

THE STATE EDUCATION DEPARTMENT / THE UNIVERSITY OF THE STATE OF NEW YORK / ALBANY, NY 12234

TO: The Professional Practice Committee

FROM: Douglas E. Lentivech

SUBJECT: Proposed Amendment of Section 29.2 of the Rules of the

Board of Regents and Addition of Section 52.48 and Subpart 79-20 to the Regulations of the Commissioner of Education Relating to the Licensing of Licensed

Pathologists' Assistants

DATE: November 2, 2017

AUTHORIZATION(S):

SUMMARY

Issue for Decision

Should the Board of Regents amend §29.2 of the Rules of the Board of Regents and add a new §52.48 and a new subpart 79-20 to the Regulations of the Commissioner of Education relating to the licensure of licensed pathologists' assistants?

Reason(s) for Consideration

Required by State statute (L. 2016, Ch. 497).

Proposed Handling

The proposed amendment will be presented to the Professional Practice Committee for recommendation and to the Full Board for adoption as an emergency action at the November 2017 meeting of the Board of Regents. A copy of the proposed rule and a Statement of Facts and Circumstances Which Necessitate Emergency Action are attached.

Procedural History

A Notice of Proposed Rule Making will be published in the State Register on November 29, 2017. A Notice of Emergency Adoption will be published in the State

Register on December 13, 2017. Supporting materials for the proposed rule are available upon request from the Secretary to the Board of Regents.

Background Information

Pathologists' assistants provide services under the direction and supervision of a licensed physician who practices anatomic pathology. These services include, but are not limited to, preparing gross tissue sections for pathology analysis, which includes, but is not limited to, cutting, staining as required, describing gross anatomic features, dissecting surgical specimens, and submitting tissues for bio-banking, histologic processing, or other analyses; and performing human postmortem examinations, which include, but are not limited to, selection of tissues and fluids for further examination, external examination, dissection, and gathering and recording information for autopsy reports.

Pathologists' assistants do not diagnose or provide a medical opinion and their services must be performed in a laboratory or other site authorized under law to perform such services.

Chapter 497 of the Laws of 2016 ("Chapter 497") amended the Education Law by adding Article 168, which establishes and defines the practice of the profession of licensed pathologists' assistants, effective, except for one provision, November 28, 2017.¹ Prior to Chapter 497, pathologists' assistants were neither licensed as a profession nor defined in Education Law. Thus, in order to practice, many pathologists' assistants practiced under the limited license authority for clinical laboratory technologists and certified histological technicians pursuant to Chapter 336 of the Laws of 2013 as amended by Chapter 194 of the Laws of 2016. In accordance with Chapter 194 of the Laws of 2016, these limited licenses and registrations will expire on September 1, 2018. Chapter 497 remedies this situation by establishing a new licensure category for pathologists' assistants in the Education Law. However, it is imperative for pathologists' assistants to become licensed in accordance with Article 168 of the Education Law before the expiration of their respective limited licenses.

Chapter 497 establishes the education, examination, age, moral character and fee requirements for applicants seeking licensure as a licensed pathologists' assistant. It also provides a grandparenting pathway for individuals who meet the requirements for a license as a pathologists' assistant, except for examination and education, and who have been performing the duties of a pathologists' assistant for two of the five years prior to the effective date of Article 168 of the Education Law, if they submit an application to the Department prior to November 28, 2019, and provided their supervising physician, who must practice anatomic pathology, attests to their experience and competence. Although this pathway will expire, the licenses issued under it will not.

The proposed amendment to subdivision (a) of §29.2 of the Rules of the Board of Regents adds the profession of licensed pathologists' assistants to the list of health care professions that are subject to its unprofessional conduct provisions.

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¹ Education Law §8852 becomes effective November 28, 2018.

The proposed addition of §52.48 to the Regulations of the Commissioner of Education establishes the program registration requirements for professional education programs. These requirements include registration and curriculum requirements for programs offered in New York State that lead to licensure as a licensed pathologists' assistant. The proposed amendment requires professional licensed pathologists' assistants' education programs to be a program in licensed pathologists' assistant or a substantially equivalent program as determined by the Department leading to a bachelor's or higher degree; and which must include course content in each of the following subjects or their equivalent as determined by the Department: (1) practices in anatomic pathology; (2) anatomy and basic microanatomy; (3) human physiology; (4) anatomic pathology, which includes surgical techniques, autopsy techniques, histological methods and techniques, and other related competencies; and (5) application of laboratory safety governmental regulations and standards as applied to anatomic pathology. The proposed amendment requires licensure qualifying programs to provide that learning experiences (e.g., courses, practica and/or other activities) are properly sequenced and include necessary content and activities to enable students to achieve entry level competence in each of the required course content disciplines.

