

2. LEGISLATIVE OBJECTIVES:

Consistent with the authority granted to the Board of Regents pursuant to Education Law section 101, the proposed amendment designates the Executive Deputy Commissioner of the State Education Department as the deputy commissioner of education as specified in Education Law section 101: "...who shall perform such duties as the regents may assign to him by rule and who, in the absence or disability of the commissioner or when a vacancy exists in the office of commissioner, shall exercise and perform the functions, power and duties conferred or imposed on the commissioner by this chapter."

3. NEEDS AND BENEFITS:

The proposed amendment is necessary to conform the Rules of the Board of Regents to changes made in the internal organization of the State Education Department, regarding filing the position of Acting Executive Deputy Commissioner. The amendment will designate the Executive Deputy Commissioner of the State Education Department as the deputy commissioner of education as specified in Education Law section 101, who, in the absence or disability of the Commissioner or when a vacancy exists in the office of Commissioner, shall exercise and perform the functions, powers and duties of the Commissioner.

4. COSTS:

a. Costs to State government: The amendments do not impose any costs on State government, including the State Education Department.

b. Costs to local government: The amendments do not impose any costs on local government.

c. Costs to private regulated parties: The amendments do not impose any costs on private regulated parties.

d. Costs to regulating agency for implementation and continued administration: The amendments do not impose any costs on the regulating agency for implementation and continued administration.

5. LOCAL GOVERNMENT MANDATES:

The proposed amendment relates solely to the internal administration of the State Education Department and does not impose any program, service, duty or responsibility upon any county, city, town, village, school district, fire district or other special district.

6. PAPERWORK:

The propose amendment does not impose any reporting or other paperwork requirements.

7. DUPLICATION:

The proposed amendment relates solely to the internal administration of the State Education Department. There are no relevant statutes, rules, or other legal requirements of the State and Federal governments, including those which may duplicate, overlap or conflict with the rule.

8. ALTERNATIVES:

The proposed amendment is necessary to conform the Rules of the Board of Regents to changes in the internal organization of the State Education Department. There are no significant alternatives and none were considered.

9. FEDERAL STANDARDS:

There are no applicable standards of the Federal government for the subject are of the proposed amendment, which relates solely to the internal administration of the State Education Department.

10. COMPLIANCE SCHEDULE:

The proposed amendment relates solely to the internal administration of the State Education Department and does not impose any compliance requirements on any regulated parties.

Regulatory Flexibility Analysis

The proposed amendment relates solely to the internal organization of the State Education Department, regarding filling the position of Acting Executive Deputy Commissioner and does not impose any adverse economic impact, reporting, recordkeeping or other compliance requirements on small businesses or local governments. Because it is evident from the nature of the proposed amendment that it does not affect small businesses or local governments, no further steps were needed to ascertain that fact and non were taken. Accordingly, a regulatory flexibility analysis for small businesses and local governments is not required and one has not been prepared.

Rural Area Flexibility Analysis

The proposed amendment relates solely to the internal organization of the State Education Department regarding filling the position of Actin Executive Deputy Commissioner and does not impose any adverse economic impact, reporting, recordkeeping or other compliance in public and private sector interests in rural areas. Because it is evident from the nature of the proposed amendment that it does not affect such interests, no further steps were needed to ascertain that fact and non were taken. Accordingly, a rural flexibility is not required and one has not been prepared.

Job Impact Statement

The proposed amendment relates solely to the internal organization of the State Education Department regarding filling the position of Acting Exec-

utive Deputy Commissioner and will not have a substantial impact on jobs and employment opportunities. Because it is evident from the nature of the proposed amendment that no substantial impact will occur, no further steps were needed to ascertain that fact and non were taken. Accordingly, a job impact statement is not required and one has not been prepared.

**PROPOSED RULE MAKING
NO HEARING(S) SCHEDULED**

Licensure of Registered Pharmacy Technicians

I.D. No. EDU-04-21-00010-P

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following proposed rule:

Proposed Action: Amendment of sections 29.2, 29.7, Part 63; addition of sections 63.14, 63.15 to Title 8 NYCRR.

Statutory authority: Education Law, sections 207, 212, 6504, 6507, 6509; L. 2019, ch. 414

Subject: Licensure of registered pharmacy technicians.

Purpose: To implement the provisions of chapter 414 of the Laws of 2019 relating to the licensure of registered pharmacy technicians.

Text of proposed rule: 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.

