



**TO:** Professional Practice Committee

**FROM:** Sarah S. Benson *Sarah S. Benson*

**SUBJECT:** Proposed Amendments to Sections 29.2 and 29.7 of the Rules of the Board of Regents and the Title of Part 63 of the Regulations of the Commissioner of Education and Addition of Sections 63.14 and 63.15 to the Regulations of the Commissioner of Education Relating to the Licensure of Registered Pharmacy Technicians

**DATE:** April 29, 2021

**AUTHORIZATION(S):** *Jim McG* *Billy*

## SUMMARY

### Issue for Decision

Should the Board of Regents amend Sections 29.2 and 29.7 of the Rules of the Board of Regents and the Title of Part 63 of the Regulations of the Commissioner of Education and add new Sections 63.14 and 63.15 to the Regulations of the Commissioner of Education relating to the licensure of registered pharmacy technicians?

### Reason for Consideration

Required by State statute (Chapter 414 of the Laws of 2019).

### Proposed Handling

The proposed amendment is being presented to the Professional Practice Committee for recommendation to the Full Board for adoption at the May 2021 meeting of the Board of Regents. A copy of the proposed rule is attached (Attachment A).

### 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 January 2021 meeting of the Board of Regents, effective April 25, 2021. A Notice of Proposed Rule Making was published in the State Register on January 27, 2021 and a Notice of Emergency Adoption was published in the State Register on April 21, 2021.

Following the 60-day public comment period required under the State Administrative Procedure Act, the Department received two comments. An Assessment of Public Comment is included as Attachment B. No changes to the amendment are recommended at this time. Supporting materials are available upon request from the Secretary to the Board of Regents.

### **Background Information**

Chapter 414 of the Laws of 2019 (Chapter 414) amends the Education Law by adding Article 137-A, which establishes and defines the practice of the profession of registered pharmacy technicians, effective April 25, 2021. Prior to Chapter 414, New York State did not have a law recognizing the role of pharmacy technicians. Chapter 414 allows registered pharmacy technicians, under the direct personal supervision of a licensed pharmacist, to assist such pharmacist, as directed, in compounding, preparing, labeling, or dispensing of drugs used to fill valid prescriptions or medication orders or in compounding, preparing, and labeling in anticipation of a valid prescription or medication order for a patient to be served by certain facilities, in accordance with Article 137 of the Education Law, where such tasks require no professional judgment. Such professional judgment shall only be exercised by a licensed pharmacist.

Chapter 414 provides that registered pharmacy technicians may only practice in facilities licensed in accordance with Article 28 of the Public Health Law (Article 28 facilities), or pharmacies owned and operated by such facilities, under the direct personal supervision of a licensed pharmacist employed in such facilities or pharmacies. Such facilities are responsible for ensuring that the registered pharmacy technicians have received appropriate training to ensure competence before they begin assisting a licensed pharmacist in compounding, preparing, labeling, or dispensing of drugs, in accordance with Articles 137-A and 137 of the Education Law. Additionally, Chapter 414 defines direct personal supervision as supervision of procedures based on instructions given directly by a supervising licensed pharmacist who remains in the immediate area where the procedures are being performed, authorizes the procedures and evaluates the procedures performed by the registered pharmacy technicians and requires the supervising licensed pharmacist to approve all work performed by the registered pharmacy technicians prior to the actual dispensing of any drug.

In addition to performing the above-referenced registered pharmacy technician tasks, pursuant to Chapter 414, registered pharmacy technicians may assist a licensed pharmacist in the dispensing of drugs by performing functions that do not require a license. Such tasks include, but are not limited to, typing prescription labels; getting drugs from stock and returning them to stock; counting dosage units of drugs; and placing dosage units of drugs in appropriate containers.

Chapter 414 establishes the education, certification, age, moral character, application, and fee requirements for applicants seeking licensure as registered pharmacy technicians. Moreover, Chapter 414 adds section 6832 to the Education Law to set limitations on how unlicensed persons can assist a pharmacist in the dispensing of drugs and sets the supervision ratio for unlicensed persons in Article 28 facilities and pharmacies owned and operated by such facilities and non-Article 28 facilities. Moreover,

Chapter 414 adds section 6841 to the Education Law to, among other things, set the supervision ratio for registered pharmacy technicians in Article 28 facilities and/or pharmacies owned and operated by such facilities. Chapter 414 also amends section 6804 of the Education Law to add two registered pharmacy technicians to the State Board of Pharmacy and makes technical changes to the duties of the State Board of Pharmacy.

### **Proposed Amendments**

The proposed amendment to subdivision (a) of section 29.2 of the Rules of the Board of Regents adds the profession of registered pharmacy technicians to the list of health care professions that are subject to its unprofessional provisions.

