

THE STATE EDUCATION DEPARTMENT / THE UNIVERSITY OF THE STATE OF NEW YORK / ALBANY, NY 12234

TO: **Professional Practice Committee** Dav I H. Handa

David H. Hamilton FROM:

SUBJECT: Proposed Amendment of Section 63.8 and Addition of

Section 63.18 to the Regulations of the Commissioner of

Education Relating to Shared Pharmacy Services

DATE: August 28, 2025

AUTHORIZATION(S):

SUMMARY

Issue for Discussion

Should the Board of Regents adopt the proposed amendment of section 63.8 and addition of section 63.18 to the Regulations of the Commissioner of Education relating to shared pharmacy services?

Reason for Consideration

Required by State statute (Chapter 491 of the Laws of 2024).

Proposed Handling

The proposed amendment is presented to the Professional Practice Committee for discussion at the September 2025 Regents meeting. A copy of the proposed rule (Attachment A) is attached.

Procedural History

A Notice of Proposed Rule Making will be published in the State Register on September 24, 2025 for a 60-day public comment period. Supporting materials are available upon request to the Secretary of the Board of Regents.

Background Information

In recent years, statutory changes have significantly expanded the scope of pharmacy practice to include greater direct patient care responsibilities, such as the administration of immunizations and medications. Additionally, throughout much of the United States, the delivery of other, more traditional, pharmacy services evolved through the adoption of new technologies and streamlined business models utilizing shared pharmacy services. In response to these developments, New York State enacted legislation authorizing the use of shared pharmacy services. This legislation includes the registration of central fill pharmacies and the use of remote prescription verification. These measures are intended to ensure that pharmacists and pharmacies in New York State can deliver high quality patient care in a manner consistent with the ongoing advancement of pharmacy practice.

Chapter 491 of the Laws of 2024, effective May 22, 2026 (Chapter 491), which will amend the Education Law to define shared pharmacy services as a system whereby a registered pharmacist or pharmacy may, upon request from another registered pharmacist or pharmacy, process or fill a prescription or order in accordance with regulations promulgated by the Commissioner of Education.

Chapter 491 also establishes the standards governing the participation of both resident and nonresident pharmacies in shared pharmacy services. It sets forth the general requirements, qualifications, operational procedures, patient notification obligations, drug storage and security protocols, and the policies and procedures applicable to pharmacists and pharmacies engaged in such services. Chapter 491 also delineates the conditions under which individuals licensed or authorized under Articles 137 or 137-A of the Education Law, and who are employed by or under contract with a pharmacy, may remotely access the pharmacy's electronic database. The implementation of shared pharmacy services will allow New York State registered pharmacists and pharmacies to keep pace with the evolution of pharmacy practice.

Proposed Amendment

The proposed addition of section 63.18 to the Commissioner's regulations implements Chapter 491 by:

- adopting the definition of "shared pharmacy services" set forth in Chapter 491;
- establishing the general requirements, qualifications, operations, notification to patients, drug storage and security, and policies and procedures for pharmacists and pharmacies engaging in shared services;
- delineating the conditions under which individuals licensed or authorized under Articles 137 or 137-A of the Education Law (and who are employed by or under

contract with a pharmacy) may remotely access the pharmacy's electronic database;

- establishing the requirements for individual practice; and
- making conforming changes for non-resident establishments to permit their participation in shared services.

Related Regents Items

Not applicable.

Recommendation

Not applicable.

<u>Timetable for Implementation</u>

It is anticipated that the proposed amendment will be presented for permanent adoption at the January 2026 Regents meeting, after 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 January 2026 meeting, the proposed amendment will become effective on May 22, 2026.

Attachment A

AMENDMENT TO THE REGULATIONS OF THE COMMISSIONER OF EDUCATION

Pursuant to sections 207, 6504, 6507, 6802, 6808-b, and 6809 of the Education

Law and Chapter 491 of the Laws of 2024.

- 1. Section 63.8 of the Regulations of the Commissioner of Education are amended by to read as follows:
- (a) Definitions. For purpose of this section and section 6808-b of the Education Law:
- (1) Nonresident establishment means any <u>pharmacy located outside of the state</u> that participates in shared pharmacy services for registered pharmacies and/or patients <u>residing in this state or</u> pharmacy, manufacturer, outsourcing facility or wholesaler located outside of New York State that ships, mails, or delivers prescription drugs or devices to other establishments, authorized prescribers and/or patients residing in New York State. Such establishments shall include, but not be limited to, pharmacies that transact business through the use of the internet.
 - (2) ...
- (3) Shared pharmacy services means a system that allows a registered pharmacist or a registered pharmacy, pursuant to a request from another registered pharmacist or pharmacy, to process or fill a prescription or order.
 - (b) Registration requirements.
- (1) All nonresident establishments that <u>participate in shared pharmacy services</u>, <u>for registered pharmacies and/or patients residing in this state or that ship</u>, mail, or deliver prescription drugs and/or devices to other registered establishments, authorized

prescribers, and/or patients into New York State shall be registered with the department in accordance with this section and section 6808-b of the Education Law, except that such registration shall not apply to intra-company transfers between any division, affiliate, subsidiaries, parent or other entities under complete common ownership and control, and except that such registration shall not apply to nonresident establishments that have been granted an exception under subdivision (e) of this section. The intra-company transfer exemption shall not apply to outsourcing facilities.

