

STATE OF NEW YORK

6349

2021-2022 Regular Sessions

IN ASSEMBLY

March 16, 2021

Introduced by M. of A. SOLAGES -- read once and referred to the Committee on Higher Education

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, and the state board of pharmacy, 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 directly to patients at certain pharmacy locations

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

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

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

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

§ 280-d. Automated patient dispensing and storage systems at pharmacies. 1. The commissioner, in consultation with the commissioner of education, the commissioner of mental health, and the state board of

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

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1 pharmacy, shall promulgate rules and regulations to authorize the
2 licensing and use of automated patient dispensing and storage systems as
3 provided in this section which shall include, but not be limited to,
4 requiring that the operator of an automated patient dispensing and stor-
5 age system holds a registration from the federal drug enforcement agency
6 for the distribution of controlled substances.

7 2. Definitions. As used in this section:

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

14 (b) "Automated patient dispensing and storage system" or "APDSS" means
15 an ADDSS for storage and dispensing of drugs directly to patients pursu-
16 ant to prior authorization by a pharmacist.

17 (c) "Drug" means a prescription drug, a non-prescription drug or over-
18 the-counter medication or supply, and/or a medical device.

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

23 (e) "Pharmacy" means a pharmacy which holds a registration from the
24 federal drug enforcement agency for the distribution of controlled
25 substances.

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 individual patients as described
30 in subdivision five of this section:

31 (a) The pharmacy obtains a license from the state board of pharmacy to
32 operate the APDSS at or adjacent to the pharmacy, as applicable. As part
33 of the application, the pharmacy shall provide the address at which the
34 APDSS shall be placed. A separate license shall be required for each
35 location and shall be renewed annually concurrent with the pharmacy
36 license. The application and renewal fee shall be three hundred dollars
37 and may be increased to five hundred dollars. The state board of phar-
38 macy is authorized to lower the renewal fee to not less than two hundred
39 dollars if a lower fee level will provide sufficient resources to
40 support the regulatory activities.

41 (b) Drugs stored in an APDSS shall be part of the inventory of the
42 pharmacy providing pharmacy services to patients and drugs dispensed
43 from the APDSS shall be considered to have been dispensed by that phar-
44 macy.

45 (c) The pharmacy shall maintain records of the acquisition and dispo-
46 sition of drugs stored in the APDSS separate from other pharmacy
47 records.

48 (d) The pharmacy shall be solely responsible for the security, opera-
49 tion, and maintenance of the APDSS.

50 (e) The pharmacy shall provide training regarding the operation and
51 use of the APDSS to pharmacy personnel using the system.

52 (f) The operation of the APDSS shall be under the supervision of a
53 pharmacist licensed pursuant to article one hundred thirty-seven of the
54 education law acting on behalf of the pharmacy. The pharmacist need not
55 be physically present at the site of the APDSS and may supervise the
56 system electronically.

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

5 (h) The state board of pharmacy, within thirty days after receipt of
6 an application for an APDSS license, shall conduct a pre-licensure
7 inspection at the proposed location of the APDSS. Relocation of the
8 APDSS shall require a new application for licensure. Replacement of an
9 APDSS shall require notice to such board within thirty days.

10 (i) The APDSS license shall be canceled by operation of law if the
11 underlying pharmacy license is not current, valid, and active. Upon
12 reissuance or reinstatement of the underlying pharmacy license, a new
13 application for an APDSS license shall be submitted to the state board
14 of pharmacy, if so required by such board.

15 (j) A pharmacy that holds an APDSS license shall advise the state
16 board of pharmacy in writing within thirty days if use of the APDSS is
17 discontinued.

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

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

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

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

32 (i) the pharmacy maintains the security of the APDSS and the drugs
33 within that APDSS;

34 (ii) the pharmacy determines and applies inclusion criteria regarding
35 which drugs are appropriate for placement in the APDSS and for which
36 patients;

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

40 (iv) the pharmacy describes the assignment of responsibilities to, and
41 training of pharmacy personnel regarding maintenance and filling proce-
42 dures for the APDSS;

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

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

50 (b) The automated patient dispensing and storage system shall only be
51 used for patients who have signed a written consent demonstrating their
52 informed consent to receive prescribed drugs from an APDSS and whose use
53 of the APDSS meet the criteria pursuant to paragraph (a) of this subdi-
54 vision.

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

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

7 (e) Drugs shall be dispensed from the automated patient dispensing and
8 storage system only upon authorization from a pharmacist after the phar-
9 macist has reviewed the prescription and the patient's profile for
10 potential contraindications and adverse drug reactions.

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

20 (g) The automated patient dispensing and storage system shall include
21 a notice, prominently posted on the automated patient dispensing and
22 storage system, that provides the name, address, and telephone number of
23 the pharmacy that holds the automated patient dispensing and storage
24 system license for that APDSS.

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

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

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

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

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

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

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

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

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

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

14 9. Review of the drugs contained within, and the operation and mainte-
15 nance of, the automated patient dispensing and storage system shall be
16 done in accordance with law and shall be the responsibility of the phar-
17 macy. The review shall be conducted on a monthly basis by a pharmacist
18 and shall include a physical inspection of the drugs in the APDSS, an
19 inspection of the APDSS machine for cleanliness, and a review of all
20 transaction records in order to verify the security and accountability
21 of the APDSS.

22 10. A pharmacy holding an automated patient dispensing and storage
23 system license shall complete an annual self-assessment, performed
24 pursuant to rules and regulations promulgated pursuant to this section,
25 evaluating the pharmacy's compliance with the education law and all
26 applicable rules and regulations relating to the use of the automated
27 patient dispensing and storage system. All information regarding opera-
28 tion, maintenance, compliance, error, omissions, or complaints pertain-
29 ing to the APDSS shall be included in the self-assessment.

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

35 12. Rules and regulations providing for the implementation of the
36 provisions of this section shall be implemented within three hundred
37 sixty-five days of the effective date of this section.

38 § 3. This act shall take effect immediately.