

**WEST VIRGINIA
SECRETARY OF STATE
NATALIE E. TENNANT
ADMINISTRATIVE LAW DIVISION**

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OFFICE WEST VIRGINIA
SECRETARY OF STATE

NOTICE OF RULE MODIFICATION OF A PROPOSED RULE

AGENCY: DIHR - BUREAU FOR PUBLIC HEALTH TITLE NUMBER: 64

CITE AUTHORITY: WV Code §§ 16-1-4, 16-1-11 and 16-5J-10

AMENDMENT TO AN EXISTING RULE: YES NO

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 57

TITLE OF RULE BEING AMENDED: CLINICAL LABORATORY TECHNICIAN AND
TECHNOLOGIST LICENSURE AND CERTIFICATION

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: _____

TITLE OF RULE BEING PROPOSED: _____

THE ABOVE PROPOSED LEGISLATIVE RULES, FOLLOWING REVIEW BY THE LEGISLATIVE RULE MAKING REVIEW COMMITTEE, IS HEREBY MODIFIED AS A RESULT OF REVIEW AND COMMENT BY THE LEGISLATIVE RULE MAKING REVIEW COMMITTEE. THE ATTACHED MODIFICATIONS ARE FILED WITH THE SECRETARY OF STATE.


Authorized Signature

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TITLE 64
LEGISLATIVE RULE
~~DIVISION OF~~ BUREAU FOR PUBLIC HEALTH

OFFICE WEST VIRGINIA
SECRETARY OF STATE

SERIES 57
CLINICAL LABORATORY TECHNICIAN AND
TECHNOLOGIST LICENSURE AND CERTIFICATION

§64-57-1. General.

1.1. Scope. -- This legislative rule sets forth standards and procedures for the licensing of laboratory technicians and laboratory technologists as 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. -- ~~March 30, 1998.~~

1.4. Effective Date. -- ~~July 1, 1998.~~

~~1.5. Supersession of Former Rule. — This rule amends and reenacts Clinical Laboratory Technician and Technologist Licensure and Certification, 64 CSR 57, effective August 1, 1997.~~

~~1.6. 1.5. Applicability. -- Except as otherwise provided in this rule, this rule applies to:~~

~~1.6.a. 1.5.a. Clinical laboratory practitioners employed as such in West Virginia who perform non-waived clinical laboratory tests as defined in section 42 CFR 493.17 of the Clinical Laboratory Improvement Amendment of 1988 (CLIA-88), including individuals employed as clinical laboratory practitioners in agencies or organizations exempted from licensure as a laboratory under the provisions of W. Va. Code §16-5J-7, i.e., county health departments organized under W. Va. Code §§16-2-1 et seq. or 16-2A-1 et seq.; primary health care centers having tax exempt status and receiving contributions which are deductible to the contributor under provisions of federal law; or any laboratory operated solely for research or teaching purposes; and~~

~~1.6.b. 1.5.b. Clinical laboratory consultants, directors, and supervisors in West Virginia.~~

~~1.7. 1.5.c. This rule does not apply to:~~

~~1.7.a. 1.5.c.1. Any individual who performs only laboratory tests published in the Federal Register as waived under CLIA by the Centers for Disease Control under the provisions of § 42 CFR 493.17;~~

~~1.7.b. 1.5.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) - (d);~~

~~1.7.c. 1.5.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; or

~~1.7.d.~~ 1.5.c.4. Any individual who performs laboratory tests only on himself or herself or members of his or her family.

~~1.8.~~ 1.6. Enforcement. -- This rule is enforced by the secretary of the West Virginia department of health and human resources.

§ 64-57-2. Definitions.

