



TO: The Honorable Members of the Board of Regents

FROM: David H. Hamilton *David H. Hamilton*

SUBJECT: Proposed Repeal of Sections 52.38, 52.39, 52.40, and 52.41, Addition of New Sections 52.38, 52.39, 52.40, and 52.41 and 52.50 to the Regulations of the Commissioner of Education Relating to the Requirements for Registration of Curricula of Licensure Qualifying Education Programs for the Professions of Clinical Laboratory Technologist, Cytotechnologist, Clinical Laboratory Technician, Histotechnician and Histotechnologist

DATE: April 25, 2024

AUTHORIZATION(S):

Donna Bellotti

SUMMARY

Issue for Decision (Consent)

Should the Board of Regents adopt the proposed amendments repealing sections 52.38, 52.39, 52.40, and 52.41 and adding new sections 52.38, 52.39, 52.40, 52.41, and 52.50 to the Regulations of the Commissioner of Education relating to the requirements for registration of curricula of licensure qualifying education programs for the professions of clinical laboratory technologist, cytotechnologist, clinical laboratory technician, histotechnician and histotechnologist?

Reason for Consideration

Review of policy and required by State statute (Chapter 446 of the Laws of 2022).

Proposed Handling

The proposed amendment is submitted to the Full Board for adoption as a permanent rule at the May 2024 meeting. A copy of the proposed rule (Attachment A) is attached.

Procedural History

A Notice of Proposed Rule Making was published in the State Register on January 24, 2024, for a 60-day public comment period.

Following publication in the State Register, the Department received no comments on the proposed amendment. Therefore, an Assessment of Public Comment is not required. The Department has made non-substantial revisions to the proposed rule as outlined below. If adopted at the May 2024 meeting, a Notice of Adoption will be published in the State Register on May 22, 2024. Supporting materials are available upon request to the Secretary of the Board of Regents.

Background Information

Clinical laboratory technology practitioners provide laboratory services that are necessary for the diagnosis, treatment, and monitoring of diseases and other health conditions. Clinical laboratories in New York have had great difficulty in recruiting and retaining staff due to a chronic workforce shortage of clinical laboratory practitioners. This workforce shortage was further exacerbated by the COVID-19 pandemic.

To address the long-term clinical laboratory practitioners' workforce shortage in New York, Chapter 446 of the Laws of 2022 (Chapter 446) was enacted to improve access to needed medical laboratory services by: (1) providing additional flexibility to license additional qualified individuals as clinical laboratory practitioners, effective January 17, 2023; and (2) establishing the licensure requirements for the new histotechnologist profession, effective January 21, 2024.

To implement Chapter 446, at its April 2023 meeting, the Board of Regents permanently adopted amendments to Subparts 79-13, 79-14, 79-15, and 79-16 of the Commissioner's regulations. While the April 2023 amendments to the Commissioner's regulations provide flexibility and multiple pathways for individuals who already meet the education and experience required for licensure, they did not establish registration requirements for the new education programs that are aligned to these pathways.

The proposed amendments conform the Commissioner's regulations to Chapter 446 by establishing registration of curricula requirements that are aligned to the multiple pathways that lead to licensure in the clinical laboratory professions.

Proposed Amendment

The proposed additions of sections 52.38, 52.39, 52.40, 52.41 and 52.50 to the Commissioner's regulations implement Chapter 446 by:

- establishing specific coursework and clinical education requirements for registered degree programs that lead to licensure as a Clinical Laboratory Technologist, Cytotechnologist, Clinical Laboratory Technician, Histotechnician, and Histotechnologist;
- establishing pathways to program registration for degree programs that lead to licensure as a Clinical Laboratory Technologist, Cytotechnologist, Clinical Laboratory Technician, Histotechnician, and Histotechnologist, which are determined by the Department to meet accreditation standards set forth by a national accrediting organization acceptable to the Department; and
- establishing pathways for the registration of programs that lead to licensure as a Clinical Laboratory Technologist, Cytotechnologist, Clinical Laboratory

Technician, Histotechnician, and Histotechnologist for clinical education programs that have qualifying degree programs as admissions requirements and that are determined by the Department to meet accreditation standards set forth by a national accrediting organization acceptable to the Department. Such accredited clinical education programs may be credit-bearing or clock-hour programs.

