

WEST VIRGINIA
SECRETARY OF STATE
KEN HECHLER
ADMINISTRATIVE LAW DIVISION

Form #2

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JUN 23 3 46 PM '95

OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

NOTICE OF A COMMENT PERIOD ON A PROPOSED RULE

AGENCY: Division of Health TITLE NUMBER: 64

RULE TYPE: Legislative; CITE AUTHORITY W. Va. Code §§ 16-1-7, 16-2E-3, 16-5B-8, 16-5C-5, 16-5H-2, 16-5I-5, 16-5J-3, 16-5J-10, 27-9-1, and 27-17-3
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

IN LIEU OF A PUBLIC HEARING, A COMMENT PERIOD HAS BEEN ESTABLISHED DURING WHICH ANY INTERESTED PERSON MAY SEND COMMENTS CONCERNING THESE PROPOSED RULES. THIS COMMENT PERIOD WILL END ON July 24, 1995 AT 4:30 p.m.

ONLY WRITTEN COMMENTS WILL BE ACCEPTED AND ARE TO BE MAILED TO THE FOLLOWING ADDRESS. In order to be considered, comments must be received by Regulatory Development no later than July 24, 1995 at 4:30 p.m.

Regulatory Development

Department of Health & Human Resources

Room 265, Building 3, Capitol Complex

Charleston, WV 25305

ATTN: Kay Howard

THE ISSUES TO BE HEARD SHALL BE LIMITED TO THIS PROPOSED RULE.

Gretchen O. Lewis
Gretchen O. Lewis, Secretary

ATTACH A **BRIEF** SUMMARY OF YOUR PROPOSAL

500

ABSTRACT - PROPOSED RULE

DEPARTMENT OF HEALTH AND HUMAN RESOURCES CLINICAL LABORATORY TECHNICIAN AND TECHNOLOGIST LICENSURE AND CERTIFICATION 64 CSR 57

Summary: This proposed new legislative rule sets forth standards and procedures for the certification and licensing of laboratory technicians and laboratory technologists as clinical laboratory scientists and establishes penalties for the use of unlicensed persons to perform the work of clinical laboratory scientists by health care facilities. Establishment of this rule will bring the Department of Health and Human Resources into compliance with W. Va. Code § 16-5J-10.

The rule sets forth application and enforcement, and defines terms. Certain federal standards relating to laboratory personnel are incorporated by reference. The rule defines certification and licensure requirements and procedures, and also exemptions from licensure and certification requirements. It specifies permitted activities and supervision of clinical laboratory scientist trainees.

Reciprocity is given to other jurisdictions with comparable requirements. The rule establishes limitations on certification, license and use of titles by health care facilities. It establishes revocation and non-issuance of clinical laboratory scientist certifications. The rule also establishes that no license shall be issued to a health care facility as long as it uses in West Virginia an unlicensed clinical laboratory scientist. Criminal penalties for certain actions are established by W. Va. Code §§ 16-1-18 and 16-5J-8. Procedures for contested case hearings are included.

For further information contact: Nancy Lovell Tyler, M.S.W., Esq., Director, Office of Health Facility Licensure and Certification, telephone (304) 558-0050; Frank W. Lambert, Jr., Dr. P.H., Director, Office of Laboratory Services, telephone (304) 558-3530, Bureau for Public Health, Department of Health and Human Resources, State Capitol Complex, Building 3, Room 518, Charleston, West Virginia, 25305; or the Office of Regulatory Development, Bureau of Operations, Department of Health and Human Resources, State Capitol Complex, Building 3, Room 265, Charleston, West Virginia, 25305, telephone (304) 558-3223.

6/23/95

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Clinical Laboratory Technician and Technologist Licensure and Certification, 64 CSR 57

Type of Rule: Legislative Interpretive Procedural

Agency: Department of Health and Human Resources

Address: Building 3, Capitol Complex
Charleston, W. Va. 25305

1. Effect of Proposed Rule	ANNUAL		FISCAL YEAR		
	Increase	Decrease	Current	Next	Thereafter
Estimated Total Cost	\$	\$	\$	\$165,567	\$185,774
Personal Services				37,272	55,740
Current Expense				108,995	129,134
Repairs & Alterations					
Equipment				19,300	900
Other					
Revenue				100,000	100,000

2. Explanation of above estimates.

Please see attached.

3. Objectives of this rule:

Provide licensure and certification of Medical Laboratory Technicians and Technologists working in West Virginia as required by Clinical Laboratories Quality Assurance Act 16-5J-10.

4. Explanation of Overall Economic Impact of Proposed Rule.

A. Economic Impact on State Government.

1. Personnel employed in medical labs would be subject to cost of licensure and certification.
2. Possible reduced income from HCFA contract with OHFLAC for CLIA-88 Inspections.

B. Economic Impact on Political Subdivisions; Specific Industries; Specific Groups of Citizens.

1. All Medical Technologist and Technicians would be subject to the cost of licensure and certification.
2. All other health care workers providing laboratory tests would be subject to licensure and certification costs.

C. Economic Impact on Citizens/Public at Large.

1. Could raise health costs if facilities paid cost of licensure and certification of personnel.
2. Could reduce availability of lab services if health care facilities choose not to have licensed employees.