2.1. Certified. -- As applied to an individual means that he or she:

2.1.a. Is certified as a medical laboratory technician or medical technologist/medical laboratory scientist/laboratory specialist by the ~~American Medical Technologists~~ or the American Society of Clinical Pathologists (ASCP) Board of Certification;

2.1.b. Is certified as a ~~clinical~~ laboratory technician or scientist by the National Certification Agency for Medical Laboratory Personnel or is certified as a medical laboratory technologist or as a laboratory technician by ~~Credentiaing~~ Commission of the International Society for Clinical Laboratory Technology the American Medical Technologists (AMT);

2.1.c. Is certified as a clinical laboratory technician or clinical laboratory ~~technologist~~ scientist by the organization formerly known as the National Certification Agency for Medical Laboratory Personnel prior to combining with ASCP under the Medicare/CLIA certification requirements in effect prior to March 14, 1990; or

2.1.d. Was performing ~~laboratory technologist or laboratory technician~~ tasks in a clinical laboratory in West Virginia on or before July 7, 1989. Is certified as a medical technologist or a medical laboratory technician by the American Association of Bioanalysts (AAB) formerly known as the International Society for Clinical Laboratory Technology (ISCLT);

2.1.e. Is certified as a laboratory technician or laboratory technologist under the Medicare/CLIA certification requirements in effect prior to March 14, 1990; or

2.1.f. Was performing laboratory technologist or laboratory technician tasks in a clinical laboratory in West Virginia on or before July 7, 1989.

2.2. CLIA. -- Clinical Laboratory Improvement Amendments of 1988, (~~Public Law 100-578~~) to Section 353 of the Public Health Service Act, 42 CFR Part 493, Revised October 1, 2006 (Title 42 United States Code Section 263a).

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 directors of:

2.5.b.1. Moderate complexity testing laboratories found at 42 CFR § 493.1405; or

2.5.b.2. High complexity testing laboratories found at 42 CFR § 493.1443.

2.6. Clinical Laboratory Practitioner. -- A laboratory technician or a laboratory technologist. The term "clinical laboratory practitioner" includes laboratory technicians, point of care technicians, cytotechnologists, and laboratory technologists, but does not include: clinical laboratory practitioner trainees; clinical laboratory directors, consultants, or supervisors whose job tasks do not include processing specimens, or performing or reporting laboratory tests; or physicians licensed under W. Va. Code §§30-3-1 et seq. or 30-14-1 et seq. who perform laboratory tests only on their own patients.

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. Contact Hours. -- The actual number of hours an individual participates in continuing education. Ten (10) contact hours equal one (1) continuing education unit.

2.10. 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.

2.11. Department. -- The West Virginia department of health and human resources.

2.12. Health Care Facility. -- An entity subject to licensure as a:

2.12.a. Birthing center under W. Va. Code §16-2E-1 et seq.;

2.12.b. Hospital or extended care facility operated in connection with a hospital, or an ambulatory surgical facility, or an ambulatory health care facility, including a medical adult day care center under W. Va. Code §16-5B-1 et seq.;

- 2.12.c. Nursing home or personal care home under W. Va. Code §16-5C-1 et seq.;
- 2.12.d. Residential board and care home under W. Va. Code §§ 16-5C-1 et seq. and 16-5H-1 et seq.;
- 2.12.e. Hospice under W. Va. Code §16-5I-1 et seq.;
- 2.12.f. Clinical laboratory under W. Va. Code §16-5J-1 et seq.;
- 2.12.g. Hospital, center or facility for the care and treatment of the mentally ill or mentally retarded, or for the prevention of such disorders under W. Va. Code §27-9-1 et seq.; or
- 2.12.h. Group residential facility for the developmentally disabled or behaviorally disabled under W. Va. Code §27-17-1 et seq.

2.13. Laboratory Technician or 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. Laboratory Technologist or Medical Technologist (CLP-MT). -- 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. 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-88, and shall perform testing under the personal supervision of a clinical laboratory director or a clinical laboratory supervisor. This supervision shall be available to the point-of-care-technician at all times when testing is being performed.

§64-57-3. Incorporation by Reference.

The following provisions of the October 1, ~~1996~~ 2006, edition of 42 CFR Part 493, Laboratory Requirements 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 § 493.1443;

3.7. 42 CFR § 493.1449;

3.8. 42 CFR § 493.1455;

3.9. 42 CFR § 493.1461; and

3.10. 42 CFR § 493.1469.

§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 clinical laboratory practitioner trainee may not perform laboratory testing as a trainee for more than one (1) year. Renewal of the trainee period may be issued on a year-to-year basis at the discretion of the department upon submission of an explanation satisfactory to the department for the applicant's failure to become licensed within the previous one year period. In no case will renewals be extended beyond three years after the original one year period.

