

**WEST VIRGINIA
SECRETARY OF STATE
KEN HECHLER
ADMINISTRATIVE LAW DIVISION**

Form #6

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OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

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

AGENCY: Division of Health TITLE NUMBER: 64

AMENDMENT TO AN EXISTING RULE: YES NO

IF YES, SERIES NUMBER OF RULE BEING AMENDED: _____

TITLE OF RULE BEING AMENDED: _____

IF NO, SERIES NUMBER OF NEW RULE BEING PROPOSED: 57

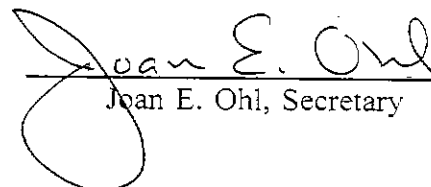
TITLE OF RULE BEING PROPOSED: Clinical Laboratory Technician and Technologist Licensure and
Certification

THE ABOVE RULE HAS BEEN AUTHORIZED BY THE WEST VIRGINIA LEGISLATURE.

AUTHORIZATION IS CITED IN (house or senate bill number) HB2345

SECTION 64-5-1(e), PASSED ON 4-12-97

THIS RULE IS FILED WITH THE SECRETARY OF STATE. THIS RULE BECOMES EFFECTIVE ON THE
FOLLOWING DATE: August 1, 1997


Joan E. Ohi, Secretary

DEPARTMENT OF HEALTH AND HUMAN RESOURCES
RULE PROMULGATION HISTORY ABSTRACT

Rule Title: Clinical Laboratory Technician and Technologist Licensure and Certification

Series Number: 57

Amendment of Existing Rule: New Rule:

Responsible Agency: Division of Health

Date Filed for Public Hearing or Comment Period: 6-23-95

Date of Public Hearing (if any):

Date Public Comment Period Ended: 7-24-95

Date Agency-Approved Rule Filed with the
Legislative Rule-Making Review Committee: 10-5-96

Date of Filing of Modified Rule as Approved by
the Legislative Rule-Making Review Committee: 10-31-96

Date of Final Filing: 6-27-97

Effective Date: 8-1-97

Authorized by: HB2345 (With amendments? Yes No)
Passed: April 12, 1997.

Dates Emergency Rule in Effect (if any):

WEST VIRGINIA DIVISION OF HEALTH LEGISLATIVE RULES

TITLE 64, SERIES 57

CLINICAL LABORATORY TECHNICIAN AND TECHNOLOGIST
LICENSURE AND CERTIFICATION

1997

WEST VIRGINIA DIVISION OF HEALTH LEGISLATIVE RULES
CLINICAL LABORATORY TECHNICIAN AND TECHNOLOGIST
LICENSURE AND CERTIFICATION

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TITLE 64
WEST VIRGINIA DIVISION OF HEALTH LEGISLATIVE RULES
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 certification and 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 § 16-5J-10.

1.3. Filing Date. -- June 27, 1997.

1.4. Effective Date. -- August 1, 1997.

1.5. Expiration Date. -- July 1, 1998.

§64-57-2. Application and Enforcement.

2.1. Application. -- Except as otherwise provided in this rule, this legislative rule applies to:

2.1.a. Clinical laboratory practitioners employed as such in West Virginia, 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

2.1.b. Clinical laboratory consultants, directors, and supervisors in West Virginia.

2.2. This rule does not apply to:

2.2.a. 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 493.7;

2.2.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 as found at § 42 CFR 493.19 (a) - (d);

2.2.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 testing as defined by CLIA, pursuant to 42 CFR 493.17; or

2.2.d. Any individual who performs laboratory tests only on himself or herself or members of his or her family.

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

§64-57-3. Definitions.

3.1. CLIA. -- Clinical Laboratory Improvement Amendments of 1988 (Public Law 100-578) to Section 353 of the Public

Health Service Act (Title 42 United States Code Section 263a).

or

3.2. 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.

3.4.b.3. Waived clinical laboratories found at 42 CFR § 493.35.

3.3. Clinical Laboratory Consultant. -- A person who:

3.5. Clinical Laboratory Practitioner. -- A laboratory technician or a laboratory technologist. The term "clinical laboratory practitioner" includes laboratory technicians 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.

3.3.a. Meets the qualifications for:

3.6. 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.

3.3.a.1. Moderate complexity testing technical consultant found at 42 CFR § 493.1411;

3.3.a.2. Moderate complexity testing clinical consultant found at 42 CFR § 493.1417; or

3.3.a.3. High complexity testing clinical consultant found at 42 CFR § 493.1455.

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

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

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

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

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

3.4.b. Meets the qualifications for directors of:

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

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

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

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

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

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

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

3.10.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.;

3.10.c. Nursing home or personal care home under W. Va. Code § 16-5C-1 et seq.;

3.10.d. Residential board and care home under W. Va. Code § 16-5C-1 et seq. and § 16-5H-1 et seq.;

3.10.e. Hospice under W. Va. Code § 16-5I-1 et seq.;

3.10.f. Clinical laboratory under W. Va. Code § 16-5J-1 et seq.;

3.10.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

3.10.h. Group residential facility for the developmentally disabled or behaviorally disabled under W. Va. Code § 27-17-1 et seq.

