



TO: The Honorable Members of the Board of Regents

FROM: Sarah Benson *Sarah D. Benson*

SUBJECT: Proposed Amendment to Section 79-13.5 of the Regulations of the Commissioner of Education Relating to Requirements for Restricted Licenses for Clinical Laboratory Technologists in Molecular Testing

DATE: November 2, 2023

AUTHORIZATION(S): *Tom N. G. Bellotti*

SUMMARY

Issue for Decision (Consent)

Should the Board of Regents adopt the proposed amendment to section 79-13.5 of the Regulations of the Commissioner of Education relating to the requirements for restricted licenses for clinical laboratory technologists in molecular testing?

Reason(s) for Consideration

Required by State statute (Chapter 186 of the Laws of 2023).

Proposed Handling

The proposed amendment is submitted to the Full Board for adoption as an emergency rule at the November 2023 Regents meeting. A copy of the proposed rule (Attachment A) and a statement of facts and circumstances which necessitate emergency action (Attachment B) is included.

Procedural History

The proposed amendment was presented to the Professional Practice Committee for discussion and recommendation to the Full Board for adoption as an emergency rule at the September 2023 meeting of the Board of Regents. A Notice of Emergency Adoption and Proposed Rule Making was published in the State Register on September 27, 2023, for a 60-day public comment period.

Because the September 2023 emergency action will expire on December 10, 2023, a second emergency action is necessary to ensure the emergency rule remains continuously in effect until it can be permanently adopted at the January 2024 Regents meeting. A Notice of Emergency Adoption will be published in the State Register on

December 27, 2023. Supporting materials are available upon request from the Secretary to the Board of Regents.

Background Information

In 2004, the Clinical Laboratory Technology Practice Act (“the Act”) was enacted (Chapter 755 of the Laws of 2004), effective September 1, 2006. Pursuant to the Act, a person could not work in a clinical laboratory without the appropriate generalist’s license in the appropriate clinical laboratory area.¹

Chapter 204 of the Laws of 2008 added Education Law §8610 to the clinical laboratory technology article (Article 165), creating a restricted license in five specific test areas.² This restricted license provision enabled laboratories to provide such tests and procedures notwithstanding that they were often not yet included in the registered programs for clinical laboratory technology. Two categories of the restricted licenses that were created were for molecular diagnosis. The molecular diagnosis restricted licenses were created with very limited language, which reflected the technology and need that existed at that time. One type of molecular diagnosis restricted license was limited to diagnosis that is included in genetic testing-molecular and molecular oncology (Education Law §8610(1)(a), 8 NYCRR 79-13.5(e)). The other type of molecular diagnosis restricted license was not limited to genetic testing-molecular and molecular oncology; however, this restricted license is only available to employees of the National Cancer Institute, a designated cancer center, or a teaching hospital that is eligible for distributions pursuant to Public Health Law §2807-m(3)(c) (Education Law §8610(1)(b), 8 NYCRR 79-13.5(f)).

On June 30, 2023, the Governor signed Chapter 186 of the Laws of 2023 (Chapter 186), which became effective immediately. Chapter 186 amended Education Law §8610 by renaming the two categories of restricted licenses in clinical laboratory technology from “molecular diagnosis” to “molecular testing” and expanded the scope of services provided by persons holding these restricted licenses. Chapter 186 was enacted in response to a shortage of clinical laboratory workers who perform critically important molecular tests to detect COVID-19, influenza, and other infectious diseases and codifies temporary flexibilities that existed under Executive Orders.

Specifically, on September 27, 2021, the Governor executed [Executive Order No. 4 of 2021](#) declaring a statewide disaster emergency due to health care staffing shortages in New York State. This Executive Order, as modified by [Executive Order No. 4.1 of 2021](#), temporarily waived specified Education Law provisions and any associated regulations to the extent necessary to allow individuals to perform any clinical laboratory test, including for the detection of COVID-19 and influenza, provided such individual was under appropriate supervision and met certain federal requirements. Therefore, under these Executive Orders, persons holding a restricted license in molecular diagnosis (typically restricted to genetics and oncology pursuant to Education Law §8610(a) were now permitted to perform the full range of molecular testing. However, these Executive Orders expired on June 22, 2023. Chapter 186 allows persons with restricted licenses in molecular testing to continue to

¹ These clinical laboratory areas currently include clinical laboratory technologists, clinical laboratory technicians, histotechnicians, and cytotechnologists.