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

5.1. General. -- Applicants for licensure as a clinical laboratory practitioner - laboratory technologist, a clinical laboratory practitioner - laboratory technician, a clinical laboratory practitioner - cytotechnologist, or a clinical laboratory practitioner - point of care technician shall submit to the secretary:

5.1.a. A completed application form supplied by the secretary with documentation required by this rule;

5.1.b. Documentation of the applicant's competency in the specialties or subspecialties of laboratory tests for which the applicant has been trained and is currently competent to perform. If the applicant is currently employed as a clinical laboratory practitioner, the documentation shall consist of a statement obtained from and signed by the applicant's laboratory director which identifies these specialties or subspecialties of laboratory tests. The evaluation of competency shall include consideration of the applicant's performance in any proficiency testing programs. If the applicant is not currently employed as a clinical laboratory practitioner, the documentation shall be adequate to identify and verify the specialty or specialties of laboratory tests for which the applicant has been trained and has previously performed; and

5.1.c. The annual licensure fee of \$25 per person shown on the application as authorized by W. Va. Code §16-5J-10 and any other special circumstance fees as outlined in subsection 5.9. of this section.

5.2. Clinical Laboratory Practitioner - Laboratory Technologist (CLP-MT). -- A person seeking licensure as a clinical laboratory practitioner - laboratory technologist shall, at the time of application for initial licensure as a clinical laboratory practitioner - laboratory technologist, apply for a license on the form provided by the secretary and submit documentation to establish that he or she meets one (1) of the following qualifications:

5.2.a. He or she is certified as defined in Subsection 2.1 of this rule;

5.2.b. He or she has earned a bachelor's degree in medical technology, and has passed a national certification examination administered by a certifying agency recognized under subsection 2.1 of this rule; or

5.2.c. He or she has earned a bachelor's degree in a chemical, physical, or biological science other than medical technology, and, in addition, has at least one (1) year of pertinent full-time experience or training, or both, designed to provide him or her the following with respect to the specialties or subspecialties he or she will perform:

5.2.c.1. The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens;

5.2.c.2. The skills required for implementing all standard laboratory procedures;

5.2.c.3. The skills required for performing each test method and for proper instrument use;

5.2.c.4. The skills required for performing preventive maintenance, trouble shooting and calibration procedures related to each test performed;

5.2.c.5. A working knowledge of reagent stability and storage;

5.2.c.6. The skills required to implement the quality control policies and procedures of the laboratory;

5.2.c.7. An awareness of the factors that influence test results; and

5.2.c.8. The skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results.

5.3. Clinical Laboratory Practitioner - Laboratory Technician (CLP-MLT). -- A person seeking licensure as a clinical laboratory practitioner - laboratory technician shall, at the time of application for initial licensure as a clinical laboratory practitioner - laboratory technician apply on the form provided by the secretary, and submit documentation sufficient to establish that he or she:

5.3.a. Is certified as defined in subsection 2.1 of this rule;

5.3.b. Has earned an associate degree in medical technology, and has passed a national certification examination administered by a certifying agency recognized under subsection 2.1 of this rule; or

5.3.c. Has successfully completed sixty (60) semester hours of academic credit at an accredited institution, including chemistry, biology, and a structured curriculum in medical laboratory techniques, and has at least one (1) year of pertinent full-time experience or training, or both, designed to provide him or her the following with respect to the specialities or subspecialties he or she will perform:

5.3.c.1. The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens;

5.3.c.2. The skills required for implementing all standard laboratory procedures;

5.3.c.3. The skills required for performing each test method and for proper instrument use;

5.3.c.4. The skills required for performing preventive maintenance, trouble shooting and calibration procedures related to each test performed;

5.3.c.5. A working knowledge of reagent stability and storage;

5.3.c.6. The skills required to implement the quality control policies and procedures of the laboratory;

5.3.c.7. An awareness of the factors that influence test results; and

5.3.c.8. The skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results; or

5.3.d. Has an associate degree from an accredited institution based on a course of study including chemistry and biology, and has at least one (1) year of pertinent full-time experience, or training, or both, designed to comply with the requirements of Paragraphs 5.3.c.1 through 5.3.c.8 of this rule.

