WEST VIRGINIA SECRETARY OF STATE

MAC WARNER

ADMINISTRATIVE LAW DIVISION

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Office of West Virginia
Secretary Of State

NOTICE OF RULE MODIFICATION OF A PROPOSED RULE

AGENCY: Health

RULE TYPE: Legislative TITLE-SERIES: 64-57

RULE NAME: Clinical Laboratory Practitioner Licensure and Certification

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

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.

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

Yes

Michelle L Bradley -- 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 ~~TECHNICIAN AND~~ ~~SCIENTIST~~ PRACTITIONER 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 medical laboratory scientists 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. -- ~~May 22, 2017~~

1.4. Effective Date. -- ~~June 1, 2017~~

1.5 Sunset Provision. -- This rule shall terminate and have no further force or effect on ~~June 1, 2022~~ August 1, 2027.

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

1.6.a. Clinical laboratory practitioners ~~employed as such in West Virginia~~ who perform non-waived clinical laboratory tests as defined ~~in section~~ by 42 CFR 493.17 of the Clinical Laboratory Improvement Amendments 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;~~ and

1.6.b. Clinical laboratory consultants, directors, ~~and~~ 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) - ~~(d)~~(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; ~~or~~

1.6.c.4. ~~Any~~ 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;

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 ~~of Clinical Pathologists~~ for Clinical Pathology (ASCP);

2.1.b. ~~American~~ American Medical Technologists (AMT); ~~and~~

2.1.c. American Association of Bioanalysts (AAB) ~~formerly known as the International Society for Clinical Laboratory Technologists (ISCLT).~~;

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~~, Revised October 1, 2006~~ 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 ~~directors of~~:

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

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

2.6. Clinical Laboratory Practitioner. -- ~~A laboratory technician or a medical laboratory scientist. The term "clinical laboratory practitioner" includes laboratory technicians,~~ Includes medical laboratory technicians, point of care technicians, cytotechnologists, histologists, ~~and~~ medical laboratory scientists, pathologist assistants, and trainees. ~~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.~~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.

~~2.11.~~2.10. 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. Long term care facility as defined by W.Va. Code §16-5L-2(b);~~

~~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.*~~

2.11. 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. ~~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 Scientist or~~ 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.

~~2.16.~~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~~-88 and shall perform testing~~ under the personal supervision of a clinical laboratory director or a ~~clinical laboratory supervisor~~ technical consultant
. 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, 2006, edition 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;

~~3.6.~~3.7. 42 CFR 493.1443;

~~3.7.~~3.8. 42 CFR 493.1449;

~~3.8.~~3.9. 42 CFR 493.1455;

~~3.9.~~3.10. 42 CFR 493.1461; ~~and~~

~~3.10.~~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 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.~~

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 ~~as a clinical laboratory practitioner – medical laboratory scientist, 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:~~ 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. A completed application form supplied by the Secretary with documentation required by this rule;~~

~~5.1.b.~~5.1.a. Documentation of the applicant's qualifying education and certification or documentation of other substitute qualification as permitted by this section; ~~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.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 ~~outlined in subsection 5.9. of~~ required by this section.

5.1.d. ~~For the renewal of a license,~~ Applicants seeking license renewal shall provide evidence of the completion of the continuing education requirements contained in subsection ~~5.7.a~~ 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), ~~the~~ applicant~~. A person seeking licensure as a clinical laboratory practitioner – medical laboratory scientist~~ shall~~, at the time of application for initial licensure as a clinical laboratory practitioner – medical laboratory scientist, apply for a license on the form provided by the Secretary and submit~~ 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 ~~accredited institution~~ 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.b.~~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 ~~following~~ skills required by CLIA with respect to the specialties or subspecialties he or she will perform.