3.11. Laboratory Technician. -- A person whose job tasks include specimen processing, laboratory test performance, or laboratory test reporting in a clinical laboratory.

3.12. Laboratory Technologist. -- A

person whose job tasks include specimen processing, laboratory test performance, or laboratory test reporting in a clinical laboratory.

3.13. 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.

§64-57-4. Incorporation by Reference.

The following provisions of the October 1, 1994, edition of 42 CFR Part 493, Laboratory Requirements, as amended in the April 24, 1995 edition of the Federal Register (60 FR 20035), and as further amended and published by January 1, 1997, are hereby incorporated by reference:

4.1. 42 CFR § 493.7;

4.2. 42 CFR § 493.17;

4.3. 42 CFR § 493.19 (a) - (d);

4.4. 42 CFR § 493.35;

4.5. 42 CFR § 493.1363.

4.6. 42 CFR § 493.1405;

4.7. 42 CFR § 493.1411;

4.8. 42 CFR § 493.1417;

4.9. 42 CFR § 493.1423;

4.10. 42 CFR § 493.1443;

4.11. 42 CFR § 493.1449;

- 4.12. 42 CFR § 493.1455;
- 4.13. 42 CFR § 493.1461;
- 4.14. 42 CFR § 493.1469;
- 4.15. 42 CFR § 493.1483; and
- 4.16. 42 CFR § 493.1489.

§64-57-5. Prohibition; Persons Subject to Licensure; Clinical Laboratory Practitioner Trainees.

5.1. 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.

5.2. 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.

§64-57-6. Licensure Requirements, Duration, Renewal.

6.1. Applicants for a clinical laboratory practitioner license shall submit to the secretary:

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

6.1.b. If employed in a clinical laboratory, a current job description and a statement identifying the specialty or specialties of laboratory tests for which the applicant has been trained and is currently competent to perform, except as specified in this rule. The required job description and statement of competency shall be signed and provided to the applicant by the applicant's clinical labo-

ratory director. The attestation shall be partially based on the applicant's performance, if any, in proficiency testing programs; and

6.1.c. The licensure fee shown on the application as authorized by W. Va. Code.

6.2. The secretary shall grant a clinical laboratory practitioner license to applicants who:

6.2.a. Are certified as a clinical laboratory practitioner under Section 7 of this rule or are exempt from certification under Section 8 of this rule; and

6.2.b. Comply with the requirements of Section 6.1 of this rule.

6.3. An applicant for renewal of either a current or an expired license shall submit the application, information and licensure fee required by Section 6.1 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.

6.4. The secretary shall renew a license if the applicant complies with the requirements of Section 6.3 of this rule.

6.5. A clinical laboratory practitioner license expires the earlier of:

6.5.a. One (1) year after issuance; or

6.5.b. The expiration of the individual's certification or exemption from certification as a clinical laboratory practitioner.

§64-57-7. Certification.

A person seeking certification as a clinical laboratory practitioner shall, at the time of application for initial licensure as a clinical laboratory practitioner, also apply for certification on the form provided by the secretary and submit documentation sufficient to establish that he or she meets one (1) of the following qualifications for certification:

7.1. He or she is certified as a medical laboratory technician or technologist by the American Medical Technologists or the American Society of Clinical Pathologists;

7.2. He or she is certified as a clinical laboratory technician or scientist by the National Certification Agency for Medical Laboratory Personnel or by the International Society for Clinical Laboratory Technology;

7.3. He or she was performing clinical laboratory practitioner tasks in a clinical laboratory in West Virginia on July 7, 1989;

7.4. He or she meets the qualifications, except for State licensure, for:

7.4.a. Testing personnel found at 42 CFR § 493.1423, for persons performing moderate complexity tests;

7.4.b. Testing personnel found at 42 CFR § 493.1489, for persons performing high complexity tests; or

7.4.c. Cytotechnologists found at 42 CFR § 493.1483, for persons performing cytological examinations; or

7.5. He or she is certified under any

other applicable federal program.

§64-57-8. Exemption from Certification.

8.1. A person seeking an exemption from certification as a clinical laboratory practitioner shall submit a request for exemption from certification on a form provided by the secretary. The request shall include a statement signed by the director of the clinical laboratory in which the applicant is employed of: the type and number of the laboratory's CLIA certificate, and which of the qualifications for exemption established by this rule the applicant meets.

The request shall include a document which identifies the type and number of CLIA certificate of the laboratory in which the person is employed and states the exemption qualification found in Section 8.2 of this rule which applies to the person seeking the exemption. The document shall be signed by the clinical director of the laboratory.

