





TO: Professional Practice Committee

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: February 29, 2024

AUTHORIZATION(S): 

SUMMARY

Issue for Decision

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 will be presented to the Professional Practice Committee for recommendation and to the Full Board for adoption as an emergency rule at the March 2024 meeting. A copy of the proposed rule (Attachment A) and a statement of facts and circumstances justifying the emergency action (Attachment B) are attached.

Procedural History

A Notice of Emergency Adoption and Proposed Rulemaking will be published in the State Register on March 27, 2024, for a 60-day public comment period. Supporting materials are available upon request from the Secretary to the Board of Regents.

Background Information

Pharmacists serve an important role in ensuring patients are adherent to their medications. 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 a period of 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.

Related Regents Items

Not applicable.

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 April 1, 2024, as an emergency action, upon the finding by the Board of Regents that such action is necessary for the preservation of the public health and general welfare in order to timely implement the provisions of Chapter 802 of the Laws of 2022, as amended by Chapter 746 of the Laws of 2023, effective April 1, 2024.

Timetable for Implementation

If adopted at the March 2024 Regents meeting, the emergency rule will become effective April 1, 2024. It is anticipated that the proposed rule will be presented to the Board of Regents for permanent adoption at the July 2024

Regents meeting, after publication in the State Register and expiration of the 60-day public comment period required under the State Administrative Procedure Act. Because the emergency action will expire before the July 2024 Regents meeting, it is anticipated that an additional emergency action will be presented for adoption at the May 2024 meeting. If adopted at the July 2024 meeting, the proposed rule 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.

(b) 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.

(c) 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.

8 NYCRR §63.17

STATEMENT OF FACTS AND CIRCUMSTANCES WHICH NECESSITATE
EMERGENCY ACTION

Chapter 802 of the Laws of 2022, as amended by Chapter 746 of the Laws of 2023 (Chapter 746), effective April 1, 2024, amends the Education Law to, inter alia, authorize certified pharmacists to administer injectable medications for the treatment of mental health and substance use disorder pursuant to a patient-specific prescription or patient-specific order. Chapter 802 also permits certified pharmacists to administer anaphylactic medications to patients if an adverse reaction occurs during or after the administration of the injectable medication.

The proposed amendment 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.

Since the Board of Regents meets at fixed intervals, the earliest the proposed rule could be adopted by regular (nonemergency) action after expiration of the 60-day public comment period provided for in the State Administrative Procedure Act (SAPA) sections 201(1) and (5), would be the July 2024 Regents meeting. Furthermore, pursuant to SAPA section 203(1), the earliest effective date for the proposed rule, if adopted at the July meeting, would be July 31, 2024, the date the Notice of Adoption would be published in the State Register.

Therefore, emergency action is necessary at the March 2024 meeting, effective April 1, 2024, for the public health and preservation of the general welfare in order to timely implement the requirements of Chapter 802, which becomes effective April 1, 2024.

It is anticipated that the proposed rule will be presented to the Board of Regents for adoption as a permanent rule at the July 2024 Regents meeting, which is the first scheduled meeting after expiration of the 60-day public comment period mandated by SAPA for state agency rule making. However, since the emergency action will expire before the June Regents meeting, it is

anticipated that an additional emergency action will be presented for adoption at the May 2024 Regents meeting.