

ment review and approval of entities or individuals seeking to become an approved provider of CE for a three-year term. These fees are set at \$45 and \$900 respectively, consistent with the fees charged in other professions.

4. MINIMIZING ADVERSE IMPACT:

The proposed rule implements Education Law section 7211's updates to the CE requirements for professional engineers and land surveyors and establishment of CE requirements for professional geologists. The statutory requirements do not make exceptions for individuals who live or work in rural areas. Thus, the Department has determined that the proposed rule's requirements should apply to all professional engineers, land surveyors and professional geologists, regardless of their geographic location, to help ensure a uniform standard of continuing competency across the State.

The Department has also determined that uniform standards for the Department's review of providers are necessary to ensure quality offerings in all parts of 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 all parties having an interest in the practice of professional engineers, land surveyors and professional geologists. Included in this group was the State Board for Engineering, Land Surveying and Geology and professional associations representing the engineering, land surveying, and geology professions. 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statutory requirements in Chapter 260 and, therefore, the substantive provisions of the proposed rule cannot be repealed or modified unless there is a further statutory change.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.

Job Impact Statement

The proposed rule is necessary to conform the Regulations of the Commissioner of Education (Commissioner's regulations) to Chapter 260 of the Laws of 2020 (Chapter 260), which amends section 7211 of the Education Law, effective January 1, 2022, by updating the continuing education (CE) requirements for professional engineers and land surveyors; establishing CE requirements for professional geologists; and consolidating the CE requirements for all three professions into one section of law. The proposed rule further conforms the Commissioner's regulations to Chapter 260, which repeals section 7212 of Education Law relating to the CE requirements for land surveyors, effective January 1, 2022.

The proposed rule implements Chapter 260 by:

- amending section 68.14 of the Commissioner's regulations to conform such section to all of Chapter 260's above-referenced continuing education requirements for professional engineers, land surveyors and professional geologists; and
- repealing section 68.15 of the Commissioner's Regulations. This section implements the land surveyor continuing education requirements provisions of section 7212 of the Education Law which Chapter 260 repeals.

Additionally, the proposed rule amends subparagraph (i) of paragraph (3) of subdivision (b) of section 29.3 of Regents Rules to add professional geologists to the provisions relating to conduct that is not considered unprofessional conduct in the design professions. When geology became a licensed profession in 2016, pursuant to Chapter 475 of the Laws of 2014, due to an oversight, this section of the Regents Rules was not amended to add this profession to it. Thus, proposed amendment corrects this inadvertent omission.

Because, the proposed regulation implements specific statutory requirements and directives, any impact on jobs and employment opportunities created by updating the CE requirements for professional engineers and land surveyors and establishing CE requirement for professional geologists licensed psychologists is attributable to the statutory requirement, not the proposed rule, which simply establishes standards that conform with the requirements of the statute. In any event, the current statutory CE requirements for professional engineers and land surveyors were established in 2002, and the Department is not aware that those requirements significantly affected jobs or employment opportunities in those professions. In addition, the statutorily updated CE requirements for professional engineers and land surveyors and the statutory establishment

of CE requirements for professional geologists may increase job and employment opportunities for prospective approved CE providers and their current and potential employees.

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 was not prepared.

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Licensure Examination, Licensure by Endorsement and Continuing Education Requirements in the Profession of Pharmacy

I.D. No. EDU-39-21-00010-P

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

Proposed Action: Amendment of 63.2, 63.3, 63.5 and 63.7 of Title 8 NYCRR.

Statutory authority: Sections 207, 6504, 6507, 6801, 6805 and 6827 of the Education Law.

Subject: Licensure Examination, Licensure by Endorsement and Continuing Education Requirements in the Profession of Pharmacy.

Purpose: To provide flexibility in determining acceptable licensure examinations and to add compounding continuing education requirements.

Text of proposed rule: 1. Subdivision (b) of section 63.2 of the Regulations of the Commissioner of Education is amended, to read as follows:

(b) [Graduates] *Effective January 1, 2022 graduates* of nonregistered and nonaccredited programs, including foreign programs in pharmacy, shall be authorized to begin an internship only after passing [Part I of the pharmacist licensing examination] *an initial examination or examinations acceptable to the board of pharmacy for licensure purposes and determined by the department to be satisfactory for measuring the applicant's knowledge regarding the curricular areas defined in subdivision (b) of section 52.29 of this Title and other matters of practice as may be deemed appropriate by the department.* Thereafter, the applicant shall complete not less than 12 months of full-time experience, or the equivalent thereof, in an internship program which meets the requirements of paragraphs (a)(1), (3) and (4) of this section. Upon completion of the internship program, the applicant may be admitted to [the practical portions (Parts II and III) of the examination] *an additional examination or examinations acceptable to the board of pharmacy for licensure purposes for measuring the applicant's knowledge regarding the practice of pharmacy, as well as the curricular areas defined in subdivision (b) of section 52.29 of this Title.*

2. Section 63.3 of the Regulations of the Commissioner of Education is amended, to read as follows:

Licensing examinations.

