboratory director or a technical consultant. This supervision shall be available at all times when testing is being performed.

§64-57-3. Incorporation by Reference.

The following provisions of 42 CFR Part 493, laboratory requirements, last amended September 2, 2020, are hereby incorporated by reference:

- 3.1. 42 CFR 493.17;
- 3.2. 42 CFR 493.19 (a) - (d);
- 3.3. 42 CFR 493.1405;
- 3.4. 42 CFR 493.1411;
- 3.5. 42 CFR 493.1417;
- 3.6. 42 CFR 493.1423;
- 3.7. 42 CFR 493.1443;

- 3.8. 42 CFR 493.1449;
- 3.9. 42 CFR 493.1455;
- 3.10. 42 CFR 493.1461;
- 3.11. 42 CFR 493.1469;
- 3.12. 42 CFR 4.93.1483; and
- 3.13. 42 CFR 493.1489.

§64-57-4. Prohibition; Persons Subject to Licensure; Clinical Laboratory Practitioner Trainees.

4.1. No person shall perform any clinical laboratory practitioner tasks in West Virginia, except as specified in this rule, unless the person is licensed by the secretary as a clinical laboratory practitioner.

4.2. A clinical laboratory practitioner trainee may perform tasks related to laboratory tests only under the personal and direct supervision of a licensed clinical laboratory practitioner or a clinical laboratory director, consultant, or supervisor.

4.3. A trainee license may be issued only to an applicant that is verified to be employed or offered employment in a clinical laboratory testing facility or that is enrolled in a laboratory training program.

§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.

5.2. Unless the applicant provides verification that he or she has met one of the substitute criteria permitted by CLIA for testing personnel, a Clinical Laboratory Practitioner – Medical Laboratory Scientist (CLP-MLS), applicant shall provide documentation to establish that he or she:

5.2.a. Has earned a bachelor's degree in medical technology/medical laboratory science from an NAACLS accredited program, and has passed a national certification examination administered by a certifying agency recognized under subsection 2.1 of this rule; or

5.2.b. Was previously certified as a medical laboratory technician by a certifying agency recognized under subsection 2.1; and

5.2.b.1. Obtained a bachelor's degree from an accredited institution; and

5.2.b.2. Has passed a national certification examination administered by a certifying agency recognized under subsection 2.1; or

5.2.c. Has earned a bachelor's degree in a chemical, physical, or biological science other than medical technology/medical laboratory science from an accredited institution, and, in addition, has at least one year of pertinent full-time experience or training, or both, designed to provide him or her the skills required by CLIA with respect to the specialties or subspecialties he or she will perform.

5.3. Unless the applicant provides verification that they have met one of the substitute criteria permitted by CLIA for testing personnel, a Clinical Laboratory Practitioner - Laboratory Technician (CLP-MLT) applicant shall provide documentation sufficient to establish that he or she:

5.3.a. Has earned an associate degree in medical technology/medical laboratory science from an NAACLS accredited program, and has passed a national certification examination administered by a certifying agency recognized under subsection 2.1 of this rule; or

5.3.b. Has earned an associate degree from an accredited institution in a chemical, physical, or biological science other than medical technology/medical laboratory science, and, in addition, has at least one year of pertinent full-time experience, or training, or both, designed to provide him or her the skills required by CLIA with respect to the specialties or subspecialties he or she will perform; or

5.3.c. Has successfully completed 60 semester hours of academic credit at an accredited institution, including at a minimum, either 24 semester hours of medical laboratory technology/medical laboratory science courses or six semester hours of chemistry, six semester hours of biology, and 12 semester hours of chemistry, biology, or medical laboratory technology/medical laboratory science, in any combination, and has at least one year of pertinent full-time experience or training, or both, designed to comply with the CLIA requirements for testing personnel. Applicants with an associate degree in medical technology/medical laboratory science are excluded from this provision.

5.4. Unless the applicant provides verification that he or she has met one of the substitute criteria permitted by CLIA for testing personnel, a Clinical Laboratory Practitioner - Cytotechnologist (CLP-CT) applicant shall provide documentation to establish that he or she:

5.4.a. Has graduated from a school of cytotechnology accredited by the Commission on Accreditation of Allied Health Education Programs, or its predecessor, the Committee on Allied Health Education and Accreditation; or

5.4.b. Has been certified in cytotechnology by a certifying agency approved by United States Department of Health and Human Services.