The proposed amendment to section 29.7 of the Rules of the Board of Regents changes the title of the section from “Special Provisions for the Profession of Pharmacy” to “Special Provisions for the Professions of Pharmacy and Registered Pharmacy Technicians.”

The proposed amendment to subparagraph (ii) of paragraph (21) of subdivision (a) of section 29.7 of the Rules of the Board of Regents changes the title of the subparagraph from “Limitations on assistance by an unlicensed person” to “Limitations on assistance by a registered pharmacy technician and an unlicensed person.” The proposed amendment to this subparagraph also implements the supervision ratio for registered pharmacy technicians and unlicensed persons employed by Article 28 facilities, or pharmacies owned and operated by such facilities and the supervision ratio for unlicensed persons employed by non-Article 28 facilities and pharmacies not owned or operated by such facilities. In addition, the proposed amendment to this subparagraph establishes that these ratios do not apply to pharmacy interns but requires that pharmacy interns must be supervised in accordance with Parts 29 and 63 of the Commissioner’s regulations.

Additionally, the proposed amendment changes the title of Part 63 of the Commissioner’s Regulations from “Pharmacy” to “Pharmacy and Registered Pharmacy Technicians”; adds a new section 63.14 to the Commissioner’s Regulations which implements Chapter 414’s definition of the practice of registered pharmacy technician and the use of the title “registered pharmacy technician”; and adds a new section 63.15 to the Commissioner’s Regulations which establishes requirements for licensure as a registered pharmacy technician, which includes education, certification, age, moral character, application and fee requirements.

### **Related Regents Items**

January 2021: [Proposed Amendments to Sections 29.2 and 29.7 of the Rules of the Board of Regents and the Title of Part 63 of the Regulations of the Commissioner of Education and Addition of Sections 63.14 and 63.15 to the Regulations of the Commissioner of Education Relating to the Licensure of Registered Pharmacy Technicians](https://www.regents.nysed.gov/common/regents/files/121ppca1.pdf)

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## **Recommendation**

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

VOTED: That Sections 29.2 and 29.7 of the Rules of the Board of Regents and the Title of Part 63 of the Regulations of the Commissioner of Education be amended, and Sections 63.14 and 63.15 of the Regulations of the Commissioner of Education be added, as submitted, effective May 26, 2021.

## **Timetable for Implementation**

If adopted at the May 2021 Regents meeting, the permanent rule will take effect on May 26, 2021.

**Attachment A**

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 and Chapter 414 of the Laws of  
2019

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, registered 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 pharmacy technicians, 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):

- (1) . . .
- (2) . . .
- (3) . . .

(4) . . .

(5) . . .

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(11) . . .

(12) . . .

(13) . . .

(14) . . .

2. The title of section 29.7 of the Rules of the Board of Regents is amended, to read as follows:

SPECIAL PROVISIONS FOR THE [PROFESSION] PROFESSIONS OF PHARMACY AND REGISTERED PHARMACY TECHNICIANS

3. Subparagraph (ii) of paragraph (21) of subdivision (a) of section 29.7 of the Rules of the Board of Regents is amended, to read as follows:

(ii) Limitations on assistance by a registered pharmacy technician and an unlicensed person.

(a) No pharmacists, employed by a facility licensed in accordance with Article 28 of the Public Health Law or a pharmacy owned and operated by such a facility, as defined in Article 137-A of Title VIII of the Education Law, shall obtain the assistance of more than two registered pharmacy technicians in the performance of licensed tasks within their scope of practice or four unlicensed persons in the performance of the activities that do

not require licensure as set forth in clauses (i)(b)-(i) of this paragraph, the total number of such persons shall not exceed four individuals at one time. No pharmacist not employed by a facility licensed in accordance with Article 28 of the Public Health Law or a pharmacy not owned and operated by such a facility, as defined in Article 137-A of Title VIII of the Education Law, shall obtain the assistance of more than [two] four unlicensed persons in the performance of the activities set forth in clauses (i)(b)-(i) of this paragraph. Pharmacy interns shall be exempt from such ratios, but shall be supervised in accordance with this Part and Part 63 of this Title. The pharmacist shall provide the degree of supervision of such persons as may be appropriate to ensure compliance with the provisions of this Part and Part 63 of this Title. Individuals who are responsible for the act of placing drugs which are in unit-dose packaging into medication carts as part of an approved unit-dose drug distribution system for patients in institutional settings shall be exempt from such ratio, provided that such individuals are not also engaged in performing the activities set forth in clauses (i)(b)-(i) of this paragraph.