(a) [Content. The examination shall consist of three parts:

Part I.: Applied chemistry, mathematics, pharmacology and pharmaceuticals and clinical pharmacy.

Part II.: Professional law, ethics and professional conduct, prescription and nonprescription required drugs and prescription problems.

Part III.: Prescription compounding and pharmacy practice.] *Effective January 1, 2022, each candidate applying for licensure as a pharmacist in New York State shall pass an examination or examinations acceptable to the board of pharmacy for licensure purposes and determined by the department to be satisfactory for measuring the applicant's knowledge regarding the curricular areas defined in subdivision (b) of section 52.29 of this Title and other matters of practice as may be deemed appropriate by the department. The passing score for such examination or examinations shall be determined by the department.*

(b) [Examination components.

(1) Part I of examination. The department may accept satisfactory scores on an examination of the National Association of Boards of Pharmacy as meeting the requirements of Part I of the licensing examination.

(2) Alternative to part III of examination.

(i) The department may accept, as meeting the requirements of part III of the licensing examination, certification that the applicant has successfully achieved each of the following competencies as part of a residency program in pharmacy practice approved by the department:

(a) sterile product preparation and technique;

(b) non-sterile compounding preparation and technique;

(c) performing dosing calculations, including but not limited to aliquot, proportions, and infusion drip-rates;

(d) medication safety procedures, including, but not limited to, identifying potential look-alike and sound-alike drugs and other medication error prevention techniques;

(e) drug distribution, including but not limited to preparing, dispensing and verifying the accuracy of filled prescriptions or medication orders; and

(f) such other competencies in pharmacy practice as may be required by the department.

(ii) Such certification shall be on a form prescribed by the commissioner and shall be completed by the residency program director who supervised the applicant's performance in such residency program, attesting that the applicant has successfully achieved such competencies and that in the supervisor's judgment the applicant is competent to practice pharmacy.

(c) Passing score. The passing score in each part of the examination shall be 75.0, as determined by the State Board of Pharmacy.

(d) Special condition. A graduate of a registered or accredited program of education who has not completed the required practical experience may be admitted to Part I of the examination only.]

A candidate may retain credit for passing scores on each required examination for licensure as a pharmacist for a period not to exceed five years from the examination or examinations dates.

(c) Special provisions. Effective January 1, 2022, candidates with a pending application for licensure may submit a form prescribed by the department, which the department will review to determine whether the candidates meet the revised requirements for licensure on or after that date.

3. Section 63.5 of the Regulations of the Commissioner of Education is amended, to read as follows:

[For] *Effective January 1, 2022, an applicant for licensure as a pharmacist by endorsement of a pharmacist license issued by another jurisdiction*, the applicant] shall:

(a) present evidence of having met all requirements of 59.6 of this Title, [except that the applicant shall have had, during the five years preceding the filing of the application, at least one year of satisfactory experience following licensure:] *except for the experience requirement in paragraph (b) of 59.6 of this Title*; and

(b) pass an examination of the laws, rules, regulations, and professional conduct pertaining to the practice of pharmacy in New York [administered by the department or an equivalent examination] acceptable to the board of pharmacy for licensure purposes and determined by the department to be satisfactory for this purpose [State Board of Pharmacy].

4. Paragraph (1) of subdivision (c) of section 63.7 of the Regulations of the Commissioner of Education is amended to read as follows:

(1) During each triennial registration period, meaning a registration period of three years' duration, an applicant for registration shall complete at least 45 hours of formal continuing education acceptable to the department, as defined in paragraph (4) of this subdivision, provided that no more than 22 hours of such continuing education shall consist of self-study courses. During registration periods beginning on or after September 1, 2003, a licensee shall complete as part of the 45 hours of formal continuing education, or pro-ration thereof, at least three hours of formal continuing education acceptable to the department in the processes and strategies that may be used to reduce medication and/or prescription errors. Any licensee participating in collaborative drug therapy management pursuant to Education Law section 6801-a, shall complete as part of the 45 hours of formal continuing education, or pro-ration thereof, at least five hours of formal continuing education acceptable to the department in the area or areas of practice generally related to any collaborative drug therapy management protocols to which the pharmacist may be subject, provided that such continuing education shall not be completed as self-study. *Commencing with registration periods beginning on or after January 1, 2023, a licensee shall complete as part of the 45 hours of formal continuing education at least three hours of formal continuing education acceptable to the department in compounding. For purposes of this requirement, the continuing education in the area of compounding shall be consistent with current compounding standards as determined by the department.*

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 112 EB, 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.

This rule was not under consideration at the time this agency submitted its Regulatory Agenda for publication in the Register.

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.

