



TO: Professional Practice Committee
FROM: Sarah S. Benson *Sarah S. Benson*
SUBJECT: Proposed Amendment to Sections 63.2, 63.3, 63.5 and 63.7 of the Regulations of the Commissioner of Education Relating to the Licensure Examination, Licensure by Endorsement and Continuing Education Requirements in the Profession of Pharmacy
DATE: December 10, 2021

AUTHORIZATION(S): *Don McG* *Bellotti*

SUMMARY

Issue for Decision

Should the Board of Regents amend sections 63.2, 63.3, 63.5 and 63.7 of the Regulations of the Commissioner of Education relating to the licensure examination, licensure by endorsement and continuing education requirements in the profession of pharmacy?

Reason for Consideration

Review of policy.

Proposed Handling

The proposed amendment is being presented to the Professional Practice Committee for recommendation and to the Full Board for permanent adoption at the December 2021 meeting of the Board of Regents. A copy of the proposed amendment is included (Attachment A).

Procedural History

The proposed amendment was presented to the Professional Practice Committee for discussion at the September 2021 meeting of the Board of Regents. A Notice of Proposed Rule Making was published in the State Register on September 29, 2021.

Following the 60-day public comment period required under the State Administrative Procedure Act, the Department received multiple comments from six commenters. An Assessment of Public Comment is included as Attachment B. No changes to the proposed rule based on public comment are recommended at this time, however, a non-substantial revision has been made to the proposed rule, as further outlined below.

A Notice of Adoption will be published in the State Register on December 29, 2021. Supporting materials are available upon request to the Secretary of the Board of Regents

Background Information

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 of the nationally offered examinations 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.

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.

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 in the 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.

Non-Substantial Revision

Since publication of the proposed amendment in the State Register, Department staff discovered that, while the beginning of the proposed amendment to section 63.2(b) of the Commissioner's regulations contains the following language:

“ . . . 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 ”,

The end of this subdivision inadvertently failed to include the following language as intended:

“ . . . and determined by the department to be satisfactory . . . ”

The Department proposed identical language in the amendment to section 63.3(a) of the Commissioner's regulations. This omitted language is needed to clarify the intent of the proposed amendment and ensure consistency in the language of the proposed amendment. Consequently, a non-substantial revision has been made to the amendment of section 63.2 of the Commissioner's regulations as follows:

[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 and **determined by the department to be satisfactory** 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. (emphasis added).

Related Regents Items

September 2021: [Proposed Amendment to Sections 63.2, 63.3, 63.5 and 63.7 of the Regulations of the Commissioner of Education Relating to the Licensure Examination, Licensure by Endorsement and Continuing Education Requirements in the Profession of Pharmacy](https://www.regents.nysed.gov/common/regents/files/921ppcd1.pdf)

(<https://www.regents.nysed.gov/common/regents/files/921ppcd1.pdf>)

Recommendation

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

VOTED: That sections 63.2, 63.3 and 63.5 of the Regulations of the Commissioner of Education be amended, as submitted, effective January 1, 2022, and section 63.7 of the Regulations of the Commissioner of Education be amended, as submitted, effective January 1, 2023.

Timetable for Implementation

If adopted at the December 2021 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.

Attachment A

AMENDMENT OF THE REGULATIONS OF THE COMMISSIONER OF EDUCATION

Pursuant to sections 207, 6504, 6507, 6801, 6805 and 6827 of the Education Law

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 and determined by the department to be satisfactory 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.

8 NYCRR §§63.2, 63.3, 63.5 and 63.7

ASSESSMENT OF PUBLIC COMMENT

Since the publication of a Notice of Proposed Rule Making in the September 29, 2021 State Register, the State Education Department received the following comments on the proposed regulatory amendments:

1. COMMENT: A pharmacy association expressed support for the proposed amendments to section 63.2(b) of the Commissioner's regulations to the degree that it provides the Board of Pharmacy with the authority to determine what examinations (exams) are acceptable for licensure purposes. It further supports the proposed amendments to section 63.3(a) of the Commissioner's Regulations as they relate to providing the Board of Pharmacy with the authority to set exam standards for the candidates. However, the association recommended that the language ". . . and other matters of practice as may be deemed appropriate by the department" as well as ". . . and other matters as may be deemed appropriate by the department" be stricken from the amendments, arguing that the Board of Pharmacy is composed of subject matter experts and is, therefore, in the best position make these determinations to protect public health.

DEPARTMENT RESPONSE: The Department appreciates the supportive comments as it works to protect the public by implementing the proposed amendments, which, among other things, amends the licensure pathway by eliminating the Part III exam for New York pharmacist licensure.

