

STATE OF NEW YORK

5639

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 corrections and community supervision, in consultation with the commissioner of health, 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 in correctional facilities

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; use in correctional facilities. 1. The commissioner of corrections and community supervision, in consultation with the commissioner of health, the

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

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

19 (c) "Correctional facility" means a correctional facility as defined in
20 section two of the correction law.

21 (d) "Drug" means a prescription drug, a non-prescription drug or over-
22 the-counter medication or supply, and/or a medical device.

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

27 (f) "Pharmacy" means a pharmacy which holds a registration from the
28 federal drug enforcement agency for the distribution of controlled
29 substances.

30 3. Pursuant to the rules and regulations authorized by subdivision one
31 of this section, if all of the following conditions are met, a pharmacy
32 located in the state may provide pharmacy services through the use of an
33 automated patient dispensing system for use by medical personnel for the
34 administration of drugs to patients confined to a correctional facility
35 through an APDSS located on the premises of the correctional facility:

36 (a) The pharmacy obtains a license from the state board of pharmacy to
37 operate the APDSS at the correctional facility. As part of the applica-
38 tion, the pharmacy shall provide the address at which the APDSS shall be
39 placed and identify the correctional facility. A separate license shall
40 be required for each location and shall be renewed annually concurrent
41 with the pharmacy license. The application and renewal fee shall be
42 three hundred dollars and may be increased to five hundred dollars. The
43 state board of pharmacy is authorized to lower the renewal fee to not
44 less than two hundred dollars if a lower fee level will provide suffi-
45 cient resources to support the regulatory activities.

46 (b) The pharmacy providing the pharmacy services to the patients
47 confined to a correctional facility, including, unless otherwise prohib-
48 ited by any other law, patients enrolled in the Medicare and Medicaid
49 programs, shall be under contract with that correctional facility to
50 provide those pharmacy services through the use of the APDSS.

51 (c) Drugs stored in an APDSS shall be part of the inventory of the
52 pharmacy providing pharmacy services to the patients and drugs dispensed
53 from the APDSS shall be considered to have been dispensed by that phar-
54 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 operation and
5 maintenance of the APDSS. The APDSS shall be deemed to be under the dual
6 security of the pharmacy and the correctional facility.

7 (f) The pharmacy shall provide training regarding the operation and
8 use of the APDSS to both pharmacy and correctional facility personnel
9 using the system.

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

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

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

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

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

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

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

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

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

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

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

1 performed by a pharmacist, or by an intern pharmacist or a pharmacy
2 technician working under the direct supervision of a pharmacist licensed
3 pursuant to article one hundred thirty-seven of the education law.

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

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

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

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

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

35 11. Rules and regulations providing for the implementation of the
36 provisions of this section within correctional facilities shall be
37 implemented by the department of corrections and community supervision
38 within three hundred sixty-five days of the effective date of this
39 section.

40 § 3. This act shall take effect immediately.