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.

Section 6801 of the Education Law defines the practice of the profession of pharmacy.

Section 6805 of the Education Law establishes the requirements for licensure as a pharmacist, which include, among other things, education, experience, examination and moral character requirements.

Section 6827 of the Education Law establishes the mandatory continuing education (CE) requirements for pharmacists and provides the Department with the discretion, as needed to contribute to the health and welfare of the public, to require the completion of CE courses in specific subjects.

2. LEGISLATIVE OBJECTIVES:

The proposed rule is consistent with the above statutory authority and is necessary conform the Commissioner's regulations to the national pharmacist licensing examination standards and to provide the Department with flexibility to implement prospective changes in examination standards. The proposed rule is also necessary to add a mandatory compounding CE requirement to the CE for pharmacists to ensure that all pharmacists are adequately trained in compounding drug products and that they maintain this competency throughout their careers, which will further such goals and interests of public health and protection.

Licensure Examination

Currently, applicants for licensure as pharmacists in New York State must complete a three-part series of examinations. Part I, the North American Pharmacist Licensure Examination (NAPLEX), tests applicants' knowledge of a wide range of topics, including, but not limited to, pharmacology and pharmaceuticals, pharmacokinetics, medication management, and medication compounding. Part II, known as the Multistate Pharmacy Jurisprudence Examination (MPJE), tests candidates' knowledge on professional law, ethics and conduct, and requirements for prescription and non-prescription drugs.

Historically, the Part III examination has been a Department prepared and administered practical examination that tested candidates' abilities to compound and prepare medications safely and accurately, including sterile products. However, since the COVID-19 pandemic and the resulting social distancing and other Centers for Disease Control and Prevention (CDC) mitigation guidelines, the Part III examination format was forced to change from an in-person, practical examination to an electronically administered examination, offered virtually and remotely proctored. Due to this format change, a Gap Analysis¹ was conducted, which found that the new format of the Part III examination's testing competencies significantly overlapped with the testing competencies tested by the nationally offered examination referenced above. Based on these findings, Department staff are recommending that sections 63.2, 63.3 and 63.5 of the Regulations of the Commissioner of Education (Commissioner's regulations) be amended to provide the Department with more flexibility in determining, based on the State Board of Pharmacy's recommendations, which examination or examinations are acceptable for licensure purposes for both the regular licensure pathway and the licensure by endorsement pathway. The proposed amendments would remove the references to the three-part series of examinations and give the Department the flexibility to adapt to the continually evolving profession of pharmacy.

Continuing Education

In recent years, throughout the United States, there have been several incidents of illnesses and deaths due to improperly and/or contaminated compounded drug products. These incidents have heightened the need to ensure all pharmacists are adequately trained in compounding drug products and that they maintain this competency throughout their careers. In furtherance of such goals and interests of public health and protection, the proposed amendment to section 63.7 of the Commissioner's regulations, effective January 1, 2023, would require pharmacists to complete three continuing education credits in compounding each triennial registration period. These compounding continuing education credits must be taken from Department approved providers.

3. NEEDS AND BENEFITS:

The proposed rule is necessary to conform the Commissioner's regulations to the national pharmacist licensing examination standards and to provide the Department with flexibility to implement prospective changes in examination standards. The proposed rule is also necessary to add a mandatory compounding CE requirement to the CE for pharmacists to

ensure that all pharmacists are adequately trained in compounding drug products and that they maintain this competency throughout their careers, which will further such goals and interests of public health and protection.

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: Currently, the total cost for the three-part series of pharmacist licensure examinations is \$1040; (1) \$575 for the NAPLEX; (2) \$250 for the MPJE; and (3) \$215 for the Part III Examination. The proposed rule eliminates the Part III examination, which would reduce the total cost of the pharmacist licensure examinations to \$825. However, it should be noted that, as of March 1, 2022, the cost of the NAPLEX will increase from \$575 to \$620 and the cost of the MPJE will increase from \$250 to \$270, which will make the total cost of the licensure examinations \$890.

As required by Education Law § 6827(6) pharmacists must pay a mandatory CE fee of \$45 each triennial registration period in addition to a \$155 triennial registration fee, pursuant to Education Law § 6805(1)(8).