Text of proposed rule and any required statements and analyses may be obtained from: Kirti Goswami, NYS Education Department, Office of Counsel, 89 Washington Avenue, Room 112EB, Albany, NY 12234, (518) 474-6400, email: legal@nysed.gov

Data, views or arguments may be submitted to: Sarah S. Benson, Deputy Commissioner, NYS Education Department, Office of the Professions, 89 Washington Avenue, 2nd Floor EB, West Wing, Albany, NY 12234, (518) 486-1727, email: REGCOMMENTS@nysed.gov

Public comment will be received until: 60 days after publication of this notice.

Regulatory Impact Statement

1. STATUTORY AUTHORITY:

Section 207 of the Education Law grants general rule-making authority to the Board of Regents to carry into effect the laws and policies of the State relating to education.

Subdivision (3) of section 212 of the Education Law authorizes the State Education Department ("Department") to determine and set fees for certifications and permits.

Section 6504 of the Education Law authorizes the Board of Regents to supervise the admission to and regulation of the practice of the professions.

Paragraph (a) of subdivision (2) of section 6507 of the Education Law authorizes the Commissioner of Education to promulgate regulations in administering the admission to and the practice of the professions.

Subdivision (9) of section 6509 of the Education Law authorizes the Board of Regents to define unprofessional conduct in the professions.

Section 6840 of the Education Law, as added by Chapter 414 of the Laws of 2019, establishes the new profession of registered pharmacy technicians.

Section 6841 of the Education Law, as added by Chapter 414 of the Laws of 2019, defines the profession of registered pharmacy technicians and the practice of registered pharmacy technicians.

Section 6842 of the Education Law, as added by Chapter 414 of the Laws of 2019, establishes definitions relating to the practice of registered pharmacy technicians.

Section 6843 of the Education Law, as added by Chapter 414 of the Laws of 2019, establishes protect for the title “register pharmacy technician.”

Section 6844 of the Education Law, as added by Chapter 414 of the Laws of 2019, establishes the education, certification, age and moral character requirements for applicants seeking licensure as registered pharmacy technicians, as well as providing the Department with the discretion to establish the fees for both the initial license and each triennial registration period.

Section 6832 of the Education Law, as added by Chapter 414 of the Laws of 2019, establishes limitations on how an unlicensed person may assist a licensed pharmacist in the dispensing of drugs, as well as supervision ratios.

2. LEGISLATIVE OBJECTIVES:

The proposed rule is consistent with the above statutory authority and is necessary to conform the Rules of the Board of Regents and the Regulations of the Commissioner of Education to Chapter 414 of the Laws of 2019 (Chapter 414), which amends the Education Law by, inter alia, adding Article 137-A, effective April 25, 2021, to establish and define the new profession of registered pharmacy technicians. 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.

The proposed rule implements Chapter 414 by:

- changing the title of Part 63 of the Commissioner’s Regulations from “Pharmacy” to “Pharmacy and Registered Pharmacy Technicians” and establishing the requirements for licensure as a registered pharmacy technician, which include education, certification, age, moral character, application and fee requirements;
- implementing Chapter 414’s definition of the practice of the profession of registered pharmacy technicians and the requirements for the use of the title “registered pharmacy technician”; amending the Rules of the Board of Regents to add the profession of registered pharmacy technicians to the list of health care professions that are subject to its unprofessional provisions;
- changing the title of the “Special Provisions for the Profession of Pharmacy” section to “Special Provisions for the Professions of Pharmacy and Registered Pharmacy Technicians,” as well as the title of the “Limitations on assistance by an unlicensed person” subparagraph to “Limitations on assistance by a registered pharmacy technician and an unlicensed person”; and
- implementing Chapter 414’s 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; and establishing that these ratios do not apply to pharmacy interns, while requiring that pharmacy interns must be supervised in accordance with Parts 29 and 63 of the Commissioner’s Regulations.

3. NEEDS AND BENEFITS:

The proposed amendment is necessary to conform the Rules of the Board of Regents and the Regulations of the Commissioner of Education to Chapter 414. 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 Article 28 facilities or pharmacies owned and operated by such facilities will improve access to these pharmacy services, while ensuring the health and safety of New Yorkers.

The purpose of the proposed rule is to implement Chapter 414 by establishing the practice of registered pharmacy technicians as a licensed profession in New York State and to establish education, certification, age, moral character, application and fee requirements for licensure in order to

protect the public by providing for a minimum standard level of competency and professional accountability, including subjecting registered pharmacy technicians to the unprofessional conduct provisions for the health care professions.

4. COSTS:

(a) Costs to State government: The proposed rule implements statutory requirements and establishes standards as directed by statute and will not impose any additional costs on State government beyond those imposed by the statutory requirements.

(b) Costs to local governments. There are no additional costs to local governments.

