



WEST VIRGINIA SECRETARY OF STATE

KRIS WARNER

ADMINISTRATIVE LAW DIVISION

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Office of West Virginia
Secretary Of State

**NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE AND FILING WITH THE LEGISLATIVE RULE-
MAKING REVIEW COMMITTEE**

AGENCY: Health TITLE-SERIES: 64-57
RULE TYPE: Legislative Amendment to Existing Rule: Yes Repeal of existing rule: No
RULE NAME: 64-57 Clinical Laboratory Practitioner Licensure and Certification

PRIMARY CONTACT

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CITE STATUTORY AUTHORITY: W. Va. Code §16-1-4, §16-1-11, and §16-5J-10

EXPLANATION OF THE STATUTORY AUTHORITY FOR THE LEGISLATIVE RULE, INCLUDING A DETAILED SUMMARY OF THE EFFECT OF EACH PROVISION OF THE LEGISLATIVE RULE WITH CITATION TO THE SPECIFIC STATUTORY PROVISION WHICH EMPOWERS THE AGENCY TO ENACT SUCH RULE PROVISION:

W. Va. Code §16-1-4 authorizes the promulgation of legislative rules.

IS THIS FILING SOLELY FOR THE SUNSET PROVISION REQUIREMENTS IN W. VA. CODE §29A-3-19(e)? No

IF YES, DO YOU CERTIFY THAT THE ONLY CHANGES TO THE RULE ARE THE FILING DATE, EFFECTIVE DATE AND AN EXTENSION OF THE SUNSET DATE? No

DATE eFiled FOR NOTICE OF HEARING OR PUBLIC COMMENT PERIOD: 6/23/2025

DATE OF PUBLIC HEARING(S) OR PUBLIC COMMENT PERIOD ENDED: 7/23/2025

COMMENTS RECEIVED: No

(IF YES, PLEASE UPLOAD IN THE COMMENTS RECEIVED FIELD COMMENTS RECEIVED AND RESPONSES TO COMMENTS)

PUBLIC HEARING: No

(IF YES, PLEASE UPLOAD IN THE PUBLIC HEARING FIELD PERSONS WHO APPEARED AT THE HEARING(S) AND TRANSCRIPTS)

RELEVANT FEDERAL STATUTES OR REGULATIONS: No

WHAT OTHER NOTICE, INCLUDING ADVERTISING, DID YOU GIVE OF THE HEARING?

N/A

SUMMARY OF THE CONTENT OF THE LEGISLATIVE RULE, AND A DETAILED DESCRIPTION OF THE RULE'S PURPOSE AND ALL PROPOSED CHANGES TO THE RULE:

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 healthcare facilities. The rule contains technical amendments and various other amendments to align with current federal guidance.

STATEMENT OF CIRCUMSTANCES WHICH REQUIRE THE RULE:

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 healthcare facilities. The rule contains technical amendments and various other amendments to align with current federal guidance.

SUMMARIZE IN A CLEAR AND CONCISE MANNER THE OVERALL ECONOMIC IMPACT OF THE PROPOSED LEGISLATIVE RULE:

A. ECONOMIC IMPACT ON REVENUES OF STATE GOVERNMENT:

N/A

B. ECONOMIC IMPACT ON SPECIAL REVENUE ACCOUNTS:

N/A

C. ECONOMIC IMPACT OF THE LEGISLATIVE RULE ON THE STATE OR ITS RESIDENTS:

N/A

D. FISCAL NOTE DETAIL:

Effect of Proposal	Fiscal Year		
	2025 Increase/Decrease (use "-")	2026 Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost	0	0	0
Personal Services	0	0	0
Current Expenses	0	0	0
Repairs and Alterations	0	0	0
Assets	0	0	0
Other	0	0	0
2. Estimated Total Revenues	0	0	0

E. EXPLANATION OF ABOVE ESTIMATES (INCLUDING LONG-RANGE EFFECT):

N/A

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

Yes

Virginia M Payne -- 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
DEPARTMENT OF HEALTH
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~~ healthcare 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~~ 2031.

