

STATE OF NEW YORK

9047

IN SENATE

October 13, 2020

Introduced by Sen. PERSAUD -- read twice and ordered printed, and when printed to be committed to the Committee on Rules

AN ACT to amend the education law and the public health law, in relation to directing the commissioner of health, in consultation with the commissioner of education, the commissioner of mental health, the state board of pharmacy and the commissioner of corrections and community supervision, to promulgate and implement rules and regulations authorizing the use of automated patient dispensing and storage systems for distribution of prescription and non-prescription drugs and medical devices

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

1 Section 1. Subdivision 1 of section 6808 of the education law, as
2 amended by section 2 of part D of chapter 60 of the laws of 2014, is
3 amended to read as follows:

4 1. No person, firm, corporation or association shall possess drugs,
5 prescriptions or poisons for the purpose of compounding, dispensing,
6 retailing, wholesaling, or manufacturing, or shall offer drugs,
7 prescriptions or poisons for sale at retail or wholesale unless regis-
8 tered by the department as a pharmacy, wholesaler, manufacturer or
9 outsourcing facility; provided, however, that the provisions of this
10 section shall not prohibit the dispensing and/or storage of
11 prescriptions, drugs or medical devices through the use of an automated
12 patient dispensing and storage system as provided in section two hundred
13 eighty-d of the public health law and rules and regulations promulgated
14 pursuant to such section.

15 § 2. The public health law is amended by adding a new section 280-d to
16 read as follows:

17 § 280-d. Automated patient dispensing and storage systems. 1. The
18 commissioner, in consultation with the commissioner of education, the
19 commissioner of mental health, the state board of pharmacy and the
20 commissioner of corrections and community supervision, shall promulgate
21 rules and regulations to authorize the licensing and use of automated
22 patient dispensing and storage systems as provided in this section which
23 shall include, but not be limited to, requiring that the operator of an
24 automated patient dispensing and storage system holds a registration

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

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1 from the federal drug enforcement agency for the distribution of
2 controlled substances.

3 2. Definitions. As used in this section:

4 (a) "Automated drug delivery system" or "ADDS" means a mechanical
5 system that performs operations or activities, other than compounding or
6 administration, relative to the storage, dispensing, or distribution of
7 drugs. An ADDS shall collect, control, and maintain all transaction
8 information to accurately track the movement of drugs into and out of
9 the system for security, accuracy, and accountability.

10 (b) "Automated patient dispensing and storage system" or "APDSS" means
11 an ADDS for storage and dispensing of drugs directly to patients or to
12 medical personnel for prompt administration to patients pursuant to
13 prior authorization by a pharmacist.

14 (c) "Covered entity" means:

15 (i) a "covered entity" as defined in Section 256b of Title 42 of the
16 United States Code; and

17 (ii) a correctional facility as defined in section two of the
18 correction law.

19 (d) "Drug" means a controlled substance as defined in section thirty-
20 three hundred six of the public health law, a non-prescription drug or
21 over-the-counter medication or supply, and/or a medical device.

22 (e) "Patient" means an individual for whom medication has been
23 prescribed by any person authorized to prescribe medication pursuant to
24 article one hundred thirty-one, one hundred thirty-one-b or one hundred
25 forty-one of the education law.

26 3. Pursuant to the rules and regulations authorized by subdivision one
27 of this section, if all of the following conditions are met, a pharmacy
28 located in the state may provide pharmacy services through the use of an
29 automated patient dispensing system to: (i) the patients of a covered
30 entity through an APDSS located on the premises of the covered entity or
31 on the premises of medical professional practices under contract to
32 provide medical services to covered entity patients, which need not be
33 the same location as the pharmacy; and (ii) individual patients as
34 described in subdivision five of this section:

35 (a) The pharmacy obtains a license from the state board of pharmacy to
36 operate the APDSS at the covered entity or an affiliated site, or at or
37 adjacent to the pharmacy, as applicable. As part of the application, the
38 pharmacy shall provide the address at which the APDSS shall be placed
39 and, if the APDSS is to be installed at a covered entity, identify the
40 covered entity. A separate license shall be required for each location
41 and shall be renewed annually concurrent with the pharmacy license. The
42 application and renewal fee shall be three hundred dollars and may be
43 increased to five hundred dollars. The state board of pharmacy is
44 authorized to lower the renewal fee to not less than two hundred dollars
45 if a lower fee level will provide sufficient resources to support the
46 regulatory activities.

