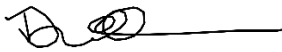





TO: The Honorable the Members of the Board of Regents

FROM: Douglas E. Lentivech 

SUBJECT: Proposed Amendment to Section 79-13.5 of the Regulations of the Commissioner of Education Relating to the Establishment of a New Restricted License for Clinical Laboratory Technologists in Toxicology

DATE: February 27, 2020

AUTHORIZATION(S):  Sharam L. Taha

SUMMARY

Issue for Decision (Consent Agenda)

Should the Board of Regents adopt, as a second emergency action, the proposed amendment to Section 79-13.5 of the Regulations of the Commissioner of Education establishing a new restricted license for clinical laboratory technologists in toxicology?

Reason for Consideration

Required by State statute (Chapter 227 of the Laws of 2019).

Proposed Handling

The proposed amendment will be presented to the Full Board for adoption as an emergency rule at the March 2020 meeting of the Board of Regents. A copy of the proposed rule and a statement of facts and circumstances justifying the emergency action are attached.

Procedural History

The proposed amendment was presented to the Professional Practice Committee for recommendation and to the Full Board for adoption as an emergency action at the December 2019 meeting of the Board of Regents, effective December 28, 2019. A Notice of Emergency Adoption and Proposed Rule Making was published in the State Register on December 24, 2019. Following the 60-day public comment period required under the State Administrative Procedure Act, the Department received one supportive comment on the proposed amendment, included as Attachment C. Because the December emergency action will expire on March 8, 2020 a second emergency action is necessary

to ensure that the emergency rule remains continuously in effect until it can be permanently adopted at the April 6-7, 2020 Regents meeting and take effect as a permanent rule. Supporting materials are available upon request from the Secretary to the Board of Regents.

Background Information

Clinical laboratory technologists, cytotechnologists, clinical laboratory technicians, and histological technicians provide critical information needed for the diagnosis and treatment of illness and disease, ensure accurate blood and tissue typing and transfusion services, and provide the core knowledge and skill needed to identify bioterrorism agents. At least 70 percent of all medical diagnoses rely on the findings of clinical laboratory tests and procedures. As with all professions, licensure as a clinical laboratory technology practitioner is intended to hold these practitioners accountable for the professional services they provide.

On August 30, 2019, Governor Cuomo signed Chapter 227 of the Laws of 2019 (Chapter 227), which, effective December 28, 2019, establishes a new restricted license for clinical laboratory technologists in toxicology and allows individuals employed by a New York State Department of Health certified laboratory, who meet the requirements for a restricted license, to receive a certification allowing them to perform toxicology laboratory services.

New York State based clinical toxicology laboratories that hold a permit from the NYS Department of Health's Clinical Laboratory Evaluation Program to provide the services and activities to test and process specimens are required to employ individuals holding valid licenses in clinical laboratory technology (CLT), or certified clinical laboratory technician (CCLT), working under supervision. Currently, in order to obtain a CLT license, an individual must complete a bachelor degree or higher in clinical laboratory technology or an advanced certificate from a program in clinical laboratory technology, or an associate's degree in clinical laboratory technician and then successfully complete a comprehensive qualifying exam in accordance with Education Law §8605 and §8606 and Commissioner's Regulations.

Toxicology laboratory volume is at a historic high, since among other matters, the services have become a useful tool in combating the opioid addiction epidemic, as well as assisting in identifying adverse effects of chemical substances in people and establishing the correct dosage of medications in patients. Laboratory results can indicate an individual's adherence to established protocols and important behavioral health outcomes. Laboratories have had great difficulty in filling available staffing positions, in part due to the shortage of licensed personnel in many of the laboratories in New York State. As a result, laboratory tests are sent out of state where they are performed by individuals over whom New York State has no licensing authority of laboratory personnel, although the laboratories are issued a permit by NYSDOH. This is a process that delays the reception of test results. Without creating a pathway to licensure for individuals who are qualified to perform the necessary toxicology laboratory services and activities by establishing a new restricted license, New York State will be further constrained in accessing in-state toxicology laboratory services.