Non-Substantial Revisions to the Proposed Amendment

Due to a clerical error, the proposed addition of section 52.42 to the Commissioner's regulations for registration of curricula for histotechnologists was inadvertently misnumbered. The filed text of the regulation cited section 52.42 of the Commissioner's regulations rather than section 52.50 of the Commissioner's regulations. The proposed addition of the inaccurately numbered section 52.42 to the Commissioner's regulations also inadvertently contained an incorrect citation to section 79-17.1 of the Commissioner's regulations rather than section 79-21.1 of the Commissioner's regulations. Therefore, the Department has made non-substantial revisions to the proposed amendment to resolve these errors.

Related Regents Items

January 2024: [Proposed Repeal of Sections 52.38, 52.39, 52.40, and 52.41 and Addition of New Sections 52.38, 52.39, 52.40, 52.41 and 52.42 to the Regulations of the Commissioner of Education Relating to the Requirements for Registration of Curricula of Licensure Qualifying Education Programs for the Professions of Clinical Laboratory Technologist, Cytotechnologist, Clinical Laboratory Technician, Histotechnician and Histotechnologist](https://www.regents.nysed.gov/sites/regents/files/124ppcd1.pdf)
(<https://www.regents.nysed.gov/sites/regents/files/124ppcd1.pdf>)

April 2023: [Proposed Amendment to the Title of Subpart 79-16 and Sections 79-13.1, 79-13.3, 79-13.6, 79-14.1, 79-14.3, 79-15.1, 79-15.3, 79-16.1, 79-16.2, 79-16.3, 79-16.4 and 79-16.5 of the Regulations of the Commissioner of Education Relating to Licensure as a Clinical Laboratory Technologist or Cytotechnologist and Certification as a Clinical Laboratory Technician or Histological Technician](https://www.regents.nysed.gov/sites/regents/files/423ppca2.pdf)
(<https://www.regents.nysed.gov/sites/regents/files/423ppca2.pdf>)

Recommendation

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

VOTED: That sections 52.38, 52.39, 52.40, and 52.41 of the Regulations of the Commissioner of Education be repealed, as submitted, and new section sections 52.38, 52.39, 52.40, 52.41, and 52.50 of the Regulations of the Commissioner of Education be added, as submitted, effective May 22, 2024.

Timetable for Implementation

If adopted at the May 2024 meeting, the proposed rule will become effective as a permanent rule on May 22, 2024.

AMENDMENT TO THE REGULATIONS TO THE COMMISSIONER OF EDUCATION

Pursuant to sections 207, 210, 212, 6501, 6504, 6507, 8600, 8601, 8602, 8603, 8605, 8606, 8606-a and 8608-b of the Education Law and Chapter 446 of the Laws of 2022.

1. Section 52.38 of the Regulations of the Commissioner of Education is REPEALED and a new section 52.38 is added to read as follows:

Section 52.38 Clinical laboratory technology.

In addition to meeting all applicable provisions of this Part, to be registered as a program recognized as leading to licensure as a clinical laboratory technologist, which meets the requirements of section 79-13.1 of this Title, the program shall:

(a) be a program in clinical laboratory technology leading to a bachelor's degree or higher degree or post-baccalaureate advanced certificate, the combination of which contains didactic and clinical education that integrates pre-analytical, analytical, and post-analytical components of laboratory services, which shall include:

(1) coursework, which may include a laboratory component, in each of the following subject areas or their equivalent as determined by the department:

(i) clinical chemistry;

(ii) clinical microscopy, including urine and body fluids analysis;

(iii) immunology/serology;

(iv) immunohematology (transfusion medicine);

(v) hematology/hemostasis;

(vi) molecular biology or cell biology or genetics;

(vii) clinical microbiology, including bacteriology, mycology, parasitology, and virology;

(viii) mathematics or statistics; and

(ix) laboratory operations, including, but not limited to, quality control, quality assurance, equipment maintenance, record keeping, laboratory procedures, and safety;
and

