STATE OF NEW YORK

5512--A

2021-2022 Regular Sessions

IN ASSEMBLY

February 19, 2021

Introduced by M. of A. DINOWITZ -- read once and referred to the Committee on Higher Education -- again reported from said committee with amendments, ordered reprinted as amended and recommitted to said committee

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 controlled substances shall obtain a machine-specific federal Drug

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

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Enforcement Administration (DEA-ADD) registration number, and the appropriate New York state licensing.

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

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

b. delivery manifests or similar electronic documentation that monitors the transport of controlled substances between the pharmacy and ADD;

c. ADD cleaning and maintenance logs or similar documentation;

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

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

(ii) location of the system accessed;

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

(iv) name, strength, dosage form, and quantity of the accessed medication;

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

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

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

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

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

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

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

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

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

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

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