

STATE OF NEW YORK

9729

IN ASSEMBLY

April 3, 2024

Introduced by M. of A. McDONALD, FAHY -- read once and referred 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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1 a. maintain records that identify, individually for each prescription
2 or order filled or processed, the name and if applicable, the license or
3 registration number of each pharmacy and individual who took part in the
4 processing or filling of the prescription or order. Such records shall
5 be maintained in accordance with subdivision five of section sixty-eight
6 hundred ten of this article and made available to the department upon
7 request. Records of prescriptions for controlled substances shall be
8 maintained pursuant to the requirements of article thirty-three of the
9 public health law;

10 b. maintain a system for the tracking of each prescription or order
11 during each step of the process including, but not limited to, the name
12 and if applicable, the license and registration number of each pharmacy
13 and individual taking part in the processing or filling of the
14 prescription or order;

15 c. notify the department, in writing, within thirty days of any disci-
16 plinary action taken by another state's regulatory agency involving
17 shared pharmacy services as defined in this article;

18 d. ensure that the labels for all prescriptions filled utilizing
19 shared pharmacy services identify the names and registration numbers of
20 the pharmacies involved in the dispensing and filling of the
21 prescriptions. All labels shall conform to sections sixty-eight hundred
22 twenty-nine and sixty-eight hundred thirty of this article and the regu-
23 lations promulgated thereunder. The labeling of prescriptions for
24 controlled substances shall be subject to additional requirements
25 provided in article thirty-three of the public health law. The
26 provisions of this paragraph shall not apply to hospitals as defined in
27 article twenty-eight of the public health law when furnishing drugs to
28 patients registered for treatment by the hospital;

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

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

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

36 (i) notify patients or the patients' authorized representative that
37 pending their consent, a portion or all of their prescriptions may be
38 processed or filled off premises. Such notification shall be conveyed
39 using conspicuously posted signage at or adjacent to the place in the
40 pharmacy where prescriptions are presented for compounding and dispens-
41 ing, in the waiting area for customers, or the area where prescribed
42 drugs are dispensed. Pharmacies that transact business through the use
43 of the internet shall conspicuously provide such notification on their
44 website; and

45 (ii) obtain an initial onetime consent to fill current and future
46 prescriptions through shared pharmacy services from the patient or
47 patient's authorized representative prior to the dispensing of one or
48 more prescriptions for the patient. For the purposes of this section,
49 such consent shall be obtained in writing or electronically and noted
50 within the patient's medication profile.

51 b. Nothing in this subdivision shall prohibit a patient or the
52 patients' authorized representative from opting out of having the
53 patients' prescription processed or filled via shared pharmacy services
54 at any time.

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

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

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

9 c. Pharmacies participating in shared pharmacy services shall have
10 adequate security that complies with all applicable federal and state
11 statutory and regulatory requirements and protects the confidentiality
12 and integrity of protected patient information.

13 6. Policies and procedures. a. Each pharmacy participating in shared
14 pharmacy services shall jointly develop, implement, review, revise, and
15 comply with joint policies and procedures for shared pharmacy services.
16 Such policies and procedures shall be made available to the department
17 upon request and maintained pursuant to regulations promulgated by the
18 commissioner.

19 b. The policies and procedures shall:

20 (i) outline the responsibilities of each pharmacy;

21 (ii) include a list of the names, addresses, telephone numbers, and
22 all registration numbers of the pharmacies involved in shared pharmacy
23 services; and

24 (iii) include policies and procedures for:

25 (A) notifying the patients or the patients' authorized representative
26 that the patients' prescriptions may be processed or filled off premises
27 and providing the names and registration numbers of the other pharmacies
28 involved in the filling or processing of the prescriptions;

29 (B) protecting the confidentiality and integrity of protected patient
30 information;

31 (C) dispensing a prescription when a prescription filled utilizing
32 shared pharmacy services is not received or the patient comes in before
33 such prescription is received;

34 (D) maintaining a required manual or electronic records to track the
35 prescription or order through each step of the process including, but
36 not limited to, the names and, if applicable, the license or registra-
37 tion numbers of each individual who participated in shared pharmacy
38 services; and

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

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

45 7. Individual practice. For the purpose of shared pharmacy services,
46 persons licensed or otherwise authorized under this article and article
47 one hundred thirty-seven-a of this title, employed by or under contract
48 with a pharmacy, acting within their respective scopes of practice, may
49 access that pharmacy's electronic database from inside or outside the
50 pharmacy and perform prescription or order processing functions, if both
51 of the following requirements are met:

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

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

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

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

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

16 2. Registration. All nonresident establishments that participate in
17 shared pharmacy services for registered pharmacies and/or patients
18 residing in this state or that ship, mail, or deliver prescription drugs
19 and/or devices to other registered establishments, authorized prescri-
20 bers, and/or patients into this state shall be registered with the
21 department; except that such registration shall not apply to intra-com-
22 pany transfers between any division, affiliate, subsidiaries, parent or
23 other entities under complete common ownership and control. The
24 provisions of this subdivision shall apply solely to nonresident estab-
25 lishments and shall not affect any other provision of this article.

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

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