

STATE OF NEW YORK

9051

IN SENATE

October 14, 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 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:

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; use in
18 correctional facilities. 1. The commissioner of corrections and communi-
19 ty supervision, in consultation with the commissioner of health, the
20 commissioner of education, the commissioner of mental health, and the
21 state board of pharmacy, shall promulgate rules and regulations to
22 authorize the licensing and use of automated patient dispensing and

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

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1 storage systems as provided in this section which shall include, but not
2 be limited to, requiring that the operator of an automated patient
3 dispensing and storage system holds a registration from the federal drug
4 enforcement agency for the distribution of controlled substances.

5 2. Definitions. As used in this section:

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

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

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

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

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

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

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

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

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

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

52 (d) The pharmacy shall maintain records of the acquisition and dispo-
53 sition of drugs stored in the APDSS separate from other pharmacy
54 records.

1 (e) The pharmacy shall be solely responsible for the operation and
2 maintenance of the APDSS. The APDSS shall be deemed to be under the dual
3 security of the pharmacy and the correctional facility.

4 (f) The pharmacy shall provide training regarding the operation and
5 use of the APDSS to both pharmacy and correctional facility personnel
6 using the system.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

37 § 3. This act shall take effect immediately.