(2) a supervised clinical experience of at least 500 clock hours of clinical laboratory technologist practice, which, at a minimum, provides each student with clinical experience in hematology/hemostasis, clinical chemistry, immunohematology, urinalysis/body fluids analysis, clinical microbiology, and immunology; or

(b) be a program that leads to a bachelor's degree in clinical laboratory technology, or an appropriate clinical education program that has at least a bachelor's degree as an admissions requirement, and that meets accreditation standards as a clinical laboratory technology program (or similarly named program) from a national accrediting organization acceptable to the department. For programs in the process of obtaining accreditation, in addition to maintaining compliance with all applicable provisions of this Part, continued registration of the program will be contingent upon the demonstration of adequate progress towards full accreditation as determined by the department. For accredited programs, in addition to maintaining compliance with all applicable provisions of this Part, re-registration will be contingent upon maintaining accreditation status.

2. Section 52.39 of the Regulations of the Commissioner of Education is REPEALED and a new section 52.39 is added to read as follows:

Section 52.39 Cytotechnology.

In addition to meeting all applicable provisions of this Part, to be registered as a program recognized as leading to licensure as a cytotechnologist, which meets the requirements of section 79-14.1 of this Title, the program shall:

(a) be a program in cytotechnology leading to a bachelor's degree or higher degree or post-baccalaureate advanced certificate, the combination of which shall include:

(1) coursework, which may include a laboratory component, in each of the following subject areas or their equivalent as determined by the department:

(i) inorganic and organic chemistry;

(ii) anatomy and physiology;

(iii) cell biology, genetics, or molecular biology;

(iv) cytopathology, including but not limited to, female genital tract, respiratory tract, gastro-intestinal and genitourinary tracts, body fluids, evaluation of specimens from washes and brushes of all body sites, and evaluation of specimens from fine needle aspiration biopsies of all body sites;

(v) cytopreparatory techniques, including but not limited to, preparation, staining and processing of specimens derived from the human body; and

(vi) microscopic evaluation and interpretation of cytopathology of the specimen types and body systems identified in paragraph (4) of this subdivision;

(vii) mathematics or statistics;

(viii) human genetics;

(ix) immunology;

(x) clinical microbiology; and

(xi) laboratory operations relevant to cytology services, including, but not limited to, quality control, quality assurance, equipment maintenance, record keeping, laboratory procedures, and safety; and

(2) include a supervised clinical experience of at least 300 clock hours of cytotechnology practice, which, at a minimum, provides each student with clinical

experience in cytopreparatory techniques and the microscopic examination of gynecologic, non-gynecologic, and fine needle aspiration specimens; or

(b) be a program that leads to a bachelor's degree in cytotechnology, or an appropriate clinical education program that has at least a bachelor's degree as an admissions requirement, and that meets accreditation standards as a cytotechnology (or similarly named) program, from a national accrediting organization acceptable to the department. For programs in the process of obtaining accreditation, in addition to maintaining compliance with all applicable provisions of this Part, continued registration of the program will be contingent upon the demonstration of adequate progress towards full accreditation as determined by the department. For accredited programs, in addition to maintaining compliance with all applicable provisions of this Part, re-registration will be contingent upon maintaining accreditation status.

3. Section 52.40 of the Regulations of the Commissioner of Education is REPEALED and a new section 52.40 is added to read as follows:

Section 52.40 Clinical laboratory technician.

In addition to meeting all applicable provisions of this Part, to be registered as a program recognized as leading to certification as a clinical laboratory technician, which meets the requirements of section 79-15.1 of this Title, the program shall:

(a) be a clinical laboratory technician program leading to an associate's or higher degree which contains didactic and clinical education that integrates pre-analytical, analytical, and post-analytical components of laboratory services that shall include:

(1) coursework, which may include a laboratory component, in each of the following subject areas or their equivalent as determined by the department:

(i) inorganic chemistry;

(ii) clinical chemistry;

(iii) physiology, with anatomy content;

(iv) microbiology, including clinical microbiology;

(v) immunology and serology;

(vi) hematology/hemostasis;

(vii) clinical microscopy, including body fluids;

(viii) immunoematology;