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

~~1.6.a.~~ 1.6.1. Clinical laboratory practitioners who perform ~~non-waived~~ moderate or high complexity clinical laboratory tests as ~~defined by~~ categorized pursuant to the criteria established in 42 CFR 493.17 of the Clinical Laboratory Improvement Amendments of 1988 (CLIA); and

~~1.6.b.~~ 1.6.2. Clinical laboratory consultants, directors, supervisors, or testing personnel not otherwise excluded in subsection 1.6.3. who perform ~~non-waived~~ moderate or high complexity testing or manipulate and report data obtained from laboratories in West Virginia.

~~1.6.c.~~ 1.6.3. This rule does not apply to:

~~1.6.c.1.~~ 1.6.3.a. 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;~~ categorized as waived under the criteria set forth in 42 CFR 493.17 and approved by the FDA pursuant to 42 U.S.C. §263a for use in a waived setting;

~~1.6.c.2.~~ 1.6.3.b. 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 within the scope of their professional license as found at pursuant to 42 CFR 493.19 (a) — (e);

~~1.6.c.3.~~ 1.6.3.c. Any respiratory care provider licensed within the state ~~providing diagnostic testing within the scope of his or her professional license~~ who performs moderate complexity blood gas and/or hemoximetry testing as follows: defined by CLIA, pursuant to 42 CFR 493.17;

1.6.3.c.1. Blood gases are limited to pH, pCO₂, pO₂, and sO₂;

1.6.3.c.2. Oximetry is limited to total hemoglobin, hemoglobin fractions, and hematocrit; and

1.6.3.c.3. Calculations derived from the listed tests may be reported.

~~1.6.c.4.~~ 1.6.3.d. An individual who performs laboratory tests only on himself or herself or members of his or her family;

~~1.6.c.5.~~ 1.6.3.e. An individual employed as a clinical laboratory practitioner in an agency or organization exempt from licensure or CLIA certification in accordance with ~~W. Va. Code §16-5j-7~~ 42 CFR 493.3;

~~1.6.c.6.~~ 1.6.3.f. A medical doctor, doctor of osteopathy, or ~~podiatrist~~ doctor of podiatry licensed to practice ~~that profession~~ medicine, osteopathy, or podiatry in West Virginia;

~~1.6.c.7.~~ 1.6.3.g. 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;~~

1.6.3.h. A clinical laboratory consultant, director, or supervisor who is not otherwise subject to one of the exceptions set forth in subsection 1.6.3. and does not perform nonwaived testing or manipulate and report data obtained from laboratories in the state; and

1.6.3.i. An individual who strictly performs specimen collection, preparation, or processing but does not perform tests. These procedures may include, but are not limited to, accessioning aliquoting specimens into secondary containers and embedding, cutting, and staining paraffin block samples.

1.6.4. Laboratories that employ exempt testing personnel are directly responsible for verifying that the individual's education, certification, and experience meet the minimum CLIA requirements for testing personnel set forth in 42 CFR 493.1423 and 42 CFR 493.1489, and maintaining documentation for inspection purposes. Laboratories must also maintain qualification documents for licensed individuals for inspection purposes.

1.7. Prohibition -- No person may perform any duty of a licensed clinical laboratory practitioner in the state, except where exempted in subsection 1.6.3., unless he or she is licensed by the Secretary as a clinical laboratory practitioner.

~~1.7.~~ 1.8. 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 -- Certifying agency means one of the following institutions:

- ~~2.1.a.~~ 2.1.1. American Society for Clinical Pathology (ASCP);
- ~~2.1.b.~~ 2.1.2. American Medical Technologists (AMT);
- ~~2.1.c.~~ 2.1.3. American Association of Bioanalysts (AAB);
- ~~2.1.d.~~ 2.1.4. American Board of Bioanalysts (ABB);
- ~~2.1.e.~~ 2.1.5. American Board of Clinical Chemistry (ABCC);
- ~~2.1.f.~~ 2.1.6. American Board of Forensic Toxicology (ABFT);
- ~~2.1.g.~~ 2.1.7. American Board of Medical Genetics and Genomics (ABMGG);
- ~~2.1.h.~~ 2.1.8. American Board of Medical Laboratory Immunology (ABMLI);
- ~~2.1.i.~~ 2.1.9. American Board of Medical Microbiology (ABMM);
- ~~2.1.j.~~ 2.1.10. American College of Histocompatibility and Immunogenetics (ACHI); and
- ~~2.1.k.~~ 2.1.11. 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~~
A facility certified by CLIA to perform clinical testing for the purpose of determining, measuring, or otherwise describing the presence or absence of various substances or organisms in the body 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.~~ 2.4.1. Moderate complexity testing technical consultant found at 42 CFR 493.1411;
- ~~2.4.b.~~ 2.4.2. Moderate complexity testing clinical consultant found at 42 CFR 493.1417; or
- ~~2.4.c.~~ 2.4.3. High complexity testing clinical consultant found at 42 CFR 493.1455.

