



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: December 29, 2020

AUTHORIZATION(S): *Don McG* *Betsy Ma*

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 will be 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. A copy of the proposed rule and a statement of facts and circumstances justifying emergency action are attached.

Procedural History

A Notice of Proposed Rule Making will be published in the State Register on January 27, 2021 and a Notice of Emergency Adoption will be published in the State Register on April 21, 2021, effective April 25, 2021. 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 Regent’s Items

None.

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 April 25, 2021, as an emergency action upon a finding by the Board of Regents that such an action is necessary for the preservation of the public health and general welfare in order to timely implement the requirements of Chapter 414 of the

Laws of 2019, which establishes and defines the practice and profession of registered pharmacy technicians.

Timetable for Implementation

If adopted at the January 2021 Regents meeting, the emergency rule will become effective April 25, 2021, which is the effective date of the Chapter 414. It is anticipated that the proposed rule will be presented to the Board of Regents for permanent adoption at the May 2021 Regents meeting, after the 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 May 2021 meeting, the proposed amendment will become effective as a permanent rule 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) . . .

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(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

STATEMENT OF FACTS AND CIRCUMSTANCES

WHICH NECESSITATE EMERGENCY ACTION

The proposed rule is necessary to implement Chapter 414 of the Laws of 2019 (Chapter 414), which is effective April 25, 2021. This amendment, inter alia, will add Article 137-A to the Education Law, which establishes and defines the practice of the profession of registered pharmacy technicians. Pursuant to Chapter 414, 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, 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 also establishes the education, certification, age, moral character, application and fee requirements for applicants seeking licensure as registered pharmacy technicians.

Since the Board of Regents meets at fixed intervals, the earliest the proposed rule can be presented for adoption, after expiration of the required 60-day public comment period provided for in the State Administrative Procedure Act (SAPA) sections 201(1) and (5), would be the May 10-11, 2021 Regents meeting. Furthermore, pursuant to SAPA section 203(1), the earliest effective date of the proposed rule, if adopted at the May meeting, would be May 26, 2021, the date the Notice of Adoption would be published in the State Register. However, Chapter 414 becomes effective April 25, 2021.

Therefore, emergency action is necessary at the January 2021 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 414, so that applicants for licensure as registered pharmacy technicians will be able to be licensed as registered pharmacy technicians, if they meet the licensure requirements of the proposed rule, on or after the April 25, 2021 effective date of Chapter 414.

It is anticipated that the proposed rule will be presented for adoption as a permanent at the May 10-11, 2021 Regents meeting, which is the first scheduled meeting after expiration of the 60-day public comment period prescribed in SAPA for State agency rule makings.