

TITLE 64 SERIES 57
LEGISLATIVE RULE
BUREAU FOR PUBLIC HEALTH
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
CLINICAL LABORATORY TECHNICIAN AND
TECHNOLOGIST LICENSURE AND CERTIFICATION

Summary of Public Comments: The Bureau received one letter containing these public comments from Pam Meadows, President of the West Virginia Society for Clinical Laboratory Sciences (WVSCLS).

Comment #1

Why are respiratory care providers exempt from the rule?

Response #1

Respiratory care providers are currently exempt from licensure as they are subject to the licensure under W.Va. Code §§ 30-34-1 et seq. However, respiratory care providers must restrict their testing to moderate complexity diagnostic testing, as defined by the federal Clinical Laboratory Improvement Amendments (CLIA), within the scope of his or her license. The Secretary does not believe the exemption will be misconstrued to permit respiratory care providers to perform laboratory testing outside of the scope of practice. Thus, no changes are necessary in response to this comment.

Comment #2

Add the terms “Medical Laboratory Scientist” and “Medical Laboratory Science”.

Response #2

The Secretary agrees that given changes in the nomenclature used by educational institutions with regard to the identification of the applicable degree, the Secretary will modify the proposed rule amendments to include a reference to “Medical Laboratory Scientist” and “Medical Laboratory Science.”

Comment #3

Subsection 5.1 does not contain a reference to continuing education requirements.

Response #3

In an effort to clarify that continuing education credits are necessary for license renewal, the Secretary will amend the current rule to include new paragraph 5.1.d. to indicate that applicants for the renewal of a license must complete all continuing education requirements contained in subdivision 5.7.a.

Comment #4

Paragraphs 5.2.b and 5.3.b. do not include certification requirements for person having an associate or bachelor degree in chemical, physical or biological science.

Response #4

Upon consideration of the suggested modifications to paragraphs 5.2.b. and 5.3.b., the Secretary declines to make any modifications as the suggested modifications would negatively impact the rule series' compliance with CLIA requirements and have an adverse impact on the State's ability to employ qualified lab technologist as the suggested changes would be inconsistent with current Division of Personnel position classifications.

Comment #5

Paragraph 5.3.c. is unclear and may be contradictory.

Response #5

The provisions of this paragraph are consistent with CLIA and are intended to provide a mechanism for the continued licensure of technicians who have been licensed for many years. Paragraph 5.3.c. is intended to recognize that there are licensees who cannot meet current educational degree requirements without significant hardship, but have substantial qualifying experience and thus, by virtue of that experience are qualified for licensure.

Comment #6

A "grandfather" provision is necessary to ensure persons currently licensed will continue to be eligible for licensure.

Response #6

The Secretary agrees that because of proposed changes a "grandfather clause" is appropriate to ensure that current licensee will continue to be qualified for license. Therefore, the Secretary will further modify the proposed rules series amendments to include a new paragraph 5.2.c. that will read "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." and a new paragraph 5.3.f. that will read as follows: read "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."

Comment #7

In an addendum to their initial comments the WVSCLS request that the fee for non-licensed or expired/lapsed license found during the course of laboratory inspection be increased in order to increase accountability of both the laboratory and practitioner. The WVSCLS proposes that the penalty fee be increased from \$40 to \$100, in addition to the \$25 licensure fee. The OLS has seen an increase in non-licensed and expired/lapsed licenses during the course of laboratory inspection, and thus, the Secretary agrees that an increase in the penalty may be warranted as a means of de-incentivizing non-compliance with the rule series.

Response #7

Accordingly, paragraph 5.9.e. is amended to increase the penalty from \$40 to \$100.

RECEIVED

JUL 27 2016

COMMISSIONER'S OFFICE
BUREAU FOR PUBLIC HEALTH



West Virginia Society for Clinical Laboratory Science

To: Brian J. Skinner, General Counsel
From: West Virginia Society for Clinical Laboratory Science
Date: July 27, 2016
Re: Clinical Laboratory Technician/Technologist Licensure and Certification
§§16-1-4.16-1-11 and 16-5J-10

Dear Mr. Skinner,

After review of the documents currently available for public comment through the WV Secretary of State Office, the West Virginia Society for Clinical Laboratory Science (WVSCLS) Board of Directors respectfully requests that the following comments be given consideration with regard to revision of the regulations for Clinical Laboratory Technician/Technologist Licensure and Certification:

- 1.5.c.3 (p. 1) Why are respiratory care providers exempt from this rule? Does professional licensure in respiratory care allow those providers to perform moderate complexity laboratory testing? Could this exemption be misconstrued to allow respiratory care providers to perform laboratory testing outside of the respiratory care scope of practice?
- The terms "Medical Technologist" and "Medical Technology" are used in several areas of the regulation. It is suggested that consideration be given to adding the terms "Medical Laboratory Scientist" when referring to individuals holding a bachelor's degree in the field, and the term "Medical Laboratory Science" when referring to educational programs in the field of laboratory medicine. The board of certification also currently utilizes the latter terms.
- §64-57-5 (p. 5) This section is titled "Licensure Requirements, Duration, Renewal" but makes no mention of continuing education requirements for license renewal. Clarification is also needed regarding acceptable forms of continuing education, as well as a description of the current auditing process utilized to verify the validity of continuing education credits submitted via the online renewal system.
- 5.2.b and 5.3.b (pp. 6-7) There is no mention of certification requirements for individuals having an associate or bachelor degree in chemical, physical or biological science. These individuals should be held to the same standards as those who graduate from a traditional clinical laboratory science program, and should be required to pass national certification from one of the agencies listed in the regulation.

- 5.3.c (p. 7) The reason for inclusion of this route is unclear. This subsection also seems contradictory. Why would individuals who have completed "24 semester hours of medical laboratory technology courses" be included in this route? Educators on the WVSCLS Board of Directors are all in agreement that the only circumstances under which this situation may occur would be if a student is admitted to a traditional MLT or MLS program, yet they fail to successfully complete all program requirements. While we appreciate the addition of the last sentence in that section, it still appears to leave a loop-hole for those individuals who begin, but fail to finish a formal MLT or MLS program. As listed for 5.2.b and 5.3.b, these individuals should also be required to attain national certification.
- The addition of a "grandfather" clause is requested to ensure that those individuals who have already been granted a practitioner's license will retain their current status upon renewal.

Thank you in advance for your consideration of the comments above. Any questions regarding these suggestions can be directed to Pam Meadows, WVSCLS President, at meadow63@marshall.edu or P.O. Box 453, Eleanor, WV 25070.

Respectfully,

West Virginia Society for Clinical Laboratory Sciences