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

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

~~5.2.b.4. The skills required for performing preventive maintenance, troubleshooting and calibration procedures related to each test performed;~~

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

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

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

~~5.2.b.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~~

~~5.2.c. Has passed a proficiency examination for technologists given by the U.S. Department of Health and Human Services (HHS) between March 1, 1986 and December 31, 1987; or~~

~~5.2.d. On or before April 24, 1995, was:~~

~~5.2.d.1. Qualified under 42 CFR 493.1489(b)(5)(i); and~~

~~5.2.d.2. Performing high complexity testing.~~

~~5.2.e. Was licensed as a CLP-MT immediately preceding the effective date of this rule series and has complied with all of the applicable requirements of paragraphs 5.1.a through 5.1.d.~~

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~~. 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~~ 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 accredited institution~~ 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 ~~following~~ skills required by CLIA with respect to the specialties or subspecialties he or she will perform; or

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

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

~~5.3.b.4. The skills required for performing preventive maintenance, troubleshooting and calibration procedures related to each test performed;~~

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

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

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

~~5.3.b.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.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 ~~of paragraphs 5.3.b.1 through 5.3.b.8 of this rule~~. Applicants with an associate degree in medical technology/medical laboratory science are excluded from this provision~~; or~~.

~~5.3.d. On or before April 24, 1995, be a high school graduate or equivalent and have either:~~

~~5.3.d.1. Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA or other organization approved by HHS; or~~

~~5.3.d.2. Successfully completed an official US military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician).; or~~

~~5.3.e. On or before July 7, 1989, was performing, at least, moderate complexity tasks in a clinical laboratory.~~

~~5.3.f. Was licensed as a CLP-MLT immediately preceding the effective date of this rule series and has complied with all of the applicable requirements of paragraphs 5.1.a through 5.1.d.~~

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~~. 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~~ 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.

~~5.5.~~ 5.7. Clinical Laboratory Practitioner - Point of Care Technician (CLP-POCT). ~~—~~applicant shall provide documentation to establish that he or she:

~~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.~~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;

~~5.5.a.2.~~5.7.b. Is employed in a clinical laboratory which holds a CLIA certificate other than a certificate of waiver; and

~~5.5.a.3.~~5.7.c. ~~Submits with the application a statement obtained from and signed by his or her~~ Written verification from the laboratory director ~~which states~~ that the applicant has had training designed to provide ~~him or her~~ the ~~following~~ skills required by CLIA with respect to the specific tests he or she will perform.

~~5.5.a.3.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.3.B. The skills required for implementing all standard laboratory procedures;~~

~~5.5.a.3.C. The skills required for performing each test method and for proper instrument use;~~

~~5.5.a.3.D. The skills required for performing preventive maintenance, troubleshooting and calibration procedures related to each test performed;~~

~~5.5.a.3.E. A working knowledge of reagent stability and storage;~~

~~5.5.a.3.F. The skills required to implement the quality control policies and procedures of the laboratory;~~

~~5.5.a.3.G. An awareness of the factors that influence test results; and~~

~~5.5.a.3.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.~~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 ~~as required by subparagraphs 5.5.a.3.A. through 5.5.a.3.H. of~~ 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.

~~5.6. Initial License. If an applicant complies with subsection 5.1 of this section, the Secretary shall grant licensure as follows:~~

~~5.6.a. A clinical laboratory practitioner – scientist license to an applicant who complies with the requirements of subsection 5.2 of this section;~~

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

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

~~5.7. Renewal License.~~

~~5.7.a.~~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 ~~ten (10) contact hours (one (1) unit)~~ 10 continuing education hours 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.~~5.10. 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.~~5.11. Fees applicable to requests for licenses under special circumstances: Additional fees shall be charged for the following:

~~5.9.a.~~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.

~~5.9.b.~~5.11.b. A fee of $20 for a replacement license.

~~5.9.c~~5.11.c. A ~~$20~~ fee of $20 for reinstatement of a lapsed license.

~~5.9.d.~~5.11.d. An ~~same-day~~ "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.

~~5.9.e.~~5.11.e. A ~~state licensure~~ penalty of $100 shall be assessed to any testing personnel found to be unlicensed ~~per non-licensed~~ or whose license has lapsed ~~licensed testing personnel found~~ during the CLIA survey process as a violation of CLIA personnel requirements. ~~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.~~5.11.f. A fee of $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.~~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, ~~laboratory or~~ medical laboratory technician, cytotechnologist, point of care technician, pathologist assistant, histologist, ~~or laboratory~~ 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 convicted of a felony involving laboratory practices.~~ 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.~~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's Rules of Procedure for Contested Case Hearings and Declaratory Rulings, ~~West Virginia Administrative Rules,~~ 64CSR1.