(b) Unlicensed persons shall not be authorized to:

(1) receive oral prescriptions from prescribers;

(2) interpret and evaluate a prescription for conformance with legal requirements, authenticity, accuracy and interaction of the prescribed drug with other known prescribed and over-the-counter drugs;

(3) make determinations of the therapeutic equivalency as such determinations apply to generic substitution or interchangeable biological product substitution;

(4) measure, weigh, compound or mix ingredients or engage in or assist in compounding;

(5) . . .

(6) . . .

(7) . . .

(c) No drug which is dispensed with the assistance of an unlicensed person, as provided in subparagraph (i) of this paragraph, shall be dispensed without the review and approval of the pharmacist.

4. The title of Part 63 of the Regulations of the Commissioner of Education is amended to read as follows:

PHARMACY AND REGISTERED PHARMACY TECHNICIANS

5. The Regulations of the Commissioner of Education is amended by adding a new section 63.14 to read as follows:

Section 63.14 Definition of the practice of registered pharmacy technician and use of the title.

(a) Definitions. As used in this section:

(1) "Licensed pharmacist" means a person licensed to practice pharmacy pursuant to Article 137 of Title VIII of the Education Law.

(2) "Pharmacy intern" means a person practicing under a limited permit pursuant to section 6806 of Title VIII of the Education Law.

(3) "Professional judgment" means professional decision-making by a licensed pharmacist, including, but not limited to, such activities as:

(i) interpreting a prescription or medication order for therapeutic acceptability and appropriateness or engaging in the calculations behind any such formulations;

(ii) interpreting and evaluating a prescription or medication order for conformance with legal requirements, authenticity, accuracy and interaction of the prescribed drug with other known prescribed and over-the-counter drugs;



(iii) receiving oral prescriptions from prescribers; or

(iv) counseling patients.

(4) “Compounding” means the combining, admixing, mixing, diluting, pooling, reconstituting, or otherwise altering of a drug or bulk drug substance to create a drug.

(5) “Drugs”, “pharmacopeia”, “labeling” and “sterile drug” shall have the same definitions as set forth in section 6802 of Title VIII of the Education Law.

(b) Definition of the practice of registered pharmacy technician and use of the title:

(1) Only a person licensed to practice as a registered pharmacy technician under Article 137-A of the Education Law or otherwise authorized to practice shall practice as a registered pharmacy technician or use the title “registered pharmacy technician.”

(2) A registered pharmacy technician may, under the direct personal supervision of a licensed pharmacist, assist such licensed pharmacist, as directed, in compounding, preparing, labeling, or dispensing of drugs used to fill valid prescriptions or medication orders or in compounding, preparing, and labeling in anticipation of a valid prescription or medication order for a patient to be served by the facility, in accordance with Article 137 of the Education Law where such tasks require no professional judgment. Such professional judgment shall only be exercised by a licensed pharmacist. A registered pharmacy technician may only practice in a facility licensed in accordance with Article 28 of the Public Health Law, or a pharmacy owned and operated by such a facility, under the direct personal supervision of a licensed pharmacist employed in such a facility or pharmacy. Such facility shall be responsible for ensuring that the registered pharmacy technician has received appropriate training to ensure competence before he or she begins assisting a licensed pharmacist in compounding, preparing, labeling, or dispensing of drugs, in accordance with Articles 137-A and 137 of the Education Law. For the

purposes of this section, direct personal supervision means supervision of procedures based on instructions given directly by a supervising licensed pharmacist who remains in the immediate area where the procedures are being performed, authorizes the procedures and evaluates the procedures performed by the registered pharmacy technicians and a supervising licensed pharmacist shall approve all work performed by the registered pharmacy technician prior to the actual dispensing of any drug.

(3) In addition to the registered pharmacy technician services included in subdivision (a) of this section, registered pharmacy technicians may also assist a licensed pharmacist in the dispensing of drugs by performing the following functions that do not require a license under Article 137-A of the Education Law:

(i) receiving written or electronically transmitted prescriptions, except that in the case of electronically transmitted prescriptions the licensed pharmacist or pharmacy intern shall review the prescription to determine whether in his or her professional judgment it shall be accepted by the pharmacy, and if accepted, the licensed pharmacist or pharmacy intern shall enter his or her initials into the records of the pharmacy;

(ii) typing prescription labels;

(iii) keying prescription data for entry into a computer-generated file or retrieving prescription data from the file, provided that such computer-generated file shall provide for verification of all information needed to fill the prescription by a licensed pharmacist prior to the dispensing of the prescription, meaning that the licensed pharmacist shall review and approve such information and enter his or her initials or other personal identifier into the recordkeeping system prior to the dispensing of the prescription or of the prescription refill;

(iv) getting drugs from stock and returning them to stock;

(v) getting prescription files and other manual records from storage and locating prescriptions;

(vi) counting dosage units of drugs;

(vii) placing dosage units of drugs in appropriate containers;

(viii) affixing the prescription label to the containers;

(ix) preparing manual records of dispensing for the signature or initials of the licensed pharmacist; or

(x) handing or delivering completed prescriptions to the patient or the person authorized to act on behalf of the patient and, in accordance with the relevant commissioner's regulations, advising the patient or person authorized to act on behalf of the patient of the availability of counseling to be conducted by the licensed pharmacist or pharmacy intern.

