

STATE OF NEW YORK

5640

2021-2022 Regular Sessions

IN ASSEMBLY

February 22, 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, 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:

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. 1. The commissioner, in consultation with the commissioner of education, the commissioner of mental health, the state board of pharmacy and the

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

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

8 2. Definitions. As used in this section:

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

15 (b) "Automated patient dispensing and storage system" or "APDSS" means
16 an ADDs for storage and dispensing of drugs directly to patients or to
17 medical personnel for prompt administration to patients pursuant to
18 prior authorization by a pharmacist.

19 (c) "Covered entity" means:

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

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

24 (d) "Drug" means a controlled substance as defined in section thirty-
25 three hundred six of this chapter, a non-prescription drug or over-the-
26 counter medication or supply, and/or a medical device.

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

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

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

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

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

5 (d) The pharmacy shall maintain records of the acquisition and dispo-
6 sition of drugs stored in the APDSS separate from other pharmacy
7 records.

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

12 (f) The pharmacy shall provide training regarding the operation and
13 use of the APDSS to both pharmacy and covered entity personnel using the
14 system.

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

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

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

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

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

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

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

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

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

52 (i) the pharmacy maintains the security of the APDSS and the drugs
53 within that APDSS;

54 (ii) the pharmacy determines and applies inclusion criteria regarding
55 which drugs are appropriate for placement in the APDSS and for which
56 patients;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

34 9. Review of the drugs contained within, and the operation and mainte-
35 nance of, the automated patient dispensing and storage system shall be
36 done in accordance with law and shall be the responsibility of the phar-
37 macy. The review shall be conducted on a monthly basis by a pharmacist
38 and shall include a physical inspection of the drugs in the APDSS, an
39 inspection of the APDSS machine for cleanliness, and a review of all
40 transaction records in order to verify the security and accountability
41 of the APDSS.

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

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

55 12. Rules and regulations providing for the implementation of the
56 provisions of this section within the facilities of all covered entities

1 shall be implemented within three hundred sixty-five days of the effec-
2 tive date of this section.

3 § 3. This act shall take effect immediately.