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

- ~~2.5.a.~~ 2.5.1. Provides overall management and direction of a clinical laboratory; and
- ~~2.5.b.~~ 2.5.2. Meets the qualifications for:

~~2.5.b.1.~~ 2.5.2.a. Moderate complexity testing laboratory director found at 42 CFR 493.1405;
or

~~2.5.b.2.~~ 2.5.2.b. High complexity testing laboratory director found at 42 CFR 493.1443.

2.6. Clinical Laboratory Practitioner. -- Includes ~~medical laboratory technicians~~ high complexity testing personnel, 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.~~ 2.7. Clinical Laboratory Supervisor. -- A person who meets the qualifications for:

~~2.8.a.~~ 2.7.1. A high complexity testing technical supervisor found at 42 CFR 493.1449;

~~2.8.b.~~ 2.7.2. A high complexity testing general supervisor found at 42 CFR 493.1461; or

~~2.8.c.~~ 2.7.3. A high complexity testing cytology general supervisor found at 42 CFR 493.1469.

2.8. Commission on Accreditation of Allied Health Programs (CAAHEP) -- The accrediting organization for cytology educational programs, recognized by the Council for Higher Education Accreditation.

~~2.9.~~ 2.9. Cytotechnologist (CT). -- ~~A type of laboratory technologist practitioner meeting CLIA requirements set forth in 42 CFR 493.1483 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 who performs the responsibilities set forth in 42 CFR 493.1485, which include examining and interpreting cytology slide preparations under the supervision of a cytology technical or general supervisor and documenting the number of slides reviewed and hours spent examining slides in each 24-hour period.~~

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

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

2.12. High Complexity Testing Personnel (HCTP). -- A laboratory practitioner meeting CLIA requirements set forth in 42 CFR 493.1489 who performs the responsibilities set forth in 42 CFR 493.1495, which include a broad range of high complexity tests and other tasks requiring the exercise of judgment and responsibility, commensurate with the individual's education, training, or experience in a clinical laboratory.

~~2.12.~~ 2.13. Histologist (CLP-HT H) -- A laboratory ~~technologist or technician~~ practitioner 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.~~ 2.14. Laboratory Test. -- The ~~biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other clinical~~ 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.

~~2.14. 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. 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.~~

~~2.16.~~ 2.15. 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.~~ 2.16 Pathologist Assistant (CLP-PA) -- A ~~type of advanced practice laboratory technologist practitioner with advanced education and training who processes a~~ performs a variety of pathology ~~tests, specimens,~~ including comprehensive macroscopic examination and evaluation (grossing) of surgical pathological specimens, under the supervision of a pathologist.

~~2.18.~~ 2.17. Point of Care Technician (CLP-POCT). -- A ~~type of laboratory technician practitioner meeting CLIA requirements set forth in 42 CFR 493.1423 to perform moderate complexity tests commensurate with the individual's education, training or experience, and technical abilities set forth in 42 CFR 493.1425 in a clinical laboratory under the supervision of a clinical laboratory director, consultant, or supervisor. 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~~ Supervision shall be available at all times when testing is being performed.

2.18. Trainee (T) -- An individual who has obtained appropriate education to perform high-complexity laboratory testing but lacks the required certification and/or experience for a regular HCTP license. Trainees may only perform tests under the personal supervision of a clinical laboratory director, consultant, or supervisor. Supervision must be available at all times when testing is being performed.

§64-57-3. Incorporation by Reference.