(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 is necessary to conform the Commissioner's regulations to the national pharmacist licensing examination standards and to provide the Department with flexibility to implement prospective changes in examination standards. The proposed rule is also necessary to add a mandatory compounding CE requirement to the CE for pharmacists to ensure that all pharmacists are adequately trained in compounding drug products and that they maintain this competency throughout their careers, which will further such goals and interests of public health and protection. 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 conform the Commissioner's regulations to the national pharmacist licensing examination standards and to provide the Department with flexibility to implement prospective changes in examination standards. The proposed rule is also necessary to add a mandatory compounding CE requirement to the CE for pharmacists to ensure that all pharmacists are adequately trained in compounding drug products and that they maintain this competency throughout their careers, which will further such goals and interests of public health and protection. 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 Commissioner's regulations to the national pharmacist licensing examination standards and to provide the Department with flexibility to implement prospective changes in examination standards. The proposed rule is also necessary to add a mandatory compounding CE requirement to the CE for pharmacists to ensure that all pharmacists are adequately trained in compounding drug products and that they maintain this competency throughout their careers, which will further such goals and interests of public health and protection. 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:

If adopted at the December 2021 Regents meeting, the proposed amendments to sections 63.2, 63.3 and 63.5 of the Commissioner's regulations will become effective on January 1, 2022 and the proposed amendment to section 63.7 of the Commissioner's regulations will become effective on January 1, 2023. It is anticipated that regulated parties will be able to comply with the proposed amendments by their respective effective dates.

¹ A Gap Analysis is a method of identifying differences between actual outcomes and those desired to fulfill a specific requirement. In this case, the competencies tested by the nationally offered examinations were compared to essential entry-level pharmacist knowledge and skills. Through this analysis, it was determined that no gaps existed; the nation-

ally offered examinations adequately tested the desired competencies, including the competencies tested by the Part III examination.

Regulatory Flexibility Analysis

(a) Small Businesses:

The proposed rule is necessary conform the Commissioner's regulations to the national pharmacist licensing examination standards and to provide the Department with flexibility to implement prospective changes in examination standards. The proposed rule is also necessary to add a mandatory compounding continuing education (CE) requirement to the CE requirement for pharmacists to ensure that all pharmacists are adequately trained in compounding drug products and that they maintain this competency throughout their careers, which will further such goals and interests of public health and protection. Applicants for licensure as pharmacists in New York State will have to comply with the proposed rule's changes to the licensure examinations. Additionally, all pharmacists, including pharmacists who are employed by small businesses/independent pharmacies, will have to comply with the proposed rule's three credit compounding CE requirement each triennial registration period.

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 conform the Commissioner's regulations to the national pharmacist licensing examination standards and to provide the Department with flexibility to implement prospective changes in examination standards. The proposed rule also adds a mandatory three credit compounding CE requirement to the CE requirement for pharmacists to ensure that all pharmacists are adequately trained in compounding drug products and that they maintain this competency throughout their careers, which will further such goals and interests of public health and protection.

The number of individuals who may seek to be licensed as pharmacists in New York State, under the proposed new licensing examination requirements, is not available and is unknown. The number of these individuals who may be employed by local governments is also unknown. The number of licensed pharmacists in New York State is 28,920 and all of them will be subject to the proposed rule's compounding CE requirement. However, the number of these pharmacists who may be employed by local governments is unknown.

2. COMPLIANCE REQUIREMENTS:

The proposed rule conforms the Commissioner's regulations to the national pharmacist licensing examination standards and to provide the Department with flexibility to implement prospective changes in examination standards. The proposed rule also adds a mandatory three credit compounding CE requirement to the CE requirement for pharmacists to ensure that all pharmacists are adequately trained in compounding drug products and that they maintain this competency throughout their careers, which will further such goals and interests of public health and protection. The proposed rule requires applicants to comply with the new pharmacist licensure examination requirements. The proposed rule also requires all pharmacists to comply with the new three credit compounding CE requirement each triennial registration period.

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. Currently, the total cost for the three-part series of examinations for pharmacist licensure applicants is \$1040; (1) \$575 for the North American Pharmacist Licensure Examination (NAPLEX); (2) \$250 for the Multistate Pharmacy Jurisprudence Examination (MPJE); and (3) \$215 for the Part III Examination. The proposed rule eliminates the Part III examination, which would reduce the total cost of the pharmacist licensure examinations to \$825. However, it should be noted that, as of March 1, 2022, the cost of the NAPLEX will increase from \$575 to \$620 and the cost of the MPJE will increase from \$250 to \$270, which will make the total cost of the licensure examinations \$890. The cost of the NAPLEX and the MPJE are set by the national organization that offers them.

As required by Education Law § 6827(6) pharmacists must pay a mandatory CE fee of \$45 each triennial registration period in addition to a \$155 triennial registration fee, pursuant to Education Law § 6805(1)(8). Pharmacists must also incur the costs of attending CE courses. The cost of such courses is not determined by the Department approved providers, not 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 conform the Commissioner's regulations to the national pharmacist licensing examination standards and to provide the Department with flexibility to implement prospective changes in examination standards. The proposed rule also adds a mandatory three credit compounding CE requirement to the CE requirement for pharmacists to ensure that all pharmacists are adequately trained in compounding drug products and that they maintain this competency throughout their careers, which will further such goals and interests of public health and protection. See above "Compliance Costs" for the minimizing adverse impact of the regulation.