(ix) mathematics or statistics; and,

(x) laboratory operations, including, but not limited to, quality control, quality assurance, equipment maintenance, record keeping, laboratory procedures, and safety;

and

(2) include a supervised clinical experience of at least 300 clock hours of clinical laboratory technician practice, which provides each student with clinical experience that includes but is not limited to: hematology, hemostasis, immunoematology, immunology, clinical chemistry, urinalysis/body fluids, and clinical microbiology; or

(b) be a program that leads to an associate degree in clinical laboratory technician, or an appropriate clinical education program that has at least an associate's degree as an admissions requirement, and that meets accreditation standards as a clinical laboratory technician (or similarly named) program, from a national accrediting organization acceptable to the department. For programs in the process of obtaining accreditation, in addition to maintaining compliance with all applicable provisions of this Part, continued registration of the program will be contingent upon the demonstration of adequate progress towards full accreditation as determined by the department. For accredited programs, in addition to maintaining compliance with all applicable provisions of this Part, re-registration will be contingent upon maintaining accreditation status.

4. Section 52.41 of the Regulations of the Commissioner of Education is REPEALED and a new section 52.41 is added to read as follows:

52.41 Histotechnician.

In addition to meeting all applicable provisions of this Part, to be registered as a program recognized as leading to certification as a histotechnician, which meets the requirements of section 79-16.1 of this Title, the program shall:

(a) be a histotechnician program leading to an associate or higher degree that shall:

(1) include curricular content in each of the following subject areas or their equivalent as determined by the department:

(i) anatomy and physiology;

(ii) inorganic chemistry;

(iii) histology;

(iv) histological techniques, to include microtome; and,

(v) laboratory operations relevant to histology services, including, but not limited to, quality control, quality assurance, equipment maintenance, record keeping, laboratory procedures, and safety; and

(2) include a supervised clinical experience of at least 240 clock hours of histotechnician practice; or

(b) be a program that leads to an associate degree in histotechnician, or be an appropriate clinical education program that has at least an associate's degree as an admissions requirement, and that meets accreditation standards as a histotechnician (or similarly named) program, from a national accrediting organization acceptable to the department. For programs in the process of obtaining accreditation, in addition to maintaining compliance with all applicable provisions of this Part, continued registration

of the program will be contingent upon the demonstration of adequate progress towards full accreditation as determined by the department. For accredited programs, in addition to maintaining compliance with all applicable provisions of this Part, re-registration will be contingent upon maintaining accreditation status.

5. A new Section 52.50 of the Regulations of the Commissioner of Education is added to read as follows:

52.50 Histotechnologist.

In addition to meeting all applicable provisions of this Part, to be registered as a program recognized as leading to licensure as a histotechnologist, which meets the requirements of section 79-21.1 of this Title, the program shall:

(a) be a histotechnology program leading to a bachelor's or higher degree or post-baccalaureate advanced certificate, the combination of which shall:

(1) include coursework, which may include a laboratory component, in each of the following subject areas or their equivalent as determined by the department:

(i) anatomy and physiology;

(ii) inorganic and organic chemistry;

(iii) histology;

(iv) histological techniques, including but not limited to; (i) specimen accessioning, grossing, fixation, processing, embedding, sectioning (including microtomy), and staining techniques; (ii) immunohistochemistry procedures; and (iii) molecular and cytology preparation techniques;

(v) laboratory operations relevant to histology services, including, but not limited to, quality control, quality assurance, equipment maintenance, record keeping, laboratory procedures, and safety; and

(2) include a supervised clinical experience of at least 500 clock hours of histotechnologist practice; or

(b) be a program that leads to a bachelor's degree in histotechnology (or similarly named program), or an appropriate clinical education program that has at least a bachelor's degree as an admissions requirement, and that meets accreditation standards as a histotechnology program (or similarly named program) from a national accrediting organization acceptable to the department. For programs in the process of obtaining accreditation, in addition to maintaining compliance with all applicable provisions of this Part, continued registration of the program will be contingent upon the demonstration of adequate progress towards full accreditation as determined by the department. For accredited programs, in addition to maintaining compliance with all applicable provisions of this Part, re-registration will be contingent upon maintaining accreditation status.