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

3.1.1. 42 CFR 493.3;

~~3.1.~~ 3.1.2. 42 CFR 493.17;

~~3.2.~~ 3.1.3. 42 CFR 493.19 (a) — (d);

- ~~3.3.~~ 3.1.4. 42 CFR 493.1405;
- ~~3.4.~~ 3.1.5. 42 CFR 493.1411;
- ~~3.5.~~ 3.1.6. 42 CFR 493.1417;
- ~~3.6.~~ 3.1.7. 42 CFR 493.1423;
- 3.1.8. 42 CFR 493.1425;
- ~~3.7.~~ 3.1.9. 42 CFR 493.1443;
- ~~3.8.~~ 3.1.10. 42 CFR 493.1449;
- ~~3.9.~~ 3.1.11. 42 CFR 493.1455;
- ~~3.10.~~ 3.1.12. 42 CFR 493.1461;
- ~~3.11.~~ 3.1.13. 42 CFR 493.1469;
- ~~3.12.~~ 3.1.14. 42 CFR 493.1483; and
- 3.1.15. 42 CFR 493.1485;
- ~~3.13.~~ 3.1.16. 42 CFR 493.1489-; and
- 3.1.17. 42 CFR 493.1495.

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

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. A~~ license shall only be issued to an individual currently residing in the United States unless he or she can provide documentation of sponsorship and a valid contract to perform laboratory testing at a facility in the state. Licenses will be issues directly to the sponsoring agency or employer.

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. Students in a clinical laboratory training program must obtain a T license before beginning clinical rotations within the State.~~

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. Individuals may not obtain clinical training, perform laboratory tests, or report results until the appropriate license is obtained.~~

§64-57-5. ~~Licensure Requirements, Duration, Renewal.~~ Documentation, Qualifications, Renewal, License Duration, and Fees.

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. 5.1.1. Documentation of the applicant's qualifying education and certification or documentation of other substitute qualification as permitted by this section.~~ Initial applications must include documentation of the applicant's credentials applicable to the license type as outlined in this section.

5.1.1.a. All initial applications must be accompanied by documentation of education obtained. If the relevant education was obtained in a post-secondary setting, a transcript is required.

5.1.1.a.1. If the relevant education was obtained outside of the United States, the applicant must provide documentation that each course and degree was verified for equivalency by a foreign equivalency evaluation service.

5.1.1.b. Documentation of training and experience received must be provided by the method determined by the Secretary at the time of application.

~~5.1.b. 5.1.1.c. The applicant's job description or education program description for which certification is sought by the applicant; and~~ All documentation relating to education, training, and experience must identify the applicant and the issuing entity.

~~5.1.c. 5.1.3. The annual licensure license 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~~ subsection 5.10.

~~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)—~~ Upon initial application for a HCTP license, the applicant shall provide documentation to establish that he or she qualifies via one of the following routes:

~~5.2.a. 5.2.1. 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~~ Has earned an associates, bachelors, masters, or doctoral degree, or completed post-baccalaureate training in laboratory technology/science at a National Accrediting Agency for Clinical Laboratory Science (NAACLS) accredited program, or has earned a bachelors, masters, or doctoral degree, or equivalent as defined by CLIA, in a chemical or biological science from an accredited institution; and

5.2.1.a. Has obtained certification from a certifying agency identified in subsection 2.1 of this rule; or

5.2.1.b. Has obtained at least one year of documented training and/or experience in a laboratory certified by CLIA to perform high complexity testing that provided the skills necessary to accurately perform testing. A minimum of three months of training or experience must have been obtained within each specialty or subspecialty of testing performed. Training in each specialty may be obtained simultaneously or consecutively.

~~5.2.b. 5.2.2. Was previously certified as a medical laboratory technician by a certifying agency recognized under subsection 2.1; and Has successfully completed 60 semester hours of academic credit at an accredited institution which includes, 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 additional semester hours of chemistry, biology, or medical laboratory technology/medical laboratory science, in any combination; and~~

~~5.2.b.1. 5.2.3. Obtained a bachelor's degree from an accredited institution; and Has obtained at least one year of documented training and/or experience in a laboratory certified by CLIA to perform high complexity testing that provided the skills necessary to accurately perform testing. A minimum of three months of training and/or experience must have been obtained within each specialty or subspecialty of testing performed. Training in each specialty may be obtained simultaneously or consecutively; or~~