The proposed §52.48 was drafted to specifically parallel the Pathologists' Assistant ("PathA") curriculum requirements from the National Accrediting Agency for Clinical Laboratory Sciences ("NAACLS") standards for accredited and approved programs. The intention is to ensure that programs deemed to be substantially equivalent to programs registered with the Department, will reflect curriculum consistent with these NACCLS standards.

Additionally, the proposed addition of Subpart 79-20 to the Regulations of the Commissioner of Education establishes the requirements for licensure as a licensed pathologists' assistant, which include, but are not limited to, education, examination, fee and limited permit requirements, as well as the requirements for the grandparenting licensure pathway.

Related Regents Items

None.

Recommendation

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

VOTED: That subdivision (a) of §29.2 of the Rules of the Board of Regents be amended and sections 52.48, 79-20.4 and 79-20.5 of the Regulations of the Commissioner of Education be added, as submitted, effective November 28, 2017, 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 requirements of Chapter 497 of the Laws of 2016, which establishes and defines the practice and profession of licensed pathologists' assistants.

<u>Timetable for Implementation</u>

If adopted at the November 2017 Regents meeting, the proposed amendment of subdivision (a) of §29.2 of the Rules of the Board of Regents and addition of sections 52.48, 79-20.4 and 79-20.5 of the Regulations of the Commissioner of Education will become effective as an emergency rule on November 28, 2017, which is the effective date of the statute (except for one provision) and expire on February 25, 2018. It is anticipated that an additional emergency action will be presented for adoption at the January 2018 Regents meeting to keep the rule continuously in effect until it 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 February 2018 Regents meeting, after publication of the proposed amendment in the State Register and expiration of the 45-day public comment period required under the State Administrative Procedure Act. At the February 2018 Regents meeting, it will be recommended that the Board of Regents adopt the proposed amendment of subdivision (a) of §29.2 of the Rules of the Board of Regents and addition of sections 52.48, 79-20.4 and 79-20.5 of the Regulations of the Commissioner of Education, on a permanent basis.

At the February 2018 Regents meeting, it will also be recommended that the Board of Regents adopt the addition of three additional sections of new subpart 79-20 – sections 79-20.1, 79-20.2 and 79-20.3 – of the Regulations of the Commissioner of Education, on a permanent basis, effective November 28, 2018.

AMENDMENT TO THE RULES OF THE BOARD OF REGENTS AND THE REGULATIONS OF THE COMMISSIONER OF EDUCATION

Pursuant to sections 207, 212, 6504, 6507, 6509, 8850, 8851, 8852, 8853, 8854, 8855, and 8856 of the Education Law and Chapter 497 of the Laws of 2016

- 1. Subdivision (a) of section 29.2 of the Rules of the Board of Regents is amended, as follows:
- (a) Unprofessional conduct shall also include, in the professions of: acupuncture, athletic training, audiology, certified behavior analyst assistant, certified dental assisting, chiropractic, creative arts therapy, dental hygiene, dentistry, dietetics/nutrition, licensed behavior analyst, licensed pathologists' assistants, licensed perfusionist, licensed practical nursing, marriage and family therapy, massage therapy, medicine, mental health counseling, midwifery, occupational therapy, occupational therapy assistant, ophthalmic dispensing, optometry, pharmacy, physical therapist assistant, physical therapy, physician assistant, podiatry, psychoanalysis, psychology, registered professional nursing, respiratory therapy, respiratory therapy technician, social work, specialist assistant, speech-language pathology (except for cases involving those professions licensed, certified or registered pursuant to the provisions of article 131 or 131-B of the Education Law in which a statement of charges of professional misconduct was not served on or before July 26, 1991, the effective date of chapter 606 of the Laws of 1991):
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 - (2) . . .
 - (3) . . .
 - (4) . . .