6. The Regulations of the Commissioner of Education are amended by adding a new section 63.15 to read as follows:

Section 63.15 Requirements for licensure as a registered pharmacy technician

(a) To qualify for licensure as a "registered pharmacy technician", an applicant shall fulfill the following requirements:

(1) Application: file an application with the department;

(2) Education: have received an education, including high school graduation or its equivalent, as determined by the department;

(3) Certification from a nationally accredited pharmacy technician certification program acceptable to the department;

(4) Age: at the time of application be at least eighteen years of age;

(5) Character: be of good moral character as determined by the department; and

(6) Fees:

(i) applicants shall pay a fee of \$75 for an initial license and a fee of \$100 for the first registration period; and

(ii) licensees shall pay a fee of \$100 for each triennial registration period.

**Attachment B**

**8 NYCRR §§29.2, 29.7, 63.14 and 63.15**

**ASSESSMENT OF PUBLIC COMMENT**

Since the publication of a Notice of Proposed Rule Making was published in the January 27, 2021 State Register, the State Education Department received the following comments:

1. COMMENT: A national pharmacy technician certification board, among other things, expressed its support for the proposed changes to the Education Law, which establishes and defines the practice of registered pharmacy technicians. The commenter also stated that it appreciates New York State's efforts to enhance medication safety for its citizens by requiring registered pharmacy technicians serving patients in Article 28 facilities to obtain certification from a nationally accredited pharmacy technician certification program. Additionally, the commenter asserted that earning national pharmacy technician certification is an important first step toward a rewarding career in healthcare and that pharmacy technicians with national certification have a stronger organizational and career commitment and view themselves as making fewer medication errors. The commenter then thanked the State and the Department for making pharmacy technician registration and certification a priority.

DEPARTMENT RESPONSE: The Department appreciates the supportive comments as it works to both protect the public and provide greater access to healthcare services to New Yorkers.

2. COMMENT: A commenter, stated that they have patient safety concerns about Article 137-A of the Education Law's increase in the supervisor to supervisees ratio. The commenter stated that, as a New York State pharmacist, they understand ". . . the need

to recognize pharmacy technicians as they are the backbone of a successful pharmacy.” The commenter further stated that this bill, among other things, gives technicians a registered pharmacy technician title in hospital settings but it does not change anything in the community setting. The commenter stated that the bill also changes the ratio from 1 pharmacist supervising 2 technicians to 4 technicians in all pharmacy settings but does not include pharmacy interns in this increased ratio, despite the fact that they would also be supervised by the same pharmacist. The commenter asserted that “[c]ommunity pharmacies have started taking advantage of this ratio and are cutting pharmacist hours. One pharmacist will be supervising too many staff.” The commenter claimed that many pharmacists are afraid to speak up because their employer will be “out to get them”.

The commenter further asserted that healthcare providers should be doing what is best for the public and not allowing companies to make changes that can put lives in jeopardy. The commenter claimed that “[i]n many settings pharmacists will be working alone verifying 400-700 prescriptions. Pharmacy technicians are being burdened with more work and more pressure trying to make up for the loss of pharmacist hours. The combination of all this truly can jeopardize patient safety.” The commenter stated that they understand the need for companies to make profits in order to be successful. However, the commenter questioned whether being successful means putting patient safety at risk. The commenter stated that we should not have to wait for a mistake to happen to make a change and that mistakes can be prevented now if we choose.

The commenter indicated that a petition was recently started on [change.org](https://www.change.org) opposing the supervisor to supervisee ratio change and that it had amassed over 300 signatures in about a week. The commenter claimed that but for fear of repercussions,

they believe that this petition would be signed by every community pharmacy employee, from pharmacy supervisors to technicians.

The commenter requested that the supervisor to supervisee ratio change be excluded from the bill when it goes into effect on April 25, 2021 because, the commenter and community pharmacy employees across the state are very concerned about patient safety while working alone as a pharmacist and supervising more staff. The commenter further stated that “[a]s the voice for all pharmacists in a community setting, we strongly advise that the ratio remains 2:1 for the safety of everyone.”

DEPARTMENT RESPONSE: The increase in the pharmacist to supervisees ratio from 1 to 2 to 1 to 4 is required by statute. Thus, the ratio cannot be eliminated or changed by the Department. The proposed amendment to the Regulations of the Commissioner of Education is consistent with the statute. Thus, no changes are necessary.