

STATE OF NEW YORK

6332

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, 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 at certain facilities

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, and the state board of pharmacy, shall

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

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1 promulgate rules and regulations to authorize the licensing and use of
2 automated patient dispensing and storage systems as provided in this
3 section which shall include, but not be limited to, requiring that the
4 operator of an automated patient dispensing and storage system holds a
5 registration from the federal drug enforcement agency for the distrib-
6 ution 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 to medical personnel for
16 prompt administration to patients pursuant to prior authorization by a
17 pharmacist.

18 (c) "Covered entity" means a covered entity as defined in Section 256b
19 of Title 42 of the United States Code.

20 (d) "Drug" means a prescription drug, a non-prescription drug or over-
21 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 (f) "Pharmacy" means a pharmacy which holds a registration from the
27 federal drug enforcement agency for the distribution of controlled
28 substances.

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

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

47 (b) The pharmacy providing the pharmacy services to 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 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.

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

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

15 (h) The state board of pharmacy may issue a license for the operation
16 of an APDSS at an address for which it has issued another site license.

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

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

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

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

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

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

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

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

54 (a) The task of placing drugs into the removable pockets, cards, draw-
55 ers, similar technology, or unit of use or single dose containers is
56 performed by a pharmacist, or by an intern pharmacist or a pharmacy

1 technician working under the direct supervision of a pharmacist licensed
2 pursuant to article one hundred thirty-seven of the education law.

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

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

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

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

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

32 11. Rules and regulations providing for the implementation of the
33 provisions of this section within the facilities of all covered entities
34 shall be implemented within three hundred sixty-five days of the effec-
35 tive date of this section.

36 § 3. This act shall take effect immediately.