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

~~5.2.c. 5.2.4. 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. Has successfully completed an official United States military medical laboratory procedures training course at least 50 weeks in duration and has enlisted in the military as a Medical Laboratory Specialist (Laboratory Technician).~~

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) Upon initial application for a CT license, the applicant must provide documentation sufficient to establish that he or she~~ qualifies via one of the following routes:

~~5.3.a. 5.3.1. 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 graduated from a school of cytotechnology accredited by the CAAHEP; or~~

~~5.3.b. 5.3.2. Has earned an associate degree from an accredited institution in a chemical, physical, or biological science other than medical technology/medical laboratory science, and, 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-obtained certification as a CT from a certifying agency identified in subsection 2.1. of this rule.~~

~~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~~ Upon initial application for a PA license, the applicant shall provide documentation to establish that he or she has graduated from a NAACLS accredited pathologist assistant program and obtained certification as a pathologist's assistant from a certifying agency identified in subsection 2.1 of this rule.

~~5.4.a. Has graduated from a school of cytotechnology accredited by the Commission on Accreditation of Allied Health Education Programs (CAAHEP), 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 he or she has met one of the substitute criteria permitted by CLIA for testing personnel,~~ Upon initial application for a Clinical Laboratory Practitioner—Pathologist Assistant (CLP-PA) H license, the applicant shall provide documentation to establish that he or she qualifies via the following route:

~~5.5.a. 5.5.1. Has graduated from a Pathologist Assistant program accredited by NAACLS~~ Meets the education requirements set forth in subsection 5.2.1. or subsection 5.2.2. of this rule, at a minimum; and

5.5.1.a. Obtained certification as a histotechnologist or histotechnician from a certifying agency identified in subsection 2.1. of this rule; or

5.5.1.b. 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.

~~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) Upon initial application for a POCT license, the applicant shall provide documentation to establish that he or she qualifies via the following route:~~

~~5.6.a. 5.6.1. Meets requirements under §493.1489 of CLIA for high complexity testing personnel~~ Has at least a high school diploma or equivalent approved by the state department of education, and

~~5.6.b. 5.6.2. Has passed a national histotechnologist or histotechnician certification examination administered by a certifying agency enumerated in subsection 2.1 of this rule; or Is employed or offered employment in a clinical laboratory certified by CLIA to perform moderate or high-complexity testing; and~~

~~5.6.c. 5.6.3. 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~~ written verification from the laboratory director or designee that the applicant will receive training designed to provide the skills required by CLIA with respect to the specific moderate complexity tests he or she will perform.

5.6.4. In the event that a POCT licensee performs tests in addition to those that he or she was initially trained to perform, the employer shall provide documentation of the relevant additional training.

5.7. Clinical Laboratory Practitioner—Point of Care Technician (CLP-POCT) Upon initial application for a T license, the applicant shall provide documentation to establish that he or she qualifies via one of the following routes:

5.7.a. 5.7.1. Has at least a high school diploma, a general education development certificate (GED), or equivalent approved by the State department of education; Is employed or offered employment in a clinical laboratory certified by CLIA to perform high complexity testing; and

5.7.b. 5.7.2. Is employed in a clinical laboratory which holds a CLIA certificate other than a certificate of waiver Meets one or more of the education requirements set forth in subsections 5.2.1. or 5.2.2. of this rule; and

5.7.c. 5.7.3. 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. Has not met the certification or training requirements listed in subsections 5.2.1.a., 5.2.1.b., and 5.2.2.a. of this rule; or

5.7.d. 5.7.4. 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 Is a student attending a NAACLS-accredited laboratory training program.

5.7.5. A T 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.

5.8. A Clinical Laboratory Practitioner—Trainee trainee (CLP-T) applicant shall provide documentation to establish that he or she: An applicant for renewal of either a current or an expired license shall submit a renewal application, licensure fees required by subsection 5.10. of this rule, and documentation of at least 10 hours of continuing education commensurate with the level of complexity of testing the individual performs, completed following the issuance of the most recent license. Acceptable continuing educational activities may include, but are not limited to, laboratory seminars, workshops, related college coursework, employer or vendor-provided in-service training, and credit-awarding continuing education courses.