² These five test areas include histocompatibility, cytogenetics, stem cell process, flow cytometry/cellular immunology and molecular diagnosis. Chapter 227 of 2019 added a sixth test area of toxicology.

perform the full range of molecular testing services they were able to provide under these Executive Orders, including, but not limited to, COVID19 and Influenza testing. Expanding the molecular testing services that can be performed with a restricted license will assist in addressing the ongoing high demand for these services, while also ensuring appropriate education and supervision.

Proposed Amendment

The proposed amendment to section 79-13.5 of the Commissioner's regulations implements Chapter 186 by:

- changing the name of two categories of restricted licenses in clinical laboratory technology from "molecular diagnosis" to "molecular testing;" and
- revising the education requirements for applicants for a restricted license in molecular testing, consistent with their expanded scope of practice.

Additionally, the proposed amendment eliminates an outdated education certification requirement in section 79-13.5(c)(3) of the Commissioner's regulations.

Related Regent's Items

September 2023: [Proposed Amendment to Section 79-13.5 of the Regulations of the Commissioner of Education Relating to Requirements for Restricted Licenses for Clinical Laboratory Technologists in Molecular Testing](https://www.regents.nysed.gov/sites/regents/files/923ppca1.pdf)
(<https://www.regents.nysed.gov/sites/regents/files/923ppca1.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 December 11, 2023, 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 in order to timely implement the provisions of Chapter 186 of the Laws of 2023, which became effective June 30, 2023, and to ensure the emergency action taken at the September 2023 meeting remains continuously in effect.

Timetable for Implementation

If adopted as an emergency rule at the November 2023 Regents meeting, the emergency rule will become effective December 11, 2023. It is anticipated that the proposed amendment will be presented for permanent adoption at the January 2024 Regents meeting, after publication of the proposed amendment in the State Register and expiration of the 60-day public comment period required under the State Administrative Procedure Act. If adopted at the January 2024 meeting, the proposed amendment will become effective as a permanent rule on January 24, 2024.

AMENDMENT TO THE REGULATIONS OF THE COMMISSIONER OF EDUCATION

Pursuant to sections 207, 210, 212, 6501, 6504, 6507, 8607, and 8610 of the Education Law and Chapter 186 of the Laws of 2023.

1. Section 79-13.5 of the Regulations of the Commissioner of Education is amended to read as follows:

Section 79-13. 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], molecular testing, and toxicology as provided in paragraph (b)(1) of this section.

(b) Notwithstanding subdivision (a) of this section, restricted licensees employed at the National Cancer Institute designated cancer centers or at teaching hospitals that are eligible for distributions pursuant to section 2807-m(3)(c) of the Public Health Law may receive a certificate that also includes the practice of molecular [diagnosis] testing including by not limited to genetic testing-molecular and molecular oncology, provided that such certificate holders may practice in such additional areas only at such centers, teaching hospitals or other sites as may be designated by the commissioner.

(1) . . .

(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) For a certificate in the area of molecular [diagnosis to the extent such molecular diagnosis is included in genetic testing-molecular and molecular oncology, the training program shall include knowledge of the role of molecular genetics in tumor diagnosis and individualized tumor therapies that are being defined and implemented. The training program shall also include, but need not be limited to, general laboratory principles; general principles of molecular biology, clinical molecular genetics, and molecular diagnosis; infection control and aseptic technique; applicable laboratory skills; quality control and quality assurance; laboratory mathematics; basic principles of

nucleic acid extraction, modification, amplification, identification, and unidirectional workflow techniques to avoid cross contamination; electrophoresis and other separation techniques; and transfer and hybridization techniques and specific techniques of nucleic acid amplification and identification.] testing, the training program shall include:

(i) knowledge of nucleic acid chemistry, human molecular biology, molecular pathology, molecular diagnosis, molecular oncology (including the role of genetics in molecular diagnosis and molecularly targeted therapies), human and microbial molecular genetics, and molecular test result calculation, interpretation, and reporting;

(ii) practicum in molecular techniques, including but not limited to, nucleic acid isolation, separation, detection, amplification, sequencing, techniques to prevent specimen contamination, and additional molecular techniques as determined by the department;

(iii) laboratory operations relevant to molecular testing, including, but not limited to, quality control, quality assurance, safety, instrument operation and maintenance, and;

(iv) knowledge of applications of molecular testing in the fields of infectious disease, oncology, genetics, genomics, transfusion medicine, pharmacogenomics, and other fields as determined by the department; and

(f) For a certificate in the area of molecular [diagnosis that is not limited to genetic testing-molecular and molecular oncology] testing as provided in Education Law, section 8610(1)(b), an applicant shall:

(1) be employed at a National Cancer Institute designated cancer center or at a teaching hospital that is eligible for distributions pursuant to Public Health Law [section] §2807m(3)(c); and

(2) have completed the training requirements for the restricted license in molecular [diagnosis to the extent such molecular diagnosis is included in genetic testing-molecular and molecular oncology] testing pursuant to clause (e) of this subparagraph; and

(3) have completed additional training requirements for the restricted license in molecular [diagnosis] testing acceptable to the department that would enable the applicant to practice competently in accordance with section 8610(1)(b) of the Education Law.

(g) . . .

[(3) In order to receive a restricted license under this section, the applicant must also certify to the department that he or she has reviewed the rules and regulations of the New York State Department of Health and the U.S. Department of Health and Human Services, relating to practice as a clinical laboratory technologist in New York State, in accordance with written guidance from the department.]

8 NYCRR §79-13.5

STATEMENT OF FACTS AND CIRCUMSTANCES
WHICH NECESSITATE EMERGENCY ACTION

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distributions pursuant to Public Health Law §2807-m(3)(c) (Education Law §8610(1)(b), 8 NYCRR 79-13.5(f)).

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molecular testing services that can be performed with a restricted license will assist in addressing the ongoing high demand for these services, while also ensuring appropriate education and supervision.

The proposed amendment to section 79-13.5 of the Commissioner's regulations implements Chapter 186 by:

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- revising the education requirements for applicants for a restricted license in molecular testing, consistent with their expanded scope of practice.

Additionally, the proposed amendment eliminates an outdated education certification requirement in section 79-13.5(c)(3) of the Commissioner's regulations.

The proposed amendment was presented to the Professional Practice Committee for recommendation to the Full Board for adoption as an emergency rule at the September 2023 meeting of the Board of Regents, effective September 12, 2023. Since the Board of Regents meets at fixed intervals, the earliest the proposed amendment could be adopted by regular (nonemergency) action after expiration of the 60-day public comment period provided for in the State Administrative Procedure Act (SAPA) sections 201(1) and (5), would be the January 2024 Regents meeting. Furthermore, pursuant to SAPA 203(1), the earliest effective date of the proposed rule, if adopted at January 2024 meeting would be January 24, 2024, the date the Notice of Adoption would be published in the State Register.

However, the emergency rule will expire on December 10, 2023. Therefore, a second emergency action is necessary at the November 2023 meeting, effective December 12, 2023, for the preservation of the public health and general welfare in

order to timely implement the requirements of Chapter of Chapter 186, which became effective June 30, 2023, and to ensure that the emergency action taken at the September 2023 meeting remains continuously in effect until the rule can be permanently adopted.

It is anticipated that the proposed rule will be presented to the Board of Regents for adoption as a permanent rule at the January 2024 meeting, which is the first scheduled meeting after expiration of the 60-day public comment period mandated by SAPA for state agency rule making.