AMENDMENT TO THE REGULATIONS OF THE COMMISSIONER OF EDUCATION

Pursuant to sections 207, 210, 6504, 6507, 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.]