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2. Section 52.48 of the Regulations of the Commissioner of Education is added, as follows:

§52.48 Licensed Pathologists' Assistants

In addition to meeting all the applicable provisions of this Part, to be registered as a program recognized as leading to licensure as a pathologists' assistant, which meets the requirements of section 79-20.1 of this Title, the program shall:

- (a) be a pathologists' assistant program or a substantially equivalent program as determined by the department, which leads to a bachelor's or higher degree;
- (b) include courses in each of the following subjects or their equivalent as determined by the department:
- (1) practices in anatomic pathology, which shall encompass surgical and autopsy pathology, including, but not limited to:
 - (i) principles and methodologies;
 - (ii) performance of procedures;

(iv) problem solving; (v) troubleshooting techniques; (vi) principles and practices of quality assurance/quality improvement; and (vii) laboratory management; (2) anatomy and basic microanatomy; (3) human physiology; (4) anatomic pathology, including, but not limited to: (i) surgical pathology techniques: (a) adult; and (b) pediatric; (ii) autopsy techniques: (a) medical autopsy techniques; (1) adult; and (2) pediatric; (b) forensic autopsy techniques: (1) adult; (2) pediatric; and (3) toxicology collection techniques; (iii) histological methods and techniques: (a) concepts of immunohistochemistry; (iv) concepts of molecular diagnostics; (v) microbiology/immunology; (vi) clinical pathology;

(iii) correlation of clinical information and gross pathology with proper technique;

- (vii) embryology;
- (viii) laboratory safety;
- (ix) laboratory information systems;
- (x) laboratory management;
- (xi) medical ethics;
- (xii) medical terminology; and
- (xiii) biomedical photography;
- (5) application of laboratory safety governmental regulations and standards as applied to anatomic pathology, including, but not limited to:
 - (i) principles and practices of professional conduct;
- (ii) principles of interpersonal and interdisciplinary communication and teambuilding skills;
- (iii) principles and practices of administration and supervision as applied to clinical laboratory science; and
 - (iv) educational methodologies;
- (6) learning experiences, including, but not limited to courses, practica and/or other required activities, must be properly sequenced and include necessary content and activities to enable students to achieve entry level competencies in each of the major disciplines listed in this section.

SUBPART 79-20

LICENSED PATHOLOGISTS' ASSISTANTS

- §79-20.1 Professional study for licensed pathologists' assistants.
- (a) As used in this section, an acceptable accrediting body for pathologists' assistants' education programs shall mean an organization acceptable to the

department as a reliable authority for the purpose of accreditation of pathologists' assistants' education programs at the postsecondary level, which applies its criteria for granting accreditation of programs in a fair, consistent, and nondiscriminatory manner.

- (b) To meet the professional educational requirement for licensure as a pathologists' assistant, the applicant shall present satisfactory evidence of holding a bachelor's or higher degree in pathologists' assistant awarded upon the successful completion of a bachelor's or higher degree program in pathologists' assistant, registered as leading to licensure pursuant to section 52.48 of this Title or accredited by an acceptable accrediting body for pathologists' assistants' education programs, or a bachelor's or higher degree program that is substantially equivalent to such a registered program as determined by the department.
 - §79-20.2 Licensing examinations for licensed pathologists' assistants.
- (a) Content. The licensing examination shall consist of an examination designed to test knowledge, skills and judgment relating to all areas of pathologists' assistant, including, but not limited to, the basic science of pathology, clinical applications of pathology, all pertinent areas of anatomic pathology, and the practice of pathologists' assistant as defined in subdivision (4) of section 8850 of the Education Law.
- (b) The department may accept a passing score on an examination determined by the department to be acceptable for licensure as a licensed pathologists' assistant.

 §79-20.3 Fees.
- (a) Applicants shall pay a fee of \$50 for an initial license and a fee of \$150 for the first registration period.
 - (b) Licensees shall pay a fee of \$150 for each triennial registration period. §79-20.4 Limited permits.

As authorized in section 8855 of the Education Law, the department may issue a limited permit to practice as a licensed pathologists' assistant in accordance with the requirements of this section.

- (a) An applicant for a limited permit to practice as a licensed pathologists' assistant shall:
- (1) file an application with the department on a form prescribed by the department together with a fee of \$105 for the limited permit;
- (2) meet all the requirements for licensure as a licensed pathologists' assistant, except the examination requirement; and
- (3) practice as a pathologists' assistant only under the direction and supervision of a licensed physician who practices anatomic pathology and pursuant to the order and direction of that licensed physician.
- (b) The limited permit in pathologists' assistant shall be valid for a period of not more than 12 months, provided that a limited permit may be extended for an additional 12 months at the discretion of the department for good cause as determined by the department. The time authorized by such limited permit and subsequent extension shall not exceed 24 months in total.