(c) Costs to private regulated parties. As authorized by Education Law § 6844(6), the proposed rule establishes fees for both the initial license and each triennial registration period: the initial license fee is \$75 and the triennial registration fee is \$100. Additionally, pursuant to Education Law § 6844(3), applicants for licensure as registered pharmacy technicians must have certification from a nationally accredited pharmacy technician program acceptable to the Department. Thus, applicants will also incur the cost of obtaining such certification, the cost of which will be set by the nationally accredited pharmacy technician program or programs acceptable to the Department.

(d) Cost to the regulatory agency: The proposed rule does not impose any additional costs on the Department beyond those imposed by statute. Any associated costs to the Department will be offset by the fees charged to applicants and no significant cost will result to the Department.

5. LOCAL GOVERNMENT MANDATES:

The proposed rule implements Chapter 414, which amends the Education Law by adding Article 137-A, to establish the standards for applicants seeking licensure as registered pharmacy technicians to ensure that only those properly educated and prepared to be registered pharmacy technicians hold themselves out as such. The proposed rule does not impose any program, service, duty, or responsibility upon local governments.

6. PAPERWORK:

The proposed rule imposes no new reporting or other paperwork requirements beyond those imposed by the statute.

7. DUPLICATION:

The proposed rule is necessary to implement Chapter 414. There are no other state or federal requirements on the subject matter of the proposed rule. Therefore, the proposed rule does not duplicate other existing New York State or federal requirements.

8. ALTERNATIVES:

The proposed rule is necessary to conform the Rules of the Board of Regents and the Regulations of the Commissioner of Education to Chapter 414. There are no significant alternatives to the proposed rule available and none were considered.

9. FEDERAL STANDARDS:

Since there are no applicable federal standards, the proposed rule does not exceed any minimum federal standards for the same or similar subject areas.

10. COMPLIANCE SCHEDULE:

The proposed amendment is necessary to conform the Rules of the Board of Regents and the Regulations of the Commissioner of Education to Chapter 414. If adopted at the January 2021 Regents meeting by emergency action, the proposed amendment will become effective on April 25, 2021, which is the effective date of the statute. It is anticipated that regulated parties will be able to comply with the proposed amendments by the effective date.

Regulatory Flexibility Analysis

(a) Small Businesses:

Pursuant to Chapter 414 of the Laws of 2019 (Chapter 414), the practice of the registered pharmacy technicians profession is limited to 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. Thus, while individuals who are employed by small businesses may seek licensure as registered pharmacy technicians, they may not practice as registered pharmacy technicians at those small businesses. Therefore, the proposed rule will not impose any new reporting, recordkeeping, or other compliance requirements, or have any adverse economic impact on small businesses. Because it is evident from the nature of the proposed rule that it will not adversely affect small businesses, no affirmative steps were needed to ascertain that fact and none were taken. Accordingly, a regulatory flexibility analysis for small businesses is not required, and one has not been prepared.

(b) Local Governments:

1. EFFECT OF RULE:

The purpose of the proposed rule is to implement Chapter 414, which, effective April 25, 2021, establishes and defines the practice of the profession of registered pharmacy technicians. Chapter 414 allows, inter alia, 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 Article 28 facilities or pharmacies owned and operated by such 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.

The number of individuals who may seek to be licensed as registered pharmacy technicians in New York State is not available and is unknown. The number of these individuals who may be employed by local governments is also unknown.

2. COMPLIANCE REQUIREMENTS:

The proposed rule implements Chapter 414, which establishes the new profession of registered pharmacy technicians and the requirements for licensure as a registered pharmacy technician. These requirements include, but are not limited to, education, certification and age requirements. Individuals seeking licensure to practice in New York State will be required to submit an application with the State Education Department and meet all the requirements for licensure, which include, but are not limited to, the education, certification, and age requirements specified in the proposed rule.

3. PROFESSIONAL SERVICES:

It is not anticipated that local governments will need professional services to comply with the proposed rule.

4. COMPLIANCE COSTS:

The proposed rule does not impose any direct costs on local governments. As authorized by Education Law § 6844(6), the proposed rule establishes fees for both the initial license and each triennial registration period: the initial license fee is \$75 and the triennial registration fee is \$100. Additionally, pursuant to Education Law § 6844(3), applicants for licensure as registered pharmacy technicians must have certification from a nationally accredited pharmacy technician program acceptable to the Department. Thus, applicants will also incur the cost of obtaining such certification, the cost of which will be set by the nationally accredited pharmacy technician program or programs acceptable to the Department.

