TO: The Honorable Members of the Board of Regents

FROM: David H. Hamilton

SUBJECT: Proposed Addition of Section 63.17 to the Regulations of the Commissioner of Education Relating to the Administration of Injectable Medications by Pharmacists for the Treatment of Mental Health and Substance Use Disorder

DATE: July 3, 2024

AUTHORIZATION(S):

SUMMARY

Issue for Decision (Consent)

Should the Board of Regents add section 63.17 to the Regulations of the Commissioner of Education relating to the administration of injectable medications by pharmacists for the treatment of mental health and substance use disorder?

Reason for Consideration

Required by State statute (Chapter 802 of the Laws of 2022, as amended by Chapter 746 of the Laws of 2023).

Proposed Handling

The proposed amendment is submitted to the Full Board for adoption as a permanent rule at the July 2024 meeting. A copy of the proposed rule (Attachment A) is attached.

Procedural History

The proposed amendment was presented to the Professional Practice Committee for discussion and recommendation to the Full Board for adoption as an emergency rule at the March 2024 meeting of the Board of Regents. A Notice of Emergency Adoption and Proposed Rulemaking was published in the State Register on March 27, 2024 for a 60-day public comment period.

Because the March 2024 emergency rule was set to expire on June 9, 2024, a second emergency action was necessary to ensure that the emergency rule remained continuously in effect until it could be permanently adopted at the July 2024 Board of Regents meeting. A Notice of Emergency Adoption was published in the State Register on June 26, 2024.

Following publication in the State Register, the Department received two comments from one commenter on the proposed amendment. An Assessment of Public Comment (Attachment B) is attached. No changes to the proposed amendment are recommended at this time in response to the comments. However, a typographical error was discovered, and a non-substantial revision has been made to the proposed rule to correct the lettering. A Notice of Adoption will be published in the State Register on July 31, 2024. Supporting materials are available upon request to the Secretary of the Board of Regents.

Background Information

Pharmacists serve an important role in ensuring patients adhere to the medication regimen they are prescribed. With mental illness and substance use on the rise, there is a need to increase patient access to, and compliance with, prescribed medications. While oral forms of medications exist, many patients do not take them as prescribed.

One way to combat non-adherence is by using long-acting injectable medications (LAI), which provide a gradual release of medication into the patient's bloodstream over time. In comparison to oral medications, LAIs are administered anywhere from every couple of weeks to every six months.

Chapter 802 of the Laws of 2022, as amended by Chapter 746 of the Laws of 2023 (Chapter 802), effective April 1, 2024, amends the Education Law to authorize certified pharmacists who receive training pursuant to Education Law §6801(3) to administer, pursuant to a patient-specific prescription or patient-specific order issued by a prescriber acting within their scope of practice, LAIs that are approved by the Federal Food and Drug Administration (FDA) for the treatment of mental illness and/or substance use disorder. Chapter 802 also authorizes pharmacists to administer medications required for emergency treatment of anaphylaxis related to such LAI administration.

Chapter 802 also requires that pharmacists notify the patient's prescriber after the administration of a LAI and in circumstances where adverse events occur or when the patient does not receive an administration of the medication. Patients, who would like to receive their LAI from a pharmacist, must have their initial injection administered by their prescriber and be considered eligible for maintenance treatment by their prescriber.

Additionally, Chapter 802 provides that pharmacists that administer LAIs must maintain continued competency regarding the populations served and medications administered; obtain pre-administration patient consent and education regarding common side effects, drug interactions, injection site reactions, and other information routinely provided to patients upon dispensing; and provide an area for the injection that provides for the patient's privacy.

Allowing pharmacists to administer LAIs will significantly expand access to healthcare for patients with mental illness and substance use disorder, which is essential to reducing patient non-adherence, clinical relapses, and patient hospitalizations.

Proposed Amendment

The proposed addition of section 63.17 to the Commissioner's regulations implements Chapter 802 by:

- establishing the standards, procedures, and reporting requirements for pharmacists to administer injectable medications approved by the FDA for the treatment of mental health and substance use disorder pursuant to a valid patient-specific prescription or patient-specific order;

- describing which patients are eligible to receive an administration, by a pharmacist, of an injectable medication approved by the FDA for the treatment of mental health and substance use disorder;

- indicating the criteria pharmacy interns must meet to administer an injectable medication approved by FDA for the treatment of mental health and substance use disorder;

- setting forth the competency requirements for training deemed satisfactory to the Commissioner of Education; and

- establishing the standards, procedures, and reporting requirements under which licensed pharmacists can administer medications for the treatment of anaphylaxis to patients receiving injectable medications.