7. LOCAL GOVERNMENT PARTICIPATION:

Statewide organizations representing all parties having an interest in the practice of pharmacy, 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.

Rural Area Flexibility Analysis

1. TYPES AND ESTIMATED NUMBERS OF RURAL AREAS:

The proposed rule will apply to all individuals seeking licensure as a pharmacist and all pharmacists licensed in New York State, 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:

The proposed rule conforms the Commissioner's regulations to the national pharmacist licensing examination standards and to provide the Department with flexibility to implement prospective changes in examination standards. The proposed rule is also necessary to add a mandatory compounding CE requirement to the CE for pharmacists to ensure that all pharmacists are adequately trained in compounding drug products and that they maintain this competency throughout their careers, which will further such goals and interests of public health and protection.

Licensure Examination

Currently, applicants for licensure as pharmacists in New York State must complete a three-part series of examinations. Part I, the North American Pharmacist Licensure Examination (NAPLEX), tests applicants' knowledge of a wide range of topics, including, but not limited to, pharmacology and pharmaceuticals, pharmacokinetics, medication management, and medication compounding. Part II, known as the Multistate Pharmacy Jurisprudence Examination (MPJE), tests candidates' knowledge on professional law, ethics and conduct, and requirements for prescription and non-prescription drugs.

Historically, the Part III examination has been a Department prepared and administered practical examination that tested candidates' abilities to compound and prepare medications safely and accurately, including sterile products. However, since the COVID-19 pandemic and the resulting social distancing and other Centers for Disease Control and Prevention (CDC) mitigation guidelines, the Part III examination format was forced to change from an in-person, practical examination to an electronically administered examination, offered virtually and remotely proctored. Due to this format change, a Gap Analysis¹ was conducted, which found that the new format of the Part III examination's testing competencies significantly overlapped with the testing competencies tested by the nationally offered examination referenced above. Based on these findings, Department staff are recommending that sections 63.2, 63.3 and 63.5 of the Regulations of the Commissioner of Education (Commissioner's regulations) be amended to provide the Department with more flexibility in determining, based on the State Board of Pharmacy's recommendations, which examination or examinations are acceptable for licensure purposes for both the regular licensure pathway and the licensure by endorsement pathway. The proposed amendments would remove the references to the three-part series of examinations and give the Department the flexibility to adapt to the continually evolving profession of pharmacy.

Continuing Education

In recent years, throughout the United States, there have been several incidents of illnesses and deaths due to improperly and/or contaminated compounded drug products. These incidents have heightened the need to ensure all pharmacists are adequately trained in compounding drug products and that they maintain this competency throughout their careers. In furtherance of such goals and interests of public health and protection, the proposed amendment to section 63.7 of the Commissioner's regulations, effective January 1, 2023, would require pharmacists to complete three continuing education credits in compounding each triennial registra-

tion period. These compounding continuing education credits must be taken from Department approved providers.

Individuals seeking licensure to practice as a pharmacist in New York State will be required to, among other things, take and pass the NAPLEX and MPJE examinations and pay the costs associated with taking them.

Pharmacists licensed in New York State, who are seeking to maintain their registration in order to practice in this State, will be required to take three CE credits in compounding as part of the 45 credits of CE that are required each triennial registration period. These pharmacists will also be required to pay a mandatory CE fee and the triennial registration fee, as well as the cost for attending CE courses.

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. Currently, the total cost for the three-part series of pharmacist licensure examinations is \$1040; (1) \$575 for the NAPLEX; (2) \$250 for the MPJE; and (3) \$215 for the Part III Examination. The proposed rule eliminates the Part III examination, which would reduce the total cost of the pharmacist licensure examinations to \$825. However, it should be noted that, as of March 1, 2022, the cost of the NAPLEX will increase from \$575 to \$620 and the cost of the MPJE will increase from \$250 to \$270, which will make the total cost of the licensure examinations \$890. The cost of the NAPLEX and the MPJE are set by the national organization that offers them.

As required by Education Law § 6827(6) pharmacists must pay a mandatory CE fee of \$45 each triennial registration period in addition to a \$155 triennial registration fee, pursuant to Education Law § 6805(1)(8). The cost of such courses is determined by the Department approved CE providers, not the Department.

4. MINIMIZING ADVERSE IMPACT:

The proposed rule is necessary to conform the Commissioner's regulations to the national pharmacist licensing examination standards and to provide the Department with flexibility to implement prospective changes in examination standards. The proposed rule is also necessary to add a mandatory compounding CE requirement to the CE for pharmacists to ensure that all pharmacists are adequately trained in compounding drug products and that they maintain this competency throughout their careers, which will further such goals and interests of public health and protection. The aforementioned statutory requirements for licensing examinations and CE 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 pharmacist and all licensed pharmacists seeking to retain their registration to practice in this State by complying with the triennial CE requirements, 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.