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	2. The Regulations of the Commissioner of Education are amended by adding
S	ection 63.18 to read as follows:

а new

Section 63.18 Shared Pharmacy Services

- (a) Definitions. As used in this section:
- (1) Shared pharmacy services means a system that allows a registered pharmacist or a registered pharmacy, pursuant to a request from another registered pharmacist or pharmacy, to process or fill a prescription or order.
- (b) General Requirements. No pharmacist or pharmacy shall provide shared pharmacy services unless they are registered in accordance with sections 6805, 6808, or 6808-b of the Education Law, and are in compliance with the provisions of this section.
- (c) Qualification. A pharmacy may provide or engage in shared pharmacy services only if the pharmacies involved share a common electronic file or technology that allows access to information necessary or required to perform shared pharmacy services in compliance with all applicable federal and state statutory and regulatory requirements and:
 - (1) have the same owner; or
- (2) have a written contract or agreement that outlines the services provided and the shared responsibilities of each pharmacy in complying with all applicable federal and state statutory and regulatory requirements.
- (d) Operations. A pharmacy or pharmacist engaged in shared pharmacy services shall:
- (1) maintain records that identify, individually for each prescription or order filled or processed, the name and if applicable, the license or registration number of each pharmacy and individual who took part in the processing or filling of the prescription or order. Such records shall be maintained in accordance with subdivision (5) of section

6810 of the Education Law and made available to the department upon request.

Records of prescriptions for controlled substances shall be maintained pursuant to the requirements of Article 33 of the Public Health Law;

(2) maintain a system for the tracking of each prescription or order during each step of the process including, but not limited to, the name and if applicable, the license and registration number of each pharmacy and individual taking part in the processing or filling of the prescription or order;

(3) notify the department, in writing, within thirty days of any disciplinary action taken by another state's regulatory agency involving shared pharmacy services as defined in subdivision (30) of section 6802 of the Education Law;

(4) ensure that the labels for all prescriptions filled utilizing shared pharmacy services identify the names and registration numbers of the pharmacies involved in the dispensing and filling of the prescriptions. All labels shall conform to sections 6829 and 6830 of the Education Law and the regulations promulgated thereunder. The labeling of prescriptions for controlled substances shall be subject to additional requirements provided in Article 33 of the Public Health Law. The provisions of this paragraph shall not apply to hospitals as defined in Article 28 of the Public Health Law when furnishing drugs to patients registered for treatment by the hospital;

(5) maintain a system that adequately protects the confidentiality and integrity of protected patient information; and

(6) maintain processes for the storage, processing and dispensing of controlled substances in accordance with Article 33 of the Public Health Law.

- (e) Notification to patients. Pharmacies participating in shared pharmacy services shall:
- (1) notify patients or the patients' authorized representative that, pending their consent, a portion or all of their prescriptions may be processed or filled off premises.

 Such notification shall be conveyed using conspicuously posted signage at or adjacent to the place in the pharmacy where prescriptions are presented for compounding and dispensing, in the waiting area for customers, or the area where prescribed drugs are dispensed. Pharmacies that transact business through the use of the internet shall conspicuously provide such notification on their website; and
- (2) obtain an initial onetime consent to fill current and future prescriptions through shared pharmacy services from the patient or patient's authorized representative prior to the dispensing of one or more prescriptions 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.
- (f) Opt-out. Nothing in this section shall prohibit a patient or the patients' authorized representative from opting out of having the patients' prescription processed or filled via shared pharmacy services at any time.
- (g) Applicability. The provisions of this section shall not apply to a hospital as defined in Article 28 of the Public Health Law which is furnishing drugs to patients registered for treatment by the hospital.
 - (h) Drug storage and security.
- (1) Drugs shall be stored and transported in a secure manner in compliance with all applicable federal and state statutory and regulatory requirements.

- (2) Access to the area where drugs are stored shall be limited to authorized personnel.
- (3) Pharmacies participating in shared pharmacy services shall have adequate security that complies with all applicable federal and state statutory and regulatory requirements and protects the confidentiality and integrity of protected patient information.
 - (i) Policies and procedures.
- (1) Each pharmacy participating in shared pharmacy services shall jointly develop, implement, review, revise, and comply with joint policies and procedures for shared pharmacy services. Such policies and procedures shall be made available to the department upon request and maintained pursuant to the requirements of this section.
 - (2) The policies and procedures shall:
 - (i) outline the responsibilities of each pharmacy;
- (ii) include a list of the names, addresses, telephone numbers, and all registration numbers of the pharmacies involved in shared pharmacy services; and
 - (iii) include policies and procedures for:
- (a) notifying the patients or the patients' authorized representative that the patients' prescriptions may be processed or filled off premises and providing the names and registration numbers of the other pharmacies involved in the filling or processing of the prescriptions;
 - (b) protecting the confidentiality and integrity of protected patient information;
- (c) dispensing a prescription when a prescription filled utilizing shared pharmacy services is not received or the patient comes in before such prescription is received;

(d) maintaining a required manual or electronic records to track the prescription or order through each step of the process including, but not limited to, the names and, if applicable, the license or registration numbers of each individual who participated in shared pharmacy services;

(e) complying with all applicable federal and state statutory and regulatory requirements; and

(f) policies and procedures for hospitals as defined in the Public Health Law are exempt from the requirements of clauses (a) and (c) of this subparagraph, when furnishing drugs to patients registered for treatment by the hospital.

(i) Individual practice. For the purpose of shared pharmacy services, persons licensed or otherwise authorized under Articles 137 and 137-a of the Education Law, employed by or under contract with a pharmacy, acting within their respective scopes of practice, may access that pharmacy's electronic database from inside or outside the pharmacy and perform prescription or order processing functions, if both of the following requirements are met:

(1) the pharmacy establishes controls to protect the confidentiality and integrity of protected patient information; and

(2) no part of the database is duplicated, downloaded, or removed from the pharmacy's electronic database.

(k) Effect. Failure to meet any or all of the requirements in this section may result in denial of renewal of registration.