5. ECONOMIC AND TECHNOLOGICAL FEASIBILITY:

The proposed rule will not impose any new technological requirements on regulated parties, including local governments, and the proposed rule is economically feasible. See above "Compliance Costs" for the economic impact of the regulation.

6. MINIMIZING ADVERSE IMPACT:

The proposed rule is necessary to implement the provisions of Chapter 414, which establishes the new profession of registered pharmacy technicians and the licensure requirements for registered pharmacy technicians. These requirements include, but are not limited to, education, certification, and age requirements. Chapter 414 authorizes the State Education Department to define, in regulation, the standards to be met for licensure as a registered pharmacy technician, including establishing the fees for the initial license and for each triennial registration period. Individuals seeking licensure to practice in New York State will be required to submit an application to the State Education Department and meet all the requirements for licensure, which include, but are not limited to, the education, certification and age requirements specified in the proposed rule. The proposed fee structure was determined by the State Education Department to be the minimum needed to support additional costs. It is on par with fee structures in other professions. It was determined that the licensure of registered pharmacy technicians who meet the minimum requirements established in the proposed rule best ensures the protection of the health and safety of the public.

7. LOCAL GOVERNMENT PARTICIPATION:

Statewide organizations representing all parties having an interest in the practice of pharmacy and pharmacy technicians, including the State Board for Pharmacy and who are members of various professional associations and groups, which include state and federal employees, were consulted and provided input into the development of the proposed rule and their comments were considered in its development.

8. INITIAL REVIEW OF RULE (SAPA § 207):

Pursuant to State Administrative Procedure Act section 207(1)(b), the State Education Department proposes that the initial review of this rule shall occur in the fifth calendar year after the year in which the rule is adopted, instead of in the third calendar year. The justification for a five year review period is that the proposed rule is necessary to implement statutory requirements in Chapter 414 and, therefore, the substantive provisions of the proposed rule cannot be repealed or modified unless there is a further statutory change. Accordingly, there is no need for a shorter review period. The Department invites public comment on the proposed five-year review period for this rule. Comments should be sent to the agency contact listed in item 10 of the Notice of Proposed Rule Making published herewith and must be received within 45 days of the State Register publication date of the Notice.

Rural Area Flexibility Analysis

1. TYPES AND ESTIMATED NUMBERS OF RURAL AREAS:

The proposed rule will apply to all individuals seeking licensure as a registered pharmacy technician, including those located in the 44 counties with less than 200,000 inhabitants and the 71 towns in urban counties with a population density of 150 per square miles or less.

2. REPORTING, RECORDKEEPING AND OTHER COMPLIANCE REQUIREMENTS; AND PROFESSIONAL SERVICES:

As required by Chapter 414 of the Laws of 2019 (Chapter 414), which becomes effective April 25, 2021, the proposed rule establishes the new profession of registered pharmacy technicians and the requirements for licensure as a registered pharmacy technician which include, but are not limited to, education, certification, and age requirements.

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 facilities licensed in accordance with Article 28 of the Public Health Law (Article 28 facilities), or pharmacies owned and operated by such 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 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. Additionally, 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.

The proposed amendment aligns the Rules of the Board of Regents and Commissioner's regulations to Chapter 414 by:

- adding the profession of registered pharmacy technicians to the list of health care professions that are subject to its unprofessional provisions;
- changing 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;"
- changing 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";
- implementing 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; and establishing 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;

- changing the title of Part 63 of the Commissioner's Regulations from "Pharmacy" to "Pharmacy and Registered Pharmacy Technicians";
- adding 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
- adding 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.

Individuals seeking licensure to practice as a registered pharmacy technician in New York State will be required to submit an application to the State Education Department and meet all the requirements for licensure, which include but are not limited to, the education, certification and examination requirements specified in the proposed rule.

The proposed rule will not impose any additional professional service requirements on entities in rural areas.

3. COSTS:

With respect to individuals seeking licensure as a registered pharmacy technician from the State Education Department, including those in rural areas, the proposed rule does not impose any additional costs beyond those required by statute. As authorized by Education Law section 6844(6), the proposed rule establishes fees for both the initial license and each triennial registration period: the initial license fee is \$75 and the triennial registration fee is \$100. Additionally, pursuant to Education Law section 6844(3), applicants for licensure as registered pharmacy technicians must have certification from a nationally accredited pharmacy technician program acceptable to the Department. Thus, applicants will also incur the cost of obtaining such certification, the cost of which will be set by the nationally accredited pharmacy technician program or programs acceptable to the Department.