¹ A Gap Analysis is a method of identifying differences between actual outcomes and those desired to fulfill a specific requirement. In this case, the competencies tested by the nationally offered examinations were compared to essential entry-level pharmacist knowledge and skills. Through this analysis, it was determined that no gaps existed; the nationally offered examinations adequately tested the desired competencies, including the competencies tested by the Part III examination.

Job Impact Statement

The proposed rule is necessary conform the Commissioner's regulations to the national pharmacist licensing examination standards and to provide the Department with flexibility to implement prospective changes in examination standards. The proposed rule is also necessary to add a mandatory compounding CE requirement to the CE for pharmacists to ensure that all pharmacists are adequately trained in compounding drug products and that they maintain this competency throughout their careers, which will further such goals and interests of public health and protection.

Licensure Examination

Currently, applicants for licensure as pharmacists in New York State must complete a three-part series of examinations. Part I, the North American Pharmacist Licensure Examination (NAPLEX), tests applicants' knowledge of a wide range of topics, including, but not limited to, pharmacology and pharmaceuticals, pharmacokinetics, medication manage-

ment, and medication compounding. Part II, known as the Multistate Pharmacy Jurisprudence Examination (MPJE), tests candidates' knowledge on professional law, ethics and conduct, and requirements for prescription and non-prescription drugs.

Historically, the Part III examination has been a Department prepared and administered practical examination that tested candidates' abilities to compound and prepare medications safely and accurately, including sterile products. However, since the COVID-19 pandemic and the resulting social distancing and other Centers for Disease Control and Prevention (CDC) mitigation guidelines, the Part III examination format was forced to change from an in-person, practical examination to an electronically administered examination, offered virtually and remotely proctored. Due to this format change, a Gap Analysis¹ was conducted, which found that the new format of the Part III examination's testing competencies significantly overlapped with the testing competencies tested by the nationally offered examination referenced above. Based on these findings, Department staff are recommending that sections 63.2, 63.3 and 63.5 of the Regulations of the Commissioner of Education (Commissioner's regulations) be amended to provide the Department with more flexibility in determining, based on the State Board of Pharmacy's recommendations, which examination or examinations are acceptable for licensure purposes for both the regular licensure pathway and the licensure by endorsement pathway. The proposed amendments would remove the references to the three-part series of examinations and give the Department the flexibility to adapt to the continually evolving profession of pharmacy.

Continuing Education

In recent years, throughout the United States, there have been several incidents of illnesses and deaths due to improperly and/or contaminated compounded drug products. These incidents have heightened the need to ensure all pharmacists are adequately trained in compounding drug products and that they maintain this competency throughout their careers. In furtherance of such goals and interests of public health and protection, the proposed amendment to section 63.7 of the Commissioner's regulations, effective January 1, 2023, would require pharmacists to complete three continuing education credits in compounding each triennial registration period. These compounding continuing education credits must be taken from Department approved providers.

It is not anticipated that the proposed rule will increase or decrease the number of jobs to be filled because, among other things, the Part III examination that is proposed to be eliminated is a Department prepared and administered examination. Additionally, pursuant to Education Law § 6827(2), pharmacists are already required to complete a minimum of 45 CE credits each triennial registration and, pursuant to Education Law § 6827(4), the Department has the discretion, as needed to contribute to the health and welfare of the public, to require completion of CE courses in specific subjects, such as the proposed rule's three credits of compounding CE requirement, as part of the existing CE requirement. While this new compounding CE requirement may result in others seeking to become Department approved pharmacist CE providers, which may increase jobs, based on Department research, it is anticipated that the existing Department approved pharmacist CE providers have sufficient compounding related CE offerings and/or could, if necessary, timely develop additional compounding related CE offerings for pharmacists to satisfy this proposed requirement. 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.

¹ A Gap Analysis is a method of identifying differences between actual outcomes and those desired to fulfill a specific requirement. In this case, the competencies tested by the nationally offered examinations were compared to essential entry-level pharmacist knowledge and skills. Through this analysis, it was determined that no gaps existed; the nationally offered examinations adequately tested the desired competencies, including the competencies tested by the Part III examination.

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Removing References to Regional Accreditation

I.D. No. EDU-39-21-00011-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 3.29, 13.10, 52.1, 52.21, 70.9, 90.7, 126.1, 246.3, 247.16 and Part 80 of Title 8 NYCRR.

Statutory authority: Education Law, sections 101, 207, 210, 215, 305, 1004, 1004-a, 3001, 3004, 3009, 5001, 5002, 7409; 84 FR 58834-58933

Subject: Removing References to Regional Accreditation.

Purpose: To remove references to "regional accreditation" in the Rules of the Board of Regents and Commissioner's regulations.

