



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: September 2, 2021

AUTHORIZATION(S): *Don McG...* *Betty...*

SUMMARY

Issue for Discussion

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 will be presented to the Professional Practice Committee for discussion at the September 2021 meeting of the Board of Regents. A copy of the proposed amendment is included (Attachment A).

Procedural History

A Notice of Proposed Rule Making will be published in the State Register on September 29, 2021. Supporting materials for the proposed rule are available upon request from the Secretary to 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 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

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.

complete three continuing education credits in compounding each triennial registration period. These compounding continuing education credits must be taken from Department approved providers.

Related Regent's Items

Not applicable.

Timetable for Implementation

It is anticipated that the proposed amendment will be presented for adoption at the December 2021 Regents meeting, after the publication of the proposed amendment in the State Register and expiration of the 60-day public comment period required under the State Administrative Procedure Act. If adopted at the 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 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-ratio 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-ratio 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.