A restricted license in five specific tests and procedures was first established in 2008 by an amendment to Article 165 of the Education Law near the outset of licensure since these specific tests and procedures were often not yet included in the registered programs for clinical laboratory technology and the restricted license enabled laboratories to provide the tests and procedures. The inclusion of toxicology among the restricted licenses in clinical laboratory technology will alleviate the high demand for these services while ensuring appropriate education and supervision. The proposed amendment to section 79-13.5 of the Regulations of the Commissioner of Education implements Chapter 227 by amending 79-13.5 (a) to add toxicology to the category of restricted licenses for clinical laboratory technologists, adding a new subdivision (g) establishing education requirements that must be provided by the Clinical Director to those applicants for a restricted license in toxicology and adding a new subdivision (b-1) establishing a pathway to licensure for individuals who are employed by a New York State Department of Health authorized toxicology laboratory, operating under the direction of a clinical laboratory director to receive a certification allowing them to perform toxicology laboratory services.

Related Regent's Items

[December 2019: Proposed Amendment to Section 79-13.5 of the Regulations of the Commissioner of Education Establishing a New Restricted License for Clinical Laboratory Technologists in Toxicology](http://www.regents.nysed.gov/common/regents/files/1219ppca1.pdf)

(<http://www.regents.nysed.gov/common/regents/files/1219ppca1.pdf>)

Recommendation

It is recommended that the Board of Regents take the following action:

VOTED: That section 79-13.5 of the Regulations of the Commissioner of Education be amended, as submitted, effective March 9, 2020, as an emergency action upon a finding by the Board of Regents that such action is necessary for the preservation of the public health and general welfare to immediately conform the Regulations of the Commissioner of Education to the requirements of Chapter 227 of the Laws of 2019, which establishes a new restricted license for clinical laboratory technologists in toxicology as long as certain requirements are met and allows individuals employed by a New York State Department of Health certified laboratory who meet the requirements for a restricted license to receive a certification allowing them to perform toxicology laboratory services and to ensure that the emergency adoption taken at the December meeting remains in effect until the proposed rule can be permanently adopted.

Timetable for Implementation

If adopted at the March 2020 Regents meeting, the emergency rule will become effective March 9, 2020. It is anticipated that the proposed rule will be presented to the Board of Regents for permanent adoption at the April 2020 Regents meeting after expiration of the 60-day public comment period required under the State Administrative Procedure Act.

Attachment A

AMENDMENT TO THE REGULATIONS OF THE COMMISSIONER OF EDUCATION

Pursuant to sections 207, 6504, 6506, 6507, 8610 of the Education Law and Chapter 227 of the Laws of 2019

Section 79-13.5 of the Regulations of the Commissioner of Education is amended, as follows:

§79-13.5. Restricted license.

(a) In accordance with section 8610(1) of the Education Law, the department may issue a restricted clinical laboratory license to perform certain examinations and procedures within the definition of clinical laboratory technology as set forth in section 8601(1) of the Education Law, provided that such a restricted licensee may only perform examinations and procedures in those of the following areas which are specifically listed in his or her certificate: histocompatibility, cytogenetics, stem cell process, flow cytometry/cellular immunology and molecular diagnosis to the extent such molecular diagnosis is included in genetic testing-molecular and molecular oncology, and toxicology as provided in subdivision (b-1) of this section.

(b)

(b-1) Only individuals employed in a New York State Department of Health authorized toxicology laboratory, operating under the direction of a clinical laboratory director, may obtain a certificate in toxicology.

(c) In addition to the requirements set forth in section 8610(1) of the Education Law, to qualify for a restricted license, an applicant shall satisfy the following requirements:

(1)

(2)

(i)

(ii).....

(iii)

(iv)

(v) The training program shall include the following curricula for certificates

issued in each of the following areas:

(a)

(b)

(c)

(d)

(e)

(f)

(g) For a certificate in the area of toxicology, the training program shall include knowledge of laboratory methods in toxicology, including qualitative and quantitative determination of xenobiotics present in biological specimens. The training program shall also include, but need not be limited to, general laboratory principles and skills; basic principles of chemistry, biology, and the physical sciences; basic principles of pharmacology; basic principles of purification, separation, and extraction techniques; instrumentation and equipment; quality control and quality assurance; laboratory mathematics; the principles of immunoassay techniques; preparation and processing of biological specimens for toxicological analysis; the principles of analytical techniques; review and certification of toxicology results; aseptic technique and infection control and specific clinical applications.