Non-substantial Revisions to the Proposed Rule

Following publication of the Notice of Emergency Adoption in the State Register on June 26, 2024, the Department discovered a typographical error in the lettering of the proposed rule. Specifically, there were two (b) paragraphs, therefore, the second (b) "Anaphylaxis treatment agents" should be changed to (c) and the (c) should be changed to (d).

Related Regents Items

May 2024: Proposed Addition of Section 63.17 to the Regulations of the Commissioner of Education Relating to the Administration of Injectable Medications by Pharmacists for the Treatment of Mental Health and Substance Use Disorder
(https://www.regents.nysed.gov/sites/regents/files/524brca8.pdf)

March 2024: Proposed Addition of Section 63.17 to the Regulations of the Commissioner of Education Relating to the Administration of Injectable Medications by Pharmacists for the Treatment of Mental Health and Substance Use Disorder
(https://www.regents.nysed.gov/sites/regents/files/324ppca1.pdf)

Recommendation

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

VOTED: That section 63.17 of the Regulations of the Commissioner of Education be added, as submitted, effective July 31, 2024.

Timetable for Implementation

If adopted at the July meeting, the proposed amendment will become effective as a permanent rule on July 31, 2024.

Attachment A

AMENDMENT TO THE REGULATIONS OF THE COMMISSIONER OF EDUCATION

Pursuant to sections 207, 6504, 6507, 6801, 6802 and Chapter 802 of the Laws of 2022, as amended by Chapter 746 of the Laws of 2023.

1. The Regulations of the Commissioner of Education are amended by adding a new section 63.17 to read as follows:

Section 63.17. Administering injectable medications pursuant to patient-specific prescriptions or patient-specific orders and emergency treatment of anaphylaxis

(a) Definitions. As used in this section:

(1) *Injectable medication* shall mean injectable medications approved by the Federal Food and Drug Administration for the treatment of mental health and substance use disorder.

(2) *Certified pharmacy intern* shall mean a pharmacy intern as defined in Education Law §6806 who has met the requirements set forth in section 63.4(d) of this Part and has been issued a certificate of administration by the department pursuant to section 63.9(a)(3) of this Part.

(b) Injection of medications.

(1) Pursuant to Education Law §6802(22), a certified pharmacist shall be authorized to administer injectable medications to patients for the treatment of mental health and substance use disorder provided that:

(i) the pharmacist has received training as prescribed in Education Law §6801(3) and has been issued a certificate of administration issued by the department pursuant to section 63.9(a)(3) of this Part;

(ii) the administration of the injectable medication is conducted pursuant to a valid patient-specific prescription or patient-specific order;

(iii) the pharmacist has maintained continued competency regarding the populations served and medications available for administration; and

(iv) the injectable medications are approved by the Federal Food and Drug Administration for the treatment of mental health and substance use disorder.

(2) With the exception of a certified pharmacy intern, a certified pharmacist shall not delegate the administration of an injectable medication to another person. When administering an injectable medication, the certified pharmacy intern shall be under the immediate personal supervision of the certified pharmacist. Administration by a certified pharmacy intern shall not occur unless the patient has been informed and has consented to such administration. If the patient does not consent to the administration of an injectable medication by a certified pharmacy intern, a certified pharmacist shall be present to administer the injectable medication to the patient.

(3) Prior to administering an injectable medication each certified pharmacist shall:

(i) verify that the patient has already received an initial dose of the injectable medication and has been deemed eligible for maintenance treatment by their prescriber. Such eligibility shall be communicated by the prescriber in writing, electronically or via facsimile. Where such means of communication are not possible, a prescriber may communicate patient eligibility to a pharmacist verbally, provided that the pharmacist documents such communication within the patient's medication profile as defined in section 63.6(b)(7) of this Part;

(ii) inform the patient, or the person legally responsible for the patient when the patient is incapable of consenting to the administration of the injectable medication, of the injectable medication's common side effects, drug interactions, injection site reactions and other information that is routinely provided to patients upon the dispensing of a medication. Such information shall be provided orally and in writing;