47 (b) The pharmacy providing the pharmacy services to the patients of a
48 covered entity, including, unless otherwise prohibited by any other law,
49 patients enrolled in the Medicare and Medicaid programs, shall be under
50 contract with that covered entity to provide those pharmacy services
51 through the use of the APDSS.

52 (c) Drugs stored in an APDSS shall be part of the inventory of the
53 pharmacy providing pharmacy services to the patients and drugs dispensed
54 from the APDSS shall be considered to have been dispensed by that phar-
55 macy.

1 (d) The pharmacy shall maintain records of the acquisition and dispo-
2 sition of drugs stored in the APDSS separate from other pharmacy
3 records.

4 (e) The pharmacy shall be solely responsible for the security, opera-
5 tion, and maintenance of the APDSS; provided, however, that an APDSS
6 installed at a correctional facility shall be deemed to be under the
7 dual security and control of the pharmacy and the correctional facility.

8 (f) The pharmacy shall provide training regarding the operation and
9 use of the APDSS to both pharmacy and covered entity personnel using the
10 system.

11 (g) The operation of the APDSS shall be under the supervision of a
12 pharmacist licensed pursuant to article one hundred thirty-seven of the
13 education law acting on behalf of the pharmacy providing services to the
14 patients of the covered entity. The pharmacist need not be physically
15 present at the site of the APDSS and may supervise the system electron-
16 ically.

17 (h) The state board of pharmacy may issue a license for the operation
18 of an APDSS at an address for which it has issued another site license,
19 including but not limited to drive-through pharmacy areas and other
20 areas adjacent to the physical location occupied by a pharmacy.

21 (i) The state board of pharmacy, within thirty days after receipt of
22 an application for an APDSS license, shall conduct a pre-licensure
23 inspection at the proposed location of the APDSS. Relocation of the
24 APDSS shall require a new application for licensure. Replacement of an
25 APDSS shall require notice to such board within thirty days.

26 (j) The APDSS license shall be canceled by operation of law if the
27 underlying pharmacy license is not current, valid, and active. Upon
28 reissuance or reinstatement of the underlying pharmacy license, a new
29 application for an APDSS license shall be submitted to the state board
30 of pharmacy, if so required by such board.

31 (k) A pharmacy that holds an APDSS license shall advise the state
32 board of pharmacy in writing within thirty days if use of the APDSS is
33 discontinued.

34 4. (a) An automated patient dispensing and storage system shall
35 collect, control, and maintain all transaction information to accurately
36 track the movement of drugs into and out of the system for security,
37 accuracy, and accountability.

38 (b) Transaction information shall be made readily available in a down-
39 loadable format for review and inspection by individuals authorized by
40 law to review such information. These records shall be maintained by the
41 pharmacy for a minimum of three years.

42 5. Drugs from an automated patient dispensing and storage system may
43 be dispensed directly to a patient from a drive-through pharmacy aisle
44 or other location adjacent to the physical location occupied by the
45 pharmacy, if all of the following requirements are met:

46 (a) The pharmacy develops, implements, and annually reviews written
47 policies and procedures with respect to all of the following:

48 (i) the pharmacy maintains the security of the APDSS and the drugs
49 within that APDSS;

50 (ii) the pharmacy determines and applies inclusion criteria regarding
51 which drugs are appropriate for placement in the APDSS and for which
52 patients;

53 (iii) the pharmacy ensures that patients are aware that consultation
54 with a pharmacist is available for any prescription medication, includ-
55 ing those delivered via the APDSS;

1 (iv) the pharmacy describes the assignment of responsibilities to, and
2 training of, pharmacy personnel, and other personnel using the APDSS at
3 the location where the APDSS is placed, regarding maintenance and fill-
4 ing procedures for the APDSS;

5 (v) the pharmacy orients participating patients on the use of the
6 APDSS, notifying patients when expected prescription medications are not
7 available in the APDSS, and ensuring that patient use of the APDSS does
8 not interfere with delivery of drugs; and

9 (vi) the pharmacy ensures delivery of drugs to patients expecting to
10 receive them from the APDSS in the event the automated patient dispens-
11 ing and storage system is disabled or malfunctions.

12 (b) The automated patient dispensing and storage system shall only be
13 used for patients who have signed a written consent demonstrating their
14 informed consent to receive prescribed drugs from an APDSS and whose use
15 of the APDSS meet the criteria pursuant to paragraph a of this subdivi-
16 sion.

