

# STATE OF NEW YORK

4102--A

Cal. No. 581

2021-2022 Regular Sessions

## IN SENATE

February 2, 2021

Introduced by Sens. SAVINO, MARTUCCI -- read twice and ordered printed, and when printed to be committed to the Committee on Health -- reported favorably from said committee, ordered to first and second report, ordered to a third reading, amended and ordered reprinted, retaining its place in the order of third reading

AN ACT to amend the education law, in relation to the automated storage and dispensing of controlled substances using an automated dispensing device

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

Section 1. Section 6802 of the education law is amended by adding a new subdivision 29 to read as follows:

29. "Automated dispensing device (ADD)" shall mean a mechanical system used in nursing homes and residential health care facilities licensed pursuant to article twenty-eight of the public health law and hospices certified pursuant to article forty of the public health law, that packages and labels patient specific medication or multiple medications for the purposes of administration by a health care professional licensed to administer medications by the state of New York based on a prescription or order that has completed final verification by a licensed pharmacist.

§ 2. The education law is amended by adding a new section 6809 to read as follows:

§ 6809. Automated storage and dispensing of medications. 1. For purposes of this section, "automated dispensing device (ADD)" shall have the same meaning as subdivision twenty-nine of section sixty-eight hundred two of this article.

2. The ADD and its contents shall remain the property of a pharmacy registered under this article. The pharmacy shall maintain all controls, record keeping as required by all laws, rules and regulations of the state. Pharmacies utilizing automated dispensing devices as permitted under this section for routine medication dispensing of

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

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1 controlled substances shall obtain a machine-specific federal Drug  
2 Enforcement Administration (DEA-ADD) registration number, and the appro-  
3 appropriate New York state licensing.

4 3. The pharmacy shall maintain records on site at the pharmacy (hard  
5 copy or electronic) for not less than five years as required by part  
6 sixty-three of the regulations of the commissioner, including but not  
7 limited to:

8 a. documentation of the approval for use and placement of the ADD  
9 received from the department and/or the board of pharmacy;

10 b. delivery manifests or similar electronic documentation that moni-  
11 tors the transport of controlled substances between the pharmacy and  
12 ADD;

13 c. ADD cleaning and maintenance logs or similar documentation;

14 d. records and/or electronic data of all events involving the ADD  
15 including but not limited to:

16 (i) identity of all personnel who access the contents;

17 (ii) location of the system accessed;

18 (iii) type of transaction with date/time stamp;

19 (iv) name, strength, dosage form, and quantity of the accessed medica-  
20 tion;

21 (v) name or other identifier of the patient for whom the medication  
22 was ordered;

23 (vi) reconciliation of all controlled substance inventories at least  
24 monthly.

25 4. The prepackaged cartridges or containers may be sent to a remote  
26 site to be loaded into such machine by personnel designated by the phar-  
27 macist-in-charge provided:

28 a. the individual cartridges or containers are transported to such  
29 remote site in a secure, tamper-evident container; and

30 b. the automated pharmacy system uses bar-coding, microchip, or other  
31 technologies to ensure that the containers are accurately loaded in the  
32 automated pharmacy system.

33 5. Access to an ADD shall be restricted to authorized pharmacy and  
34 facility nursing licensed personnel, registered pharmacy technicians,  
35 and pharmacy aides as established by the facility administration in  
36 conjunction with the pharmacist-in-charge. A list of such authorized  
37 personnel shall be maintained at all times within the system and shall  
38 be reviewed and updated periodically.

39 6. All medications, including controlled substances shall be dispensed  
40 from an automated dispensing device pursuant to a valid, patient-specif-  
41 ic prescription or order.

42 7. The pharmacy and the facility shall implement and maintain  
43 adequate and appropriate policies, procedures and quality assurance  
44 programs to ensure safety, accuracy, security, accountability, patient  
45 confidentiality, and functionality with respect to administration and  
46 usage of ADD.

47 8. The ADD will be monitored at the facility continuously by video and  
48 under visual supervision by a pharmacist during the loading process.

49 9. Any losses of medication shall be reported in accordance with the  
50 requirements of the servicing pharmacy's licensing body.

51 § 3. This act shall take effect on the sixtieth day after it shall  
52 have become a law.