5.8.a. 5.8.1. Is employed in a clinical laboratory which holds a CLIA certificate other than a certificate of waiver; and meets one of the following qualifications The following activities are not accepted for continuing education:

5.8.a.1. 5.8.1.a. Has earned an associate degree from an accredited institution in medical technology/medical laboratory science but has not met requirements for national certification; or Time spent conducting laboratory inspections as part of a survey team; and

5.8.a.2. 5.8.1.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

~~has less than one year of prior non-waived laboratory experience; or~~ Performance of proficiency testing unless continuing education credits are issued by the accrediting organization or proficiency testing provider.

~~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.a.6. 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.~~ 5.9. Term Duration 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 initial license as described in subsection 5.1. of this section rule.~~

~~5.11.~~ 5.10. ~~Fees applicable to requests for licenses under special circumstances:~~ Additional fees ~~shall be~~ are charged for the following:

~~5.11.a.~~ 5.10.1. A mandatory late fee of \$10 ~~per license~~ for licensee renewal ~~requests~~ applications that are ~~postmarked~~ submitted after the application due date ~~but before the license has lapsed.~~

~~5.11.b.~~ 5.10.2. A An optional fee of ~~\$20~~ \$10 ~~for~~ to print and mail a replacement license.

5.10.3. A mandatory fee of \$20 for reinstatement of a lapsed license.

~~5.11.c.~~ 5.10.4. ~~A fee of \$20 for reinstatement of a lapsed license.~~ Any fees required for the use of online licensing systems including, but not limited to, convenience fees, transaction fees, and payment processing fees, as set by and paid to the software vendor or financial institution.

~~5.11.d.~~ 5.10.5. An optional "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 to process an application or other request within three business days.~~

~~5.11.e.~~ 5.10.6 A penalty of \$100 ~~shall be~~ is assessed to any testing personnel ~~found to be unlicensed or whose license has lapsed~~ identified as not having a valid license during the CLIA survey process as a laboratory inspection, which is a violation of CLIA personnel requirements under 42 CFR 493.1423(a) and 493.1489(a). The penalty must be paid before a license can be issued or renewed.

~~5.11.f.~~ 5.10.7. 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.~~ 5.10.8. A fee of \$35 for payments returned due to non-sufficient funds.

§64-57-6. Reciprocity.

6.1. 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 initial application the license application fee, all required documentation, 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~~ Healthcare Facilities.

7.1. Licensure as a clinical laboratory practitioner does not authorize the person to perform laboratory tests ~~unless his or her clinical~~ until the CLIA laboratory director has determined that the person is qualified by education, training, or experience required by 42 CFR 493.1423, 42 CFR 493.1483, or 42 CFR 493.1489 to perform such tests.

7.2. ~~Health-care~~ Healthcare facilities may not use the terms ~~clinical laboratory practitioner, medical laboratory technician, cytotechnologist, point of care technician, pathologist assistant, histologist, or medical laboratory scientist, high complexity testing personnel~~ or abbreviations thereof, to refer to a person who is not licensed as a clinical laboratory practitioner ~~in accordance with this rule~~. A facility is not prohibited from using the designations, variations, or abbreviations of medical laboratory technician, medical technologist, medical laboratory scientist, pathologist assistant, or histologist to describe, classify, and compensate its employees if the individual holds a valid HCTP license. Each facility is responsible for determining its personnel qualifications, which must be at least as stringent as federal CLIA requirements and this rule.

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

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

~~8.1.~~ 8.1.1. Has misrepresented material facts in an application or has assisted another person in doing so;

~~8.2.~~ 8.1.2. Does not meet the requirements for licensure; or

~~8.3.~~ 8.1.3. Has been found to have intentionally falsified laboratory results or to have engaged in negligent laboratory practices.

~~8.4.~~ 8.2. The Secretary may consider reinstatement of a revoked license ~~which has been revoked upon a showing that if~~ the applicant can provide proof documentation of meeting the license requirements of this rule: *Provided*, That no reinstatement ~~shall be~~ is available for ~~revocation of a license revoked pursuant to subsection 8.3~~ subsections 8.1.1. and 8.1.3.

§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~~ healthcare 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.