Date: June 23, 1995

Signature of Agency Head or Authorized Representative

Gretchen O. Lewis, Secretary
Department of Health and Human Resources

Fiscal Note for Proposed Rule (Cont'd)

Rule Title: Clinical Laboratory Technician and Technologist Licensure and Certification, 64 CSR 57

2. Explanation of above estimates.

<u>Personal Services</u>	<u>First Year</u>	<u>Second Year</u>
1.0 Secretary II	\$ 16,116	\$ 16,116
1.0 Administrative Services Assistant III	\$ 21,156	\$ 21,156
1.0 Investigator		\$ 18,468

Current Expenses

Fringe Benefits	\$ 16,955	\$ 25,394
Postage	2,200	2,200
Copier Lease	4,000	4,000
Telephone (800 Number)	36,000	36,000
Printing	8,000	8,000
Records Microfilm	2,000	2,000
Travel (investigations) + car lease	10,000	20,000
Telephone	5,000	5,000
Equipment Maintenance Contracts		1,700
Lease Space 12' x 15' @ \$11.50 sq. ft.	24,840	24,840

Equipment

2 Computers & Software	\$ 12,000	
3 File Cabinets	800	
1 Typewriter	1,200	
2 Desks	1,800	
2 Computer Tables	1,000	
1 FAX Machine	2,500	
1 Desk		900

Revenue

There is no information on the total number of individuals required to be licensed; the Department has used an estimate of 4,000 to estimate revenue.

[PROPOSED]

WEST VIRGINIA ADMINISTRATIVE RULES
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
CLINICAL LABORATORY TECHNICIAN AND TECHNOLOGIST
LICENSURE AND CERTIFICATION

64 CSR 57

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For Public Comment Period
Ending July 24, 1995

**WEST VIRGINIA ADMINISTRATIVE RULES
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
CLINICAL LABORATORY TECHNICIAN AND TECHNOLOGIST
LICENSURE AND CERTIFICATION
64 CSR 57**

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PROPOSED RULE - TITLE 64
WEST VIRGINIA ADMINISTRATIVE RULES
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
SERIES 57
CLINICAL LABORATORY TECHNICIAN AND TECHNOLOGIST
LICENSURE AND CERTIFICATION

FILED
JUN 23 3 46 PM '95
OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

§64-59-1. 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 scientists and establishes penalties for the use of unlicensed persons to perform the work of clinical laboratory scientists by health care facilities.

1.2. **Authority** - W. Va. Code §§ 16-1-7, 16-2E-3, 16-5B-8, 16-5C-5, 16-5H-2, 16-5I-5, 16-5J-3, 16-5J-10, 27-9-1, and 27-17-3.

1.3. **Filing Date** -

1.4. **Effective Date** -

§64-59-2. Application and Enforcement -

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

2.1.1. Clinical laboratory scientists employed as such in West Virginia;

2.1.2. Health care facilities performing laboratory tests in West Virginia; and

2.1.3. Clinical laboratory directors in West Virginia.

2.2. This rule does not apply to:

2.2.1. County health departments organized under W. Va. Code § 16-2-1 et seq. or § 16-2A-1 et seq., or to the clinical laboratory directors of the clinical laboratories of county health departments: **Provided**, That it does apply to clinical laboratory scientists employed as such by county health departments;

2.2.2. Primary health care centers having tax exempt status and receiving contributions which are deductible to the contributor under provisions of federal law, or the clinical laboratory directors of the clinical laboratories of such centers: **Provided**, That it does apply to clinical laboratory scientists employed as such in the clinical laboratories of such centers;

2.2.3. Any laboratory operated by the federal government; or

2.2.4. Any laboratory operated purely for research or teaching purposes.

2.3. **Enforcement** - This rule is enforced by the Secretary of the West Virginia Department of Health and Human Resources.

§64-59-3. 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).

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.

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

3.3.1. Meets the qualifications for:

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

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

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

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

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

3.4.2. Meets the qualifications for directors of:

3.4.2.a. Moderate complexity testing laboratories found at 42 CFR § 493.1405; or

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

3.5. **Clinical Laboratory Scientist** - A person whose job tasks include specimen processing, laboratory test performance, or laboratory test reporting in a clinical labo-

ratory for remuneration. The term "clinical laboratory scientist" includes laboratory technicians and laboratory technologists, but does not include: clinical laboratory scientist trainees, directors, consultants, or supervisors; 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.

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

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

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

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

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

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

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

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

3.9.2. 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.;

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

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

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

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

3.9.7. Hospital, center or institution 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

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

3.10. **Laboratory Technician** - A clinical laboratory scientist.

3.11. **Laboratory Technologist** - A clinical laboratory scientist.

3.12. **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.

§64-59-4. Incorporation by Reference.

The 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)**, are hereby incorporated by reference.

§64-59-5. Prohibition; Persons Subject to Licensure; Clinical Laboratory Scientist Trainees.