Substance of proposed rule (Full text is posted at the following State website: <http://www.counsel.nysed.gov/rules/full-text-indices>): Prior to February 2020, the United States Department of Education (USDOE) recognized institutional accrediting agencies as either "regional" accrediting agencies or "national" accrediting agencies. In February 2020, USDOE issued new regulations which eliminated the distinction between "regional" or "national" to refer to an accrediting agency. USDOE issued a letter explaining that:

Because the Department holds all accrediting agencies to the same standards, distinctions between regional and national accrediting agencies are unfounded. Moreover, we have determined that most regional accreditors operate well outside of their historic geographic borders, primarily through the accreditation of branch campuses and additional locations. As a result, our new regulations have removed geography from an accrediting agency's scope. Instead of distinguishing between regional and national accrediting agencies, the Department will distinguish only between institutional and programmatic accrediting agencies.

Therefore, it is necessary to amend the Rules of the Board of Regents and the Commissioner's regulations to remove references to regional accrediting institutions of higher education as there is no longer such a distinction. The proposed amendment removes such references and replaces such language with the following: "accredited by an institutional accrediting agency recognized for this purpose by the United States Department of Education."

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: Petra Maxwell, NYS Education Department, Office of Counsel, 89 Washington Avenue, Room 112EB, Albany, NY 12234, (518) 474-6400, email: OHEREGComments@nysed.gov

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

This rule was not under consideration at the time this agency submitted its Regulatory Agenda for publication in the Register.

Regulatory Impact Statement

1. STATUTORY AUTHORITY:

Education Law § 101 (not subdivided) charges the Department with the general management and supervision of all public schools and all of the educational work of the state.

Education Law § 207 grants general rule-making authority to the Regents to carry into effect State educational laws and policies.

Education Law § 210 authorizes the Regents to register domestic and foreign institutions in terms of New York standards.

Education Law § 215 authorizes the Regents and/or the Commissioner to visit, examine and inspect any institution in the university and any school or institution under the educational supervision of the state.

Education Law § 305 authorizes the Commissioner to enforce the educational policies of this State and execute all educational policies determined by the Regents and shall prescribe the licensing of teachers employed in this State.

Education Law § 1004 empowers the State Education Department with certain powers and duties regarding vocational rehabilitation.

Education Law § 1004-a contains special provisions related to mentally and physically disabled persons in extended sheltered employment in workshops.

Education Law § 3001 establishes the qualifications of teachers in the classroom.

Education Law § 3004(1) authorizes the Commissioner to promulgate regulations governing the certification requirements for teachers employed in public schools.

Education Law § 3009 prohibits school districts from paying the salary of an unqualified teacher.

Education Law § 5001 authorizes the Commissioner to deny, suspend, revoke or decline to renew any license if she determines that a school's financial condition may result in the interruption or cessation of instruction or jeopardize student tuition funds.

Education Law § 5002 sets forth the standards governing all licensed schools subject to the jurisdiction of the Department.

Education Law § 7409 prescribes mandatory continuing education for certified public accountants and public accountants.

84 FR 58834-58933 authorizes the U.S. Department of Education to

amend the regulations governing the recognition of accrediting agencies, certain student assistance provisions, and institutional eligibility, as well as makes various technical corrections.

2. LEGISLATIVE OBJECTIVES:

The proposed amendment is consistent with the above statutory authority and is necessary to align the Regulations of the Commissioner of Education with the United States Department of Education's (USDOE) regulations by removing references to regional accrediting institutions of higher education as the USDE no longer recognizes such a distinction. The proposed amendment removes such references and replaces such language with the following: "accredited by an institutional accrediting agency recognized for this purpose by the United States Department of Education."

3. NEEDS AND BENEFITS:

Prior to February 2020, the United States Department of Education (USDOE) recognized institutional accrediting agencies as either "regional" accrediting agencies or "national" accrediting agencies. In February 2020, USDOE issued new regulations which eliminated the distinction between "regional" or "national" to refer to an accrediting agency. USDOE issued a letter¹ explaining that:

Because the Department holds all accrediting agencies to the same standards, distinctions between regional and national accrediting agencies are unfounded. Moreover, we have determined that most regional accreditors operate well outside of their historic geographic borders, primarily through the accreditation of branch campuses and additional locations. As a result, our new regulations have removed geography from an accrediting agency's scope. Instead of distinguishing between regional and national accrediting agencies, the Department will distinguish only between institutional and programmatic accrediting agencies.

Therefore, it is necessary to amend the Rules of the Board of Regents and the Commissioner's regulations to remove references to regional accrediting institutions of higher education as there is no longer a need for this distinction, as explained above.

4. COSTS:

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

b. Costs to local government: The amendment does not impose any costs on local government.

c. Costs to private regulated parties: The amendment does not impose any costs on private regulated parties.

d. Costs to regulating agency for implementation and continued administration: See above.

5. LOCAL GOVERNMENT MANDATES:

The proposed amendment does not impose any additional program, service, duty or responsibility upon any local government.