(iii) assess the patient for any contraindications to the injectable medication;

(iv) be responsible for having emergency anaphylaxis treatment agents, related syringes and needles available at the location where the injectable medication is being administered;

(v) obtain written consent from the patient to administer the injectable medication. If the patient is incapable of providing written consent, it may be obtained from the person legally responsible for the patient. For the purposes of this section, such consent shall be obtained in writing or electronically and noted within the patient's medication profile as defined in section 63.6(b)(7) of this Part;

(vi) provide the patient, or person legally responsible for the patient if the patient is not able to consent to the administration of the injectable medication, with written instructions regarding the course of action to be taken if an adverse reaction or contraindication occurs; and

(vii) provide an area that ensures patient privacy when administering the injectable medication.

(4) Reporting of injectable medications:

(i) the certified pharmacist or the pharmacist's designee shall notify the patient's prescriber within five days of administering the injectable medication. Such notification may occur via an electronic medical records system, an electronic prescribing technology or pharmacy records, facsimile, electronic transmission or other electronic means. If an electronic means is not available to communicate the administration of the injectable medication, a certified pharmacist or their designee may communicate the information via telephone. Such notification shall be documented in the patient's medication profile as defined in section 63.6(b)(7) of this Part.

(ii) in the event that the patient does not receive their scheduled injectable medication, the certified pharmacist shall notify the patient's prescriber within 72 hours after the injectable medication was scheduled to be administered.

(iii) If the patient experiences any side effects or adverse reactions to the medications the certified pharmacist shall notify the prescriber immediately and make themselves available to discuss the adverse reaction with the patient's prescriber.

(c) Anaphylaxis treatment agents.

(1) Each certified pharmacist who receives training as prescribed in Education Law §6801(3) and is issued a certificate of administration pursuant to section 63.9(a)(3) of this Part shall be authorized to administer medications for the treatment of anaphylaxis to patients receiving injectable medications.

(2) each certified pharmacist who administers medication for the treatment of anaphylaxis to patients receiving an injectable medication shall follow the standards, procedures and reporting requirements for the administration of anaphylactic medication set forth in section 63.9(b) of this Part.

(d) Nothing in this section shall prevent a certified pharmacist from refusing to administer an injectable medication if, in their professional judgment, potential adverse effects, interactions, or other therapeutic complications could endanger the health of a patient.

Attachment B

ASSESSMENT OF PUBLIC COMMENT

Following the publication of a Notice of Emergency Adoption and Proposed Rule Making in the State Register on March 27, 2024, the State Education Department received the following comments on the proposed regulation:

1. COMMENT: An association for psychiatrists commented that, since the proposed rule defines the terms “injectable medications” and “certified pharmacy interns,” it should also define the term “licensed prescriber.”

DEPARTMENT RESPONSE: The term “licensed prescriber” is generally understood by health care providers and in health care settings to mean a health care provider licensed to prescribe medication in New York. Similarly, Public Health Law §4408(8)(vii) defines a “prescriber” as a health care provider licensed to prescribe medication or medical devices in this State. Therefore, no changes to the proposed rule are necessary. However, the Department will consider issuing guidance regarding this term.

2. COMMENT: An association for psychiatrists commented that pharmacists who refuse to administer a long-acting injectable medication to a patient due to potential adverse effects, interactions, or other therapeutic complications should be required to notify the prescriber contemporaneously or within 24 hours of such refusal.

DEPARTMENT RESPONSE: Chapter 802 of the Laws of 2022, as amended by Chapter 746 of the Laws of 2023, does not specify a timeframe in which pharmacists are required to notify a prescriber when a patient misses a dose. Thus, the proposed rule conforms with the statute. However, to provide the field with additional guidance regarding long-acting injectable medication administration, the Department has posted information on its pharmacy profession’s frequently asked questions (FAQs) website

advising that it is a best practice for pharmacists to notify the patient's prescriber as soon as possible when a dose is missed but no later than 72 hours after the medication was scheduled to be administered. See: https://www.op.nysed.gov/professions/pharmacist/frequently-asked-questions/Long-Acting-Injectable-Medication-Administration. Therefore, no changes to the proposed rule are necessary.