5.5. Unless the applicant provides verification that her or she has met one of the substitute criteria permitted by CLIA for testing personnel, a Clinical Laboratory Practitioner - Pathologist Assistant (CLP-PA) applicant shall provide documentation to establish that he or she:

5.5.a. Has graduated from a Pathologist Assistant program accredited by NAACLS; and

5.5.b. Is certified by a certifying agency enumerated in subsection 2.1 of this rule.

5.6. Unless the applicant provides verification that he or she has met one of the substitute criteria permitted by CLIA for testing personnel, a Clinical Laboratory Practitioner - Histologist (CLP-H) applicant shall provide documentation to establish that he or she:

5.6.a. Meets requirements under §493.1489 of CLIA for high complexity testing personnel; and

5.6.b. Has passed a national histotechnologist or histotechnician certification examination administered by a certifying agency enumerated in subsection 2.1 of this rule; or

5.6.c. Has at least one year of pertinent full-time experience or training in the gross examination of human tissue specimens performed under the supervision of a pathologist, such as to provide the skills required by CLIA with respect to the specific tests that he or she will perform.

5.7. Clinical Laboratory Practitioner - Point of Care Technician (CLP-POCT) applicant shall provide documentation to establish that he or she:

5.7.a. Has at least a high school diploma, a general education development certificate (GED), or an equivalent approved by the State department of education;

5.7.b. Is employed in a clinical laboratory which holds a CLIA certificate other than a certificate of waiver; and

5.7.c. Written verification from the laboratory director that the applicant has had training designed to provide the skills required by CLIA with respect to the specific tests he or she will perform.

5.7.d. In the event that a person licensed as a clinical laboratory practitioner - point of care technician is to perform tests in addition to those which he or she is licensed to perform, he or she shall submit to the secretary documentation of training related to the additional tests in the skills, knowledge, and awareness consistent with the requirements of this subsection.

5.8. A Clinical Laboratory Practitioner – Trainee (CLP-T) applicant shall provide documentation to establish that he or she:

5.8.a. Is employed in a clinical laboratory which holds a CLIA certificate other than a certificate of waiver; and meets one of the following qualifications:

5.8.a.1. Has earned an associate degree from an accredited institution in medical technology/medical laboratory science but has not met requirements for national certification; or

5.8.a.2. Has earned an associate degree from an accredited institution in a chemical, physical, or biological science other than medical technology/medical laboratory science and has less than one year of prior non-waived laboratory experience; or

5.8.a.3. Has successfully completed 60 semester hours of academic credit at an accredited institution, including at a minimum, either 24 semester hours of medical laboratory technology/medical laboratory science courses or six semester hours of chemistry, six semester hours of biology, and 12

semester hours of chemistry, biology, or medical laboratory technology/medical laboratory science, in any combination and has less than one year of prior non-waived laboratory experience; or

5.8.a.4. Has earned a bachelor's degree in medical technology/medical laboratory science from an accredited institution but has not met requirements for national certification; or

5.8.a.5. Has earned a bachelor's degree in a chemical, physical, or biological science other than medical technology/medical laboratory science from an accredited institution and has less than one year of prior non-waived laboratory experience; or

5.8.a.6. Is enrolled in a clinical laboratory technology/science training program that is accredited by the National Accrediting Agency for Clinical Laboratory Science (NAACLS); and

5.8.b. Written verification by the laboratory director or program director which states that the applicant will have training designed to provide the skills required by CLIA with respect to the specific tests he or she will perform.

5.8.c. The trainee license is designed to provide applicants meeting the qualifications in this section the ability to obtain clinical training or experience until such time he or she qualifies for full licensure as a CLP-MLS, CLP-MLT, CLP-CT, OR CLP-PA.

5.8.d. Trainees licensed under paragraphs 5.8.a.2., 5.8.a.3., or 5.8.a.5. of this rule may qualify for a full license upon completion of one year of training/experience and submission of the "verification of competency" document, to be completed by the laboratory director or a designee.