5.4. Clinical Laboratory Practitioner - Cytotechnologist (CLP-CT). -- A person seeking licensure as a clinical laboratory practitioner - cytotechnologist shall, at the time of application for initial licensure as a clinical laboratory practitioner - cytotechnologist, apply for licensure on the form provided by the secretary and submit documentation to establish that he or she:

5.4.a. Is certified as defined in Subsection 2.1 of this rule;

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

5.5. Clinical Laboratory Practitioner - Point of Care Technician (CLP-POCT). --

5.5.a. A person seeking licensure as a clinical laboratory practitioner - point of care technician shall, at the time of application for initial licensure as a clinical laboratory practitioner - point of care technician, apply on the form provided by the secretary, and submit documentation to establish that he or she:

5.5.a.1. Is certified as defined in Subsection 2.1 of this rule; or

5.5.a.2. Has at least a high school diploma, a general education development certificate (GED), or an equivalent approved by the State department of education;

5.5.a.3. Is employed in a clinical laboratory which holds a CLIA certificate other than a certificate of waiver; and

5.5.a.4. Submits with the application a statement obtained from and signed by his or her laboratory director which states that the applicant has had training designed to provide him or her the following with respect to the specific tests he or she will perform:

5.5.a.4.A. The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens;

5.5.a.4.B. The skills required for implementing all standard laboratory procedures;

5.5.a.4.C. The skills required for performing each test method and for proper instrument use;

5.5.a.4.D. The skills required for performing preventive maintenance, trouble shooting and calibration procedures related to each test performed;

5.5.a.4.E. A working knowledge of reagent stability and storage;

5.5.a.4.F. The skills required to implement the quality control policies and procedures of the laboratory;

5.5.a.4.G. An awareness of the factors that influence test results; and

5.5.a.4.H. The skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results.

5.5.b. 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 as required by paragraphs 5.5.a.4.A through 5.5.a.4.H of this ~~rule~~ section.

5.6. Initial License. -- If an applicant complies with Subsection 5.1 of this ~~rule~~ section, the secretary shall grant licensure as follows:

5.6.a. A clinical laboratory practitioner - technologist license to an applicant who complies with the requirements of Subsection 5.2 of this ~~rule~~ section;

5.6.b. A clinical laboratory practitioner - technician license to an applicant who complies with the requirements of Subsection 5.3 of this ~~rule~~ section;

5.6.c. A clinical laboratory practitioner - cytotechnologist license to an applicant who complies with the requirements of Subsection 5.4 of this ~~rule~~ section; or

5.6.d. A clinical laboratory practitioner - point of care technician license to an applicant who complies with the requirements of Subsection 5.5 of this ~~rule~~ section.

5.7. Renewal License.

5.7.a. 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 ten (10) contact hours (one (1) continuing education unit) of educational 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, activities such as: lectures, seminars, workshops, formal classes, in-service programs or correspondence courses.

5.7.b. The secretary shall renew a license if the applicant submits the licensure fee, a completed application form and otherwise is in compliance with the requirements of this rule.

5.8. Term of License. -- A clinical laboratory practitioner license expires one (1) year after the date it was issued.

5.8.a. A license which has lapsed or been inactive for more than five years may not be reinstated through renewal.

5.8.b. 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.

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

5.9.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.

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

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

5.9.d. A same-day "emergency" issuance fee of \$35 for processing and issuance of license requested by the licensee or management to be issued within a 24 hour turn-around time.

5.9.e. A state licensure penalty of \$40 per non-licensed or lapsed licensed testing personnel found during the CLIA survey process for non-compliance with federal CLIA-88 Personnel Requirements, 42 CFR 493.1489 or 493.1423, failure to possess a current license issued by the state.

5.9.f. A \$10 fee for issuing an official licensure source verification on paper as opposed to using the electronic verification system available online at www.wvdhhr.org/labservices at no charge. In the event that the electronic system is non-functional, no charge will be applied for a paper verification.

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

§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 which 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 shall not use the terms clinical laboratory practitioner, laboratory or medical technician, cytotechnologist, point of care technician, or laboratory or medical technologist, or abbreviations thereof, to refer to a person who is not licensed as a clinical laboratory practitioner.

§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 convicted of a felony involving 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 any person convicted of a felony involving laboratory practices in subsection 8.3. of this section.

§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 Rules of Procedure for Contested Case Hearings and Declaratory Rulings, West Virginia Administrative Rules, 64 CSR 1.