6. PAPERWORK:

The proposed amendment does not impose any additional paperwork requirements.

7. DUPLICATION:

The proposed amendment does not duplicate existing State or Federal requirements.

8. ALTERNATIVES:

The proposed amendment is necessary to align the Commissioner's regulations with the United States Department of Education's (USDOE) regulations by removing references to regional accreditation as the USDOE has removed the distinction between regional and national accreditors. There are no significant alternatives to the proposed amendment and none were considered.

9. FEDERAL STANDARDS:

In February 2020, the USDOE issued new regulations which eliminated the distinction between "regional" or "national" to refer to an accrediting agency.

10. COMPLIANCE SCHEDULE:

It is anticipated that the proposed amendment will be presented to the Board of Regents for adoption at its January 2022 meeting. If adopted at the January 2022 meeting, the proposed amendment will become effective on January 26, 2022.

¹ See USDE letter re: FINAL ACCREDITATION AND STATE AUTHORIZATION REGULATIONS <https://sacsoc.org/app/uploads/2020/03/State-Authorization-Letter-w-Diane-Signature-2.26.19.pdf>

Regulatory Flexibility Analysis

The proposed amendment applies to all higher education institutions including those located in the 44 rural counties with fewer than 200,000 inhabitants and the 71 towns and urban counties with a population density of 150 square miles or less.

Prior to February 2020, the United States Department of Education (USDOE) recognized institutional accrediting agencies as either "regional" accrediting agencies or "national" accrediting agencies. In February 2020, USDOE issued new regulations which eliminated the distinction between

"regional" or "national" to refer to an accrediting agency. USDOE issued a letter¹ explaining that:

Because the Department holds all accrediting agencies to the same standards, distinctions between regional and national accrediting agencies are unfounded. Moreover, we have determined that most regional accreditors operate well outside of their historic geographic borders, primarily through the accreditation of branch campuses and additional locations. As a result, our new regulations have removed geography from an accrediting agency's scope. Instead of distinguishing between regional and national accrediting agencies, the Department will distinguish only between institutional and programmatic accrediting agencies.

Therefore, it is necessary to amend the Rules of the Board of Regents and the Commissioner's regulations to remove references to regional accrediting institutions of higher education as there is no longer such a distinction. The proposed amendment removes such references and replaces such language with the following: "accredited by an institutional accrediting agency recognized for this purpose by the United States Department of Education."

The amendment does not impose any new recordkeeping or other compliance requirements and will not have an adverse economic impact on small businesses or local governments. Because it is evident from the nature of the proposed technical amendment that it will not affect small businesses or local governments, no further 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.

¹ See USDE letter re: FINAL ACCREDITATION AND STATE AUTHORIZATION REGULATIONS <https://sacsoc.org/app/uploads/2020/03/State-Authorization-Letter-w-Diane-Signature-2.26.19.pdf>

Rural Area Flexibility Analysis

The purpose of the proposed amendments to the Rules of the Board of Regents and the Regulations of the Commissioner of Education is to align the Commissioner's regulations with the United States Department of Education's (USDOE) regulations by removing references to regional accreditation as the USDOE has removed the distinction between regional and national accreditors.

Thus, the proposed amendment does not have any adverse economic impact entities in rural areas of New York State or impose any reporting, recordkeeping, or compliance requirements on public or private entities in rural areas. Accordingly, no further steps were needed to ascertain the impact of the proposed amendment on entities in rural areas and none were taken. Thus, a rural flexibility analysis is not required and one has not been prepared.

Job Impact Statement

Prior to February 2020, the United States Department of Education (USDOE) recognized institutional accrediting agencies as either "regional" accrediting agencies or "national" accrediting agencies. In February 2020, USDOE issued new regulations which eliminated the distinction between "regional" or "national" to refer to an accrediting agency. USDOE issued a letter explaining that:

Because the Department holds all accrediting agencies to the same standards, distinctions between regional and national accrediting agencies are unfounded. Moreover, we have determined that most regional accreditors operate well outside of their historic geographic borders, primarily through the accreditation of branch campuses and additional locations. As a result, our new regulations have removed geography from an accrediting agency's scope. Instead of distinguishing between regional and national accrediting agencies, the Department will distinguish only between institutional and programmatic accrediting agencies.

Therefore, it is necessary to amend the Rules of the Board of Regents and the Commissioner's regulations to remove references to regional accrediting institutions of higher education as there is no longer such a distinction. The proposed amendment removes such references and replaces such language with the following: "accredited by an institutional accrediting agency recognized for this purpose by the United States Department of Education."

Because it is evident from the nature of the proposed amendment that it will have no impact on the number of jobs or employment opportunities in New York State, no further steps were needed to ascertain that fact and none were taken.

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Prohibits Schools from Filing a Law Suit Against Parents or Guardians for Unpaid Meal Fees

I.D. No. EDU-39-21-00012-P

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