5.8.e. Trainees licensed under paragraphs 5.8.a.1., 5.8.a.4., or 5.8.a.6. of this rule are expected to obtain the required national certification within one year of obtaining the trainee license, and any application for renewal without national certification shall provide documentation of attempts to become certified.

5.8.f. A trainee license may be renewed no more than twice and shall be issued at the discretion of the secretary. A person may not be licensed as a trainee for more than three years.

5.9. An applicant for renewal of either a current or an expired license shall submit the application, information and licensure fee required by subsection 5.1. of this rule and evidence that the applicant has completed at least 10 continuing education hours of activities commensurate with the level of complexity of testing the individual performs from a program or programs approved by the secretary, since the issuance of his or her current or expired license, as applicable. Acceptable continuing educational activities include, but are not limited to lectures, seminars, workshops, formal classes, in-service programs, or correspondence courses.

5.10. Term of License. -- A clinical laboratory practitioner license expires one year after the date it was issued. In the case of a license which has lapsed or been inactive for five years the individual shall comply with the requirements for issuance of an original license as described in subsection 5.1. of this section.

5.11. Fees applicable to requests for licenses under special circumstances: Additional fees shall be charged for the following:

5.11.a. A late fee of \$10 per license for licensee renewal requests that are postmarked after the application due date but before the license has lapsed.

5.11.b. A fee of \$20 for a replacement license.

5.11.c. A fee of \$20 for reinstatement of a lapsed license.

5.11.d. An “emergency” issuance fee of \$35 for processing and issuance of a license requested by the licensee or management to be issued within a 24-hour turn-around time.

5.11.e. A penalty of \$100 shall be assessed to any testing personnel found to be unlicensed or whose license has lapsed during the CLIA survey process as a violation of CLIA personnel requirements.

5.11.f. A fee of \$10 for issuing an official licensure source verification.

5.11.g. A special handling fee of \$10 per license processing for practitioner license mailed directly to laboratory management in lieu of the licensee home address.

5.11.h. A fee of \$35 for payments returned due to non-sufficient funds.

§64-57-6. Reciprocity.

The secretary may issue a clinical laboratory practitioner license to a person who holds a license or certification from another jurisdiction that has licensure and certification requirements at least as stringent as the requirements of this rule. Applicants for reciprocity shall submit with their application the license application fee and a statement from their licensing or certifying jurisdiction that they are in good standing.

§64-57-7. Limitations on License and Use of Titles by Health Care Facilities.

7.1. Licensure as a clinical laboratory practitioner does not authorize the person to perform laboratory tests unless his or her clinical laboratory director has determined that the person is qualified by education, training, or experience to perform such tests.

7.2. Health care facilities may not use the terms clinical laboratory practitioner, medical laboratory technician, cytotechnologist, point of care technician, pathologist assistant, histologist, or medical laboratory scientist, or abbreviations thereof, to refer to a person who is not licensed as a clinical laboratory practitioner in accordance with this rule.

§64-57-8. Revocation and Non-issuance of Clinical Laboratory Practitioner Licenses.

A clinical laboratory practitioner license shall not be issued or shall be revoked if the applicant for or holder thereof:

8.1. Has misrepresented material facts in an application or has assisted another person in doing so;

8.2. Does not meet the requirements for licensure; or

8.3. Has been found to have intentionally falsified laboratory results or to have engaged in negligent laboratory practices.

8.4. The secretary may consider reinstatement of a license which has been revoked upon a showing that the applicant can provide proof of meeting the license requirements of this rule: *Provided*, That no reinstatement shall be available for revocation of a license pursuant to subsection 8.3.

§64-57-9. Hearings.

9.1. A request for a hearing may be made to the secretary by an applicant for a clinical laboratory practitioner license, by a holder thereof, or by a health care facility. The request shall specify the grounds relied upon as a basis for the relief requested.

9.2. Hearings shall be conducted in accordance with the provisions of W. Va. Code §§ 29A-5-1 *et seq.*, and Bureau's Rules of Procedure for Contested Case Hearings and Declaratory Rulings, 64CSR1.