§79-20.5 Special provisions.

An individual who meets the requirements for a license as a licensed

pathologists' assistant except for examination and education and who has been

performing the duties of a pathologists' assistant for two of the past five years prior to

November 28, 2017 may be licensed without meeting additional requirements, provided

that such individual submits an application to the department on or before November

27, 2019. As part of the application, the applicant's supervising physician or physicians,

who practice anatomic pathology, must attest to the applicant's experience and competence.

8 NYCRR §§29.2 and 52.48, and Subpart 79-20 STATEMENTS OF FACTS AND CIRCUMSTANCES WHICH NECESSITATE EMERGENCY ACTION

The proposed rule is necessary to implement Chapter 497 of the Laws of 2016. which is effective, except for one provision, on November 28, 2017.² This amendment added Article 168 to the Education Law, which establishes and defines the practice of the profession of licensed pathologists' assistants. Pursuant to Chapter 497, pathologists' assistants provide the following services under the direction and supervision of a licensed physician who practices anatomic pathology: (1) preparing gross tissue sections for pathology analysis, which includes, but is not limited to, cutting, staining as required. describing gross anatomic features, dissecting surgical specimens, and submitting tissues for bio-banking, histologic processing, or other analyses; and (2) performing human postmortem examinations, which includes, but is not limited to, selection of tissues and fluids for further examination, external examination, dissection, and gathering and recording information for autopsy reports. Chapter 497 also establishes the requirements for licensed pathologists' assistant education programs offered in New York State that lead to licensure as a licensed pathologists' assistant. In addition, this amendment to the Education Law establishes requirements for the licensure of licensed pathologists'

² Education Law §8852 becomes effective November 28, 2018.

assistants, which include education, examination, age, moral character, fee and limited permit requirements. This amendment to the Education Law further provides for a grandparenting licensure pathway for individuals who meet the requirements for a license as a pathologists' assistant, except for the education and examination requirements, and who have been performing the duties of a pathologists' assistant for two of the five years prior to the effective date of Article 168 of the Education Law, if they submit an application to the Department prior to November 28, 2019, and provided their supervising physician, who must practice anatomic pathology, attests to their experience and competence. Although this pathway will expire on November 27, 2019, the licenses issued under it will not. Additionally, this amendment adds the profession of licensed pathologists' assistant to the list of health care professionals that are subject to the Education Laws' unprofessional conduct provisions.

Prior to Chapter 497, pathologists' assistants were neither licensed as a profession nor defined in Education Law. Thus, in order to practice, many pathologists' assistants practiced under the limited license authority for clinical laboratory technologists and certified histological technicians pursuant to Chapter 336 of the Laws of 2013 as amended by Chapter 194 of the Laws of 2016. However, under Chapter 194 of the Laws of 2016, these limited licenses and registrations will expire on September 1, 2018. Chapter 497 remedies this situation by establishing a new licensure category for pathologists' assistants in the Education Law. Therefore, it is imperative for pathologists' assistants to become licensed in accordance with Article 168 of the Education Law before the expiration of their respective limited licenses.

Since the Board of Regents meets at fixed intervals, the earliest the proposed rule can be presented for adoption, after expiration of the required 45-day public comment

period provided for in the State Administrative Procedure Act (SAPA) sections 201(1) and (5), would be the February 12-13, 2018 Regents meeting. Furthermore, pursuant to SAPA section 203(1), the earliest effective date of the proposed rule, if adopted at the February meeting, would be February 28, 2018, the date a Notice of Adoption would be published in the State Register. However, except for one provision, the provisions of Chapter 497 become effective November 28, 2017.

Therefore, emergency action is necessary at the November 2017 Regents meeting for the preservation of the public health and the general welfare in order to enable the State Education Department to immediately establish requirements to timely implement Chapter 497, so that applicants for licensure as licensed pathologists' assistants, including those who currently hold limited licenses for clinical laboratory technologists and certified histological technicians which expire on September 1, 2018, will be able to be licensed as licensed pathologists' assistants, if they meet the licensure requirements of the proposed rule, which will increase the number of licensed professionals qualified to practice as licensed pathologists' assistants.

It is anticipated that the proposed rule will be presented for adoption as a permanent rule at the February 12-13, 2018 Regents meeting, which is the first scheduled meeting after expiration of the 45-day public comment period prescribed in the State Administrative Procedure Act for State agency rule makings.