17 (c) The automated patient dispensing and storage system shall have a
18 means to identify each patient and only release the identified patient's
19 drugs to the patient or the patient's agent.

20 (d) A pharmacist shall perform all clinical services conducted as part
21 of the dispensing process, including, but not limited to, drug utiliza-
22 tion review and consultation.

23 (e) Drugs shall be dispensed from the automated patient dispensing and
24 storage system only upon authorization from a pharmacist after the phar-
25 macist has reviewed the prescription and the patient's profile for
26 potential contraindicated and adverse drug reactions.

27 (f) All drugs dispensed from the automated patient dispensing and
28 storage system for the first time shall be accompanied by a consultation
29 conducted by a pharmacist licensed pursuant to article one hundred thir-
30 ty-seven of the education law in one of the following manners: (i) in
31 person; (ii) through a drive-through prescription dispensing window;
32 (iii) via a telecommunications link that has two-way audio and video; or
33 (iv) through a telephone call between the pharmacist and the patient or
34 the patient's appointed representative with the prescribing physician
35 present for the duration of the call.

36 (g) The automated patient dispensing and storage system shall include
37 a notice, prominently posted on the automated patient dispensing and
38 storage system, that provides the name, address, and telephone number of
39 the pharmacy that holds the automated patient dispensing and storage
40 system license for that APDSS.

41 (h) The labels on all drugs dispensed by the automated patient
42 dispensing and storage system shall comply with all New York state and
43 federal requirements for labelling of drugs prescribed and dispensed in
44 this state.

45 (i) Any complaint, error, or omission involving the automated patient
46 dispensing and storage system shall be reviewed as part of the pharma-
47 cy's quality assurance program.

48 (j) The state board of pharmacy shall not issue a pharmacy more than
49 fifteen licenses for automated patient dispensing and storage system
50 units under this section. The state board of pharmacy may adopt regu-
51 lations to reduce the number of APDSS licenses that may be issued to a
52 pharmacy.

53 (k) The pharmacy holding the license for the automated patient
54 dispensing and storage system shall maintain the policies and procedures
55 developed pursuant to paragraph a of this subdivision for three years
56 after the last date of use of that APDSS.

6. Access to the automated patient dispensing and storage system shall be controlled and tracked using an identification or password system or biosensor. A system that is accessed via a password system shall include a camera that records a picture of the individual accessing the machine. Picture records shall be maintained for a minimum of one hundred eighty days.

7. The automated patient dispensing and storage system shall make a complete and accurate record of all transactions that will include all users accessing the APDSS and all drugs added to, or removed from, the APDSS.

8. The stocking of an automated patient dispensing and storage system shall be performed by a pharmacist. If the APDSS utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers as defined by the United States Pharmacopeia, the stocking system may be done outside of the APDSS and be delivered to the facility if all of the following conditions are met:

(a) The task of placing drugs into the removable pockets, cards, drawers, similar technology, or unit of use or single dose containers is performed by a pharmacist, or by an intern pharmacist or a pharmacy technician working under the direct supervision of a pharmacist licensed pursuant to article one hundred thirty-seven of the education law.

(b) The removable pockets, cards, drawers, similar technology, or unit of use or single dose containers are transported between the pharmacy and the APDSS in a secure tamper-evidence container.

(c) The pharmacy, in conjunction with the covered entity, has developed policies and procedures to ensure that the removable pockets, cards, drawers, similar technology, or unit of use or single dose containers are properly placed into the automated patient dispensing and storage system.

9. Review of the drugs contained within, and the operation and maintenance of, the automated patient dispensing and storage system shall be done in accordance with law and shall be the responsibility of the pharmacy. The review shall be conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the APDSS, an inspection of the APDSS machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the APDSS.

10. A pharmacy holding an automated patient dispensing and storage system license shall complete an annual self-assessment, performed pursuant to rules and regulations promulgated pursuant to this section, evaluating the pharmacy's compliance with the education law relating to the use of the automated patient dispensing and storage system. All information regarding operation, maintenance, compliance, error, omissions, or complaints pertaining to the APDSS shall be included in the self-assessment.

11. The pharmacy shall comply with all recordkeeping and quality assurance requirements pursuant to this section and article one hundred thirty-seven of the education law and shall maintain those records within the pharmacy holding the APDSS license and separately from other pharmacy records.

12. Rules and regulations providing for the implementation of the provisions of this section within the facilities of all covered entities shall be implemented within three hundred sixty-five days of the effective date of this section.

§ 3. This act shall take effect immediately.