Pursuant to Education Law §6508, the State Boards of the Professions are appointed by the Board of Regents for the purpose of assisting the Board of the Regents and the Department on matters of professional licensing, practice, and

conduct. Pursuant to Education Law §6805, candidates must pass an exam satisfactory to the Board of Pharmacy and in accordance with the Commissioner's regulations. The proposed amended language at issue provides the Department with the flexibility to update the matters of practice that are covered on the licensing examination as needed to ensure the protection of public health without requiring further regulatory amendments and does not diminish the Board of Pharmacy's advisory role to the Department, nor the fact that the exam(s) chosen must be acceptable to such Board. Therefore, no changes to the proposed rule are required.

2. COMMENT: A New York college with a school of pharmacy and a pharmacy association both commented that they fully support the elimination of the Part III exam. The college noted that long grading times and the limited twice a year offering of the exam caused delays in licensure of qualified applicants, resulting in many individuals obtaining licensure from and choosing to work in other states.

The college further stated that most states do not require a practical compounding exam for licensure and there is no evidence to show that compounding errors occur more frequently in those states. The college also stated that New York schools are required to teach compounding to a high degree to adhere to the national standards of education established by the Accreditation Council for Pharmacy Education (ACPE).

DEPARTMENT RESPONSE: The Department appreciates the supportive comments as it works to protect the public by implementing the proposed regulations, which, among other things, amend the licensure pathway by eliminating the Part III exam for applicants seeking to practice the profession of pharmacy in New York. Since the comments are supportive, no changes to the proposed rule are necessary.

3. COMMENT: A college of pharmacy and a pharmacy association agreed with the findings of the gap analysis, which compared the virtual Part III exam against the national exams to determine what competency gaps, if any, existed. However, they also stated that had the analysis been conducted using the pre-pandemic version of the Part III exam, rather than the virtual Part III version of the exam, competency gaps would have been identified. They further commented that the elimination of the Part III exam would hinder the State Board of Pharmacy's ability to assess whether candidates are adequately prepared for state licensure, which would decrease the assurance of public safety.

DEPARTMENT RESPONSE: In both the virtual and practical formats, the Part III exam tests applicants on the competencies outlined in Part 52.29 of the Commissioner's regulations. The gap analysis findings indicated that the competencies outlined in the regulations, including compounding, were also tested on the nationally offered exam, under its revised competency blueprint, resulting in duplicative testing. As a result, the Part III exam no longer serves a unique purpose. Therefore, no changes to the proposed rule are required.

4. COMMENT: A college of pharmacy and two pharmacy associations commented that the Board of Pharmacy and the Department should consider expanding the Part III exam to include additional topics relevant to the scope of practice – such as patient counseling and immunization administration. One pharmacy association stated that, due to the new Registered Pharmacy Technician profession, it is now even more important for newly licensed pharmacists to have, at least, minimum competency in compounding to be able to properly supervise them in compounding related work. Furthermore, they requested that a comprehensive blueprint of their proposed expanded Part III exam be developed to provide candidates with a thorough overview of

what is being tested and that pharmacy professors be utilized to develop and prepare their proposed expanded exam.

DEPARTMENT RESPONSE: The nationally administered NAPLEX exam, under its revised competency blueprint, tests candidates on six areas within the profession of pharmacy, the subcategories of which include, but are not limited to: techniques for drug administration, obtaining, interpreting or assessing medical or patient information and expanded practice responsibilities. Part 52.29 (a)(5) of the Commissioner's regulations requires pharmacy schools to include, as part of their clinical sciences content area, an appropriate mix of clinical experiences in both community and institutional pharmacies. Thus, the currently required curriculum, in conjunction with the national testing standards, ensure that newly licensed pharmacists are adequately prepared to practice at an entry level. Should the national exams fall below the standards outlined in the current regulations, the proposed amendments to the regulations provide the Department with the flexibility to require an additional exam or exams if necessary. Moreover, if the Part III exam is eliminated as proposed, the other above-referenced comments will be moot. Therefore, no changes to the proposed rule are required.

5. COMMENT: A pharmacy association commented that the removal of the Part III exam might alter the level to which the schools of pharmacy teach compounding and recommended that Part 52.29 of the Commissioner's regulations be amended to emphasize training in compounding as a curricular requirement.

DEPARTMENT RESPONSE: Section 52.29(a)(4)(ii) of the Commissioner's regulations currently lists compounding as a curricular area required for general education in the pharmacy profession. Furthermore, to sit for the nationally offered exam, students are required to graduate from an accredited program. ACPE is the

national agency responsible for the accreditation of pharmacy degree programs.