8.2. The secretary shall exempt a person from certification as a clinical laboratory practitioner if:

8.2.a. He or she is employed in a clinical laboratory which holds a CLIA certificate other than a certificate of waiver; and

8.2.b. His or her laboratory director states that the person applying for exemption from certification meets the qualifications, except for State licensure, for:

8.2.b.1. Testing personnel found at 42 CFR § 493.1423: Provided, That the applicant shall submit with his or her application documentation that he or she has at least a high school diploma, a general education development certificate (GED), or an equivalent approved by the State

department of education, and has had training designed to provide him or her the following with respect to the specific tests he or she will perform:

8.2.b.1.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;

8.2.b.1.B. The skills required for implementing all standard laboratory procedures;

8.2.b.1.C. The skills required for performing each test method and for proper instrument use;

8.2.b.1.D. The skills required for performing preventive maintenance, trouble shooting and calibration procedures related to each test performed;

8.2.b.1.E. A working knowledge of reagent stability and storage;

8.2.b.1.F. The skills required to implement the quality control policies and procedures of the laboratory;

8.2.b.1.G. An awareness of the factors that influence test results; and

8.2.b.1.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, and Provided further: That, in the event that the individual is to perform additional tests, 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 Sections 8.2.2.a(1) through 8.2.2.a(8) of this rule; or

8.2.b.2. For persons performing cytotechnological examinations, the qualifications for cytotechnologists found at 42 CFR § 493.1483.

§64-57-9. Expiration of Certification and Exemption.

An individual's certification or exemption from certification as a clinical laboratory practitioner expires when the person holding the certification or the exemption no longer meets the qualifications stated in this rule for certification or for exemption from certification.

§64-57-10. Reciprocity.

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

§64-57-11. Limitations on Certification, License and Use of Titles by Health Care Facilities.

11.1. Licensure or certification 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.

11.2. Health care facilities shall not use the terms clinical laboratory practitioner, laboratory or medical technician or laboratory or medical technologist, or abbreviations thereof, to refer to a person who is not

licensed as a clinical laboratory practitioner.

§64-57-12. Revocation and Non-issuance of Clinical Laboratory Practitioner Certifications.

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

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

12.2. Does not meet requirements for licensure, certification, or exemption from certification; or

12.3. Has been convicted of a felony involving laboratory practices.

§64-57-13. Hearings.

13.1. A request for a hearing may be made to the secretary by an applicant for a clinical laboratory practitioner certification or 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.

13.2. Hearings shall be conducted in accordance with the provisions of W. Va. Code § 29A-5-1 et seq., and Rules of Procedure for Contested Case Hearings and Declaratory Rulings, West Virginia Administrative Rules, 64 CSR 1.

KEN HECHLER
Secretary of State

MARY P. RATLIFF
Deputy Secretary of State

JAN CASTO
Deputy Secretary of State

CATHERINE FREROTTE
Executive Assistant

Telephone: (304) 558-6000
Corporations: (304) 558-8000
FAX: (304) 558-0900



WILLIAM H. HARRINGTON
Chief of Staff

RECEIVED JUDY COOPER
Director, Administrative Law

JUL 16 1997 PENNEY BARKER
Supervisor, Corporations

STATE OF WEST VIRGINIA

SECRETARY OF STATE **REGULATORY DEVELOPMENT**

Building 1, Suite 157-K
1900 Kanawha Blvd., East
Charleston, WV 25305-0770

(Plus all the volunteer
help we can get)

OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

AUG 4 3 54 PM '97

FILED

TO: KAY HOWARD

AGENCY: DIVISION OF HEALTH

FROM: JUDY COOPER, DIRECTOR, ADMINISTRATIVE LAW DIVISION

DATE: July 14, 1997

THE ATTACHED RULE FILED BY YOUR AGENCY HAS BEEN ENTERED INTO OUR COMPUTER SYSTEM. PLEASE REVIEW, PROOF AND RETURN IT WITH ANY CORRECTIONS. IF THERE ARE NO CORRECTIONS, PLEASE SIGN THIS MEMO AND RETURN IT TO THIS OFFICE. YOU WILL BE SENT A FINAL VERSION OF THE RULE FOR YOUR RECORDS.

PLEASE RETURN EITHER THE CORRECTED RULE OR THIS FORM WITHIN TEN (10) WORKING DAYS OF THE DATE YOU RECEIVED THIS REQUEST. CALL IF YOU HAVE ANY QUESTIONS.

SERIES: 57 TITLE: 64 DIVISION OF HEALTH

* THE ATTACHED RULE HAS BEEN REVIEWED AND IS CORRECT.

SIGNED: _____

TITLE OF PERSON SIGNING: _____

DATE: _____

* THE ATTACHED RULE HAS BEEN REVIEWED AND NEEDS CORRECTING. THE CORRECTIONS HAVE BEEN MARKED.

SIGNED: Kay Howard

TITLE OF PERSON SIGNING: Director, Regulatory Development

DATE: 8/4/97

NOTE: IF YOU ARE NOT THE PERSON WHO HANDLES THIS RULE, PLEASE FORWARD TO THE CORRECT PERSON.