(3)

8 NYCRR §79-13.5

**STATEMENT OF FACTS AND CIRCUMSTANCES
WHICH NECESSITATE EMERGENCY ACTION**

The proposed amendment to section 79-13.5 of the Regulations of the Commissioner of Education is necessary to implement Chapter 227 (Chapter 227) of the Laws of 2019, which amended the Education Law, effective December 28, 2019, which establishes a new restricted license for clinical laboratory technologists in toxicology and allows individuals employed by a New York State Department of Health certified laboratory who meet the requirements for a restricted license to receive a certification allowing them to perform toxicology laboratory services.

The proposed amendment to section 79-13.5 of the Regulations of the Commissioner of Education implements Chapter 227 by adding toxicology to the category of restricted licenses for clinical laboratory technologists, establishing education requirements that must be provided by the Clinical Director to those applicants for a restricted license in toxicology and establishing a pathway to licensure for individuals who are employed by a New York State Department of Health authorized toxicology laboratory, operating under the direction of a clinical laboratory director to receive a certification allowing them to perform toxicology laboratory services.

The proposed amendment was presented to the Professional Practice Committee for recommendation and to the Full Board for adoption as an emergency action at the December 2019 meeting of the Board of Regents, effective December 28, 2019. Since the Board of Regents meets at fixed intervals, the earliest the proposed rule can be presented for permanent adoption, after expiration of the required 60-day comment period provided for in the State Administrative Procedure Act (SAPA) sections 201(1) and (5),

would be the April 6-7, 2020 Regents meeting. Furthermore, pursuant to SAPA 203(1), the earliest effective date of the proposed rule, if adopted at the April meeting would be April 22, 2020, the date the Notice of Adoption would be published in the State Register. However, the December emergency rule will expire on March 8, 2020. If the rule were to lapse, it would impede the ability of the Department to issue restricted licenses for clinical laboratory technologists in toxicology, which could adversely impact the public's access to the services these licensees provide in this State.

Therefore, a second emergency action is necessary at the March 2020 meeting for the preservation of the public health and general welfare in order to immediately conform the Rules of the Board of Regents and the Regulations of the Commissioner of Education to the requirements of Chapter 227 of the Laws of 2019, effective March 9, 2020, which establishes a new restricted license for clinical laboratory technologists in toxicology as long as certain requirements are met and allows individuals employed by a New York State Department of Health certified laboratory who meet the requirements for a restricted license to receive a certification allowing them to perform toxicology laboratory services and to ensure that the emergency adoption taken at the December meeting remains in effect until the proposed rule can be permanently adopted.

It is anticipated that the proposed rule will be presented for adoption as a permanent rule at the April 2020 Regents meeting, which is the first scheduled meeting after the 60-day public comment period prescribed in SAPA for State agency rule makings.

ASSESSMENT OF PUBLIC COMMENT

Following publication of the Notice of Emergency Adoption and Proposed Rule Making in the State Register on December 24, 2019, the Department received the following comments on the proposed regulation:

1. COMMENT: A commenter writes in support of the proposed regulation noting that New York toxicology laboratories have been seeking to hire individuals educated in toxicology, however, they have been unable to do so due to the licensure requirement for clinical laboratories in New York. They state that this has resulted in acute staff shortages in the face of the ongoing opioid epidemic. The commenter notes that without a viable pathway to licensure, many graduates of institutions of higher education have been forced to seek employment outside of New York State. The commenter recognizes that the proposed amendment ensures that an individual eligible to obtain restricted toxicology licensure possess knowledge of certain laboratory methods in toxicology, obtain additional on the job training, and possess the appropriate educational background. Additionally, the commenter writes that they “commend SED, and in particular the State Board for Clinical Laboratory Technology, for thoughtfully analyzing and ultimately recommending the appropriate principles and skills than an individual must achieve in order to receive a restricted toxicology certificate.”

Response: The Department agrees with this positive comment. The proposed amendment is intended to create a pathway to licensure for individuals who are qualified to perform the necessary toxicology laboratory services and activities by

establishing a new restricted license in order to increase access to in-state toxicology laboratory services.