Extemporaneous compounding is a required element of an ACPE accredited Doctor of Pharmacy curriculum. Should there be any changes to the scope of pharmacy practice, which require additional or revised testing, the proposed regulatory amendments give the Board and Department the flexibility to determine what additional exams, if any, are required to test such new competencies. Therefore, no changes to the proposed rule are required.

6. COMMENT: A pharmacy association commented that it opposes the proposed amendment to section 63.3(a) of the Commissioner's regulations which states: "The passing score for such examination or examinations shall be determined by the department," citing that not providing a numeric score within the proposed regulations leaves candidates without a sense of certainty and will cause unsuccessful candidates to challenge the outcome of their exam results as arbitrary and capricious.

DEPARTMENT RESPONSE: In addition to revising its competency blueprint(s), the National Association of Boards of Pharmacy (NABP®) recently discontinued its issuance of numeric scores for the North American Pharmacist Licensure Examination (NAPLEX) and Multistate Pharmacy Jurisprudence Examination (MPJE) – opting instead to implement only a "pass/fail" result. Thus, if the proposed amendment cited a specific numeric value, it would not be in line with the current reporting system, which would hinder the ability of the Department to stay consistent with the evolving profession of pharmacy and its testing requirements. Additionally, not including a specific numeric passing score is consistent with other professions' examination requirements, as indicated in Commissioner's regulations. Therefore, no changes to the proposed rule are required.

7. COMMENT: A pharmacy association expressed its support of the proposed amendment to section 63.5 of the Commissioner's regulations regarding licensure by endorsement and the incorporation of section 59.6 in such regulation, thereby eliminating the inconsistency between these provisions.

DEPARTMENT RESPONSE: The Department appreciates the supportive comments as it works to protect the public by, among other things, increasing access to pharmacy services by implementing the proposed amendments which amends both the regular licensure and licensure by endorsement pathways for applicants seeking to practice the profession of pharmacy in New York. Because the comment is supportive, no changes to the proposed rule are needed.

8. COMMENT: A New York college with a school of pharmacy commented that it supported adding the new three credit compounding continuing education (CE) requirement for pharmacists for each triennial registration period.

DEPARTMENT RESPONSE: The Department appreciates the supportive comments as it works to protect the public by implementing the proposed amendments, including mandating that pharmacists complete three CE credits in compounding each triennial registration period to assist in ensuring that they maintain their competency in this area throughout their careers. Because the comment is supportive, no changes to the proposed rule are needed.

9. COMMENT: A New York college of pharmacy commented that not all accredited pharmacy CE providers may be able to provide sufficient compounding related CE offerings for all New York licensed pharmacists. However, they noted that they themselves are well positioned to develop and offer these types of educational activities.

DEPARTMENT RESPONSE: Education Law §6827(4) states that CE courses must be taken from a Department approved provider. The proposed amendment is not effective until January 1, 2023. This effective date allows sufficient time for approved providers and prospective approved providers to develop appropriate compounding CE courses and content.

10. COMMENT: A pharmacist and a pharmacy association commented that instead of compounding, the Department should implement CE in more relevant topics, such as pharmacy law/ethics and immunization administration.

DEPARTMENT RESPONSE: Pursuant to section 63.7(c)(4) of the Commissioner's regulations, the list of acceptable CE subjects is not exhaustive, which means that an approved CE provider could offer a course in the subject matter(s) of pharmacy law/ethics and/or immunization administration, as long as the course contributes to the profession of pharmacy. The Department will continue to assess the need to further refine the CE requirements going forward. Therefore, no change to the proposed rule is necessary.

11. COMMENT: A New York licensed pharmacist commented that it would be more beneficial for the Department to require all compounding CE courses be given in a live format with a hands-on component.

DEPARTMENT RESPONSE: Pharmacists are required by Education Law §6827(2) to complete at least 23 of the required 45 CE credits by taking live courses. The existing CE requirements allow appropriate flexibility for licensed pharmacists and recognize the value of various CE modalities, which include live format courses. Therefore, no changes to the proposed rule are required.

12. COMMENT: A pharmacist, a college of pharmacy, and a pharmacy association within New York commented that only pharmacists who were actively engaged in sterile

and non-sterile compounding should be required to complete the proposed CE credits in compounding each triennial registration period.

DEPARTMENT RESPONSE: Pursuant to Education Law §6801(1), compounding is part of the scope of practice of the profession of pharmacy. Likewise, Education Law §6827(4) authorizes the Department to require pharmacists to complete CE in specific subjects consistent with that scope of practice. Given the serious consequences of improperly compounded medications, and the fact that a pharmacist can change jobs or duties at any time, requiring compounding CE for all pharmacists will contribute to the health and welfare of the public by assisting in ensuring that pharmacists maintain competency in compounding throughout their careers. Therefore, no change to the proposed rule is necessary.