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

5.2. A clinical laboratory scientist trainee may perform tasks related to laboratory tests except that tasks related to tests categorized by CLIA as moderate or high complexity tests shall be performed only under the personal and direct supervision of: a licensed clinical laboratory scientist; a clinical laboratory director, consultant or supervisor; or a physician licensed under W. Va. Code § 30-3-1 et seq. or 30-14-1 et seq. who performs laboratory tests only on his or her own patients.

§64-59-6. Licensure Requirements, Duration, Renewal.

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

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

6.1.2. 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

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this rule. The required job description and statement of competency shall be signed and provided to the applicant by the applicant's clinical laboratory director, or, if the clinical laboratory holds a CLIA certificate of waiver and does not have a clinical laboratory director, the job description shall be provided by his or her supervisor, and the required statement of competency shall be signed and provided by either a clinical laboratory supervisor or clinical laboratory consultant who is knowledgeable of the competency of the applicant. The attestation shall be partially based on the applicant's performance, if any, in proficiency testing programs; and

6.1.3. The licensure fee shown on the application as may be set by W. Va. Code or rule.

6.2. The requirements of paragraph 6.1.2 of this rule do not apply to an applicant employed in a county health department, or a primary health care center having tax exempt status and receiving contributions which are deductible to the contributor under provisions of federal law.

6.3. The secretary shall grant a clinical laboratory scientist license to applicants who:

6.3.1. Are certified as a clinical laboratory scientist or are exempt from such certification under this rule; and

6.3.2. Comply with the requirements of subsection 6.1 of this rule.

6.4. An applicant for renewal of an unexpired license shall submit the application, information and licensure fee required by subsection 6.1 of this rule and evidence that the applicant has completed at least ten (10) hours of continuing education from a program or programs approved by the secretary, since issuance of his or her initial or renewal license, as applicable.

6.5. An applicant for renewal of an expired license shall submit the application, information and licensure fee required by subsection 6.1 of this rule and evidence that the applicant has completed at least ten (10) hours of continuing education from a program or programs approved by the secretary, since issuance of the expired license.

6.6. The secretary shall renew a license if the applicant complies with the requirements of subsection 6.4 or 6.5, as applicable, of this rule.

6.7. A clinical laboratory scientist license expires the earlier of:

6.7.1. One (1) year after issuance; or

6.7.2. The expiration of the individual's certification or exemption from certification as a laboratory scientist.

§64-59-7. Certification Requirements.

7.1. A person seeking certification as a clinical laboratory scientist shall, at the time of application for initial licensure as a clinical laboratory scientist, 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 qualifications for certification established by this rule.

7.2. An individual qualifies for certification as a clinical laboratory scientist if the individual:

7.2.1. Is certified as a medical laboratory technician or technologist by the American Medical Technologists or the American Society of Clinical Pathologists;

7.2.2. Is certified as a clinical laboratory technician or scientist by the National Certification Agency for Medical Laboratory Personnel;

7.2.3. Was performing clinical laboratory scientist tasks in a clinical laboratory in West Virginia on July 7, 1989; or

7.2.4. Meets the qualifications, except for State licensure, for:

7.2.4.a. Testing personnel found at: 42 CFR §493.1423, §493.1489, or §493.1491; or

7.2.4.b. Cytotechnologists found at 42 CFR § 493.1483; or

7.2.5. Is certified under any other applicable federal program.

§64-59-8. Exemption from Certification.

8.1. A person seeking an exemption from certification as a clinical laboratory scientist 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.

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

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

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

8.2.2.a. Testing personnel found at: 42 CFR § 493.1423, § 493.1489, or § 493.1491; or

8.2.2.b. Cytotechnologists found at 42 CFR § 493.1483.

§64-59-9. Expiration of Certification and Exemption.

An individual's certification or exemption from certification as a clinical laboratory scientist 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.

§64-59-10. Reciprocity.

The secretary may issue a clinical laboratory scientist license or certification to a person who holds a license or certification from another jurisdiction which has licensure or certification requirements at least comparable to 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.

§64-59-11. Limitations on Certification, License and Use of Titles by Health Care Facilities.

11.1. Licensure or certification as a clinical laboratory scientist 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, or, in the case of a clinical laboratory scientist employed in a clinical laboratory which holds a CLIA certificate of waiver and does not have a clinical laboratory director, a clinical laboratory supervisor or clinical laboratory consultant 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 scientist, laboratory technician or laboratory technologist, or abbreviations thereof, to refer to a person who is not licensed as a clinical laboratory scientist.

§64-59-12. Revocation and Non-issuance of Clinical Laboratory Scientist Certifications and Licenses and Health Care Facility Licenses.

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

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

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

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

12.2. No license shall be issued to a health care facility as long as it uses in West Virginia an unlicensed clinical laboratory scientist.

§64-59-13. Criminal Penalties.

A violator of the provisions of this rule is subject to fine or imprisonment as found at W. Va. Code §§ 16-1-18 and 16-5J-8.

§64-59-14. Hearings.

14.1. A request for a hearing may be made to the secretary by an applicant for a clinical laboratory scientist 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.

14.2. 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.**

§64-59-15. Severability.

The provisions of this rule are severable. If any provision of this rule is held invalid, the remaining provisions remain in effect.