STATE OF NEW YORK

9186

IN SENATE

May 3, 2024

Introduced by Sen. STAVISKY -- read twice and ordered printed, and when printed to be committed to the Committee on Higher Education

AN ACT to amend the education law, in relation to shared pharmacy services

The People of the State of New York, represented in Senate and Assembly, do enact as follows:

Section 1. Section 6802 of the education law is amended by adding a new subdivision 30 to read as follows:

(30) "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, pursuant to regulations promulgated by the commissioner.

§ 2. The education law is amended by adding a new section 6809 to read as follows:

§ 6809. Shared pharmacy services. 1. General requirements. No pharmacist or pharmacy shall provide shared pharmacy services unless they are registered in accordance with sections sixty-eight hundred five, sixty-eight hundred eight, or sixty-eight hundred eight-b of this article, and are in compliance with the provisions of this section.

2. Qualification. A pharmacy may provide or engage in shared pharmacy services only if the pharmacies involved:

a. (i) have the same owner; or

(ii) 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; and

b. 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.

3. Operations. A pharmacy or pharmacist engaged in shared pharmacy services shall:

EXPLANATION--Matter in *italics* (underscored) is new; matter in brackets [-] is old law to be omitted.

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a. 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 five of section sixty-eight hundred ten of this article and made available to the department upon request. Records of prescriptions for controlled substances shall be maintained pursuant to the requirements of article thirty-three of the public health law;

b. 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;

c. 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 this article;

d. 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 sixty-eight hundred twenty-nine and sixty-eight hundred thirty of this article and the regulations promulgated thereunder. The labeling of prescriptions for controlled substances shall be subject to additional requirements provided in article thirty-three of the public health law. The provisions of this paragraph shall not apply to hospitals as defined in article twenty-eight of the public health law when furnishing drugs to patients registered for treatment by the hospital;

e. maintain a system that adequately protects the confidentiality and integrity of protected patient information; and

f. maintain processes for the storage, processing and dispensing of controlled substances in accordance with article thirty-three of the public health law.

4. Notification to patients. a. Pharmacies participating in shared pharmacy services shall:

(i) 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

(ii) 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.

b. Nothing in this subdivision 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.

c. The provisions of this subdivision shall not apply to a hospital as defined in article twenty-eight of the public health law which is furnishing drugs to patients registered for treatment by the hospital.

5. Drug storage and security. a. Drugs shall be stored and transported in a secure manner in compliance with all applicable federal and state statutory and regulatory requirements.

b. Access to the area where drugs are stored shall be limited to authorized personnel.

c. 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.

6. Policies and procedures. a. 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 regulations promulgated by the commissioner.

b. 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; and

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

(iv) policies and procedures for hospitals as defined in the public health law are exempt from the requirements of clauses (A) and (C) of subparagraph (iii) of this paragraph, when furnishing drugs to patients registered for treatment by the hospital.

7. Individual practice. For the purpose of shared pharmacy services, persons licensed or otherwise authorized under this article and article one hundred thirty-seven-a of this title, 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:

a. the pharmacy establishes controls to protect the confidentiality and integrity of protected patient information; and

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

8. Effect. Failure to meet any or all of the requirements of this section may result in a denial of renewal of registration.

§ 3. Subdivisions 1, 2, and 3 of section 6808-b of the education law, as amended by chapter 567 of the laws of 2002, subdivision 1 as amended by section 5 of part D of chapter 60 of the laws of 2014, are amended to read as follows:

1. Definition. The term "nonresident establishment" shall mean any **pharmacy located outside of the state that participates in shared pharmacy services for registered pharmacies and/or patients residing in this state or** pharmacy, manufacturer, wholesaler, or outsourcing facility located outside of the state that ships, mails or delivers prescription drugs or devices to other establishments, authorized prescribers and/or patients residing in this state. Such establishments shall include, but not be limited to, pharmacies that transact business through the use of the internet.

2. Registration. All nonresident establishments that **participate in shared pharmacy services for registered pharmacies and/or patients residing in this state or that** ship, mail, or deliver prescription drugs and/or devices to other registered establishments, authorized prescribers, and/or patients into this state shall be registered with the department; 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. The provisions of this subdivision shall apply solely to nonresident establishments and shall not affect any other provision of this article.

3. Agent of record. Each nonresident establishment that **participates in shared pharmacy services or** ships, mails or delivers drugs and/or devices into this state shall designate a resident agent in this state for service of process pursuant to rule three hundred eighteen of the civil practice law and rules.

§ 4. This act shall take effect eighteen months after it shall have become a law. Effective immediately, the addition, amendment and/or repeal of any rule or regulation necessary for the implementation of this act on its effective date are authorized to be made and completed on or before such effective date.