4. MINIMIZING ADVERSE IMPACT:

The proposed rule is necessary to implement the provisions of Chapter 414, which establishes the new profession of registered pharmacy technicians and the licensure requirements for registered pharmacy technicians, which include education, experience, examination, age, moral character and fee requirements. The statutory requirements do not make exceptions for individuals who live or work in rural areas. Thus, the State Education Department has determined that the proposed rule's requirements should apply to all individuals seeking licensure as a registered pharmacy technician, regardless of the geographic location, to help insure continuing competency across the State. Because of the nature of the proposed rule, alternative approaches for rural areas were not considered.

5. RURAL AREA PARTICIPATION:

Comments on the proposed rule were solicited from statewide organizations representing parties having an interest in the practice of pharmacy and pharmacy technicians. These organizations included the State Board for Pharmacy and professional associations representing the pharmacy profession and/or pharmacy technicians. These groups have members who live or work in rural areas.

6. INITIAL REVIEW OF RULE (SAPA § 207):

Pursuant to State Administrative Procedure Act section 207(1)(b), the State Education Department proposes that the initial review of this rule shall occur in the fifth calendar year after the year in which the rule is adopted, instead of in the third calendar year. The justification for a five year review period is that the proposed rule is necessary to implement statutory requirements in Chapter 414 and, therefore, the substantive provisions of the proposed rule cannot be repealed or modified unless there is a further statutory change. Accordingly, there is no need for a shorter review period.

Job Impact Statement

The proposed rule is necessary to conform the Rules of the Board of Regents and the Regulations of the Commissioner of Education to Chapter 414 of the Laws of 2019 (Chapter 414). The proposed rule implements Chapter 414, which establishes and defines the practice of registered pharmacy technicians. Chapter 414 allows, inter alia, 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 facilities licensed in accordance with Article 28 of the Public Health Law (Article 28 facilities), or pharmacies owned and operated by such facilities, in accordance with Article 137 of the Education Law, where such tasks require no professional judgment.

The proposed aligns the Rules of the Board of Regents and the Commissioner's regulations to Chapter 414 by:

- adding the profession of registered pharmacy technicians to the list of health care professions that are subject to its unprofessional provisions;
- changing 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";

- changing 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."

- implementing 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; and establishing 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;

- changing the title of Part 63 of the Commissioner's Regulations from "Pharmacy" to "Pharmacy and Registered Pharmacy Technicians";

- adding 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

- adding 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.

It is not anticipated that the proposed rule will increase or decrease the number of jobs to be filled because, among other things, Chapter 414 limits the practice of registered pharmacy technicians to 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. It is anticipated that unlicensed persons currently working in or seeking to work in such facilities or pharmacies owned and operated by such facilities may seek to apply for licensure as registered pharmacy technicians. Therefore, the proposed rule will not have a substantial adverse impact on jobs and employment opportunities. Because it is evident from the nature of the proposed rule that it will not affect job and employment opportunities, no affirmative steps were needed to ascertain that fact and none were taken. Accordingly, a job impact statement is not required and one has not been prepared.

Department of Environmental Conservation

NOTICE OF ADOPTION

Repeal and Replacement of 6 NYCRR Part 230 Gasoline Dispensing Sites and Transport Vehicles

I.D. No. ENV-06-20-00018-A

Filing No. 9

Filing Date: 2021-01-12

Effective Date: 30 days after filing

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Action taken: Amendment of Part 200; repeal of Part 230; addition of new Part 230 to Title 6 NYCRR.

Statutory authority: Environmental Conservation Law, sections 1-0101, 3-0301, 19-0103, 19-0105, 19-0301, 19-0303, 19-0304, 71-2103 and 71-2105

Subject: Repeal and replacement of 6 NYCRR Part 230 Gasoline Dispensing Sites and Transport Vehicles.

Purpose: To further reduce harmful volatile organic compounds (VOCs) emitted into the atmosphere.

Substance of final rule: 6 NYCRR Part 230, "Gasoline Dispensing Sites and Transport Vehicles"

6 NYCRR Part 200, "General Provisions"

The New York State Department of Environmental Conservation (Department) has revised Part 200.9 "General Provisions, Referenced Material, Table1" and repealed and replaced Part 230 "Gasoline Dispensing Sites and Transport Vehicles" of the Official Compilation of Codes, Rules, and Regulations of New York State (6 NYCRR).

The revisions to 6 NYCRR Part 200.9 "General Provisions, Referenced Material, Table1" were made to incorporate the applicable standards, guidelines and methodologies necessary to meet the specific requirements of 6 NYCRR Part 230.

Repeal and replacement of 6 NYCRR Part 230 "Gasoline Dispensing Sites and Transport Vehicles" will further reduce volatile organic com-