STATE OF NEW YORK

10784

IN ASSEMBLY

July 10, 2020

Introduced by COMMITTEE ON RULES -- (at request of M. of A. Dinowitz) -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 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 2 new subdivision 29 to read as follows:

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- 29. "Automated dispensing device (ADD)" shall mean a mechanical system 4 designed for use in health care facilities allowing for computer-controlled storage, packaging and dispensing of drugs and devices to licensed health care professionals near the point of care.
 - § 2. The public health law is amended by adding a new section 280-d to read as follows:
- 9 § 280-d. Automated storage and dispensing of controlled substances. 1. 10 For purposes of this section, "automated dispensing device (ADD)" shall mean a mechanical system designed for use in health care facilities 12 allowing for computer-controlled storage, packaging and dispensing of drugs and devices to licensed health care professionals near the point 13 14 of care.
- 15 2. Notwithstanding any provision of law, rule or regulation to the 16 contrary, licensed health care facilities throughout the state shall be permitted to use automated dispensing devices to store, package and 17 dispense medications, including controlled substances, as authorized by 18 19 such facility's licensing body.
 - 3. The ADD and its contents shall remain the property of the pharmacy.
- 21 4. Licensed health care facilities shall implement and maintain 22 adequate and appropriate policies, procedures and quality assurance programs to ensure safety, accuracy, security, accountability, patient 23 24 confidentiality and functionally with respect to the administration and usage of automated dispensing devices. 25
- 26 5. Access to an automated dispensing device within a licensed health 27 care facility shall be restricted to authorized licensed personnel, and

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

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- 1 <u>a list of such authorized personnel shall be maintained at all times</u>
 2 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 servicing pharmacy shall maintain records on-site for a period of not less than five years with respect to the use of automated dispensing devices. Such records shall include:
- 9 <u>(a) documentation of the approval for use and placement of an auto-</u>
 10 <u>mated dispensing device by such licensed health care facility from such</u>
 11 <u>facility's licensing body, if applicable;</u>
- 12 (b) the location of all automated dispensing devices being used at such facility;
- 14 (c) delivery manifests or similar electronic documentation which moni-15 tors the transport of controlled substances between the servicing phar-16 macy and the automated dispensing device;
- 17 <u>(d) automated dispensing device maintenance and cleaning logs, or</u> 18 <u>similar documentation;</u>
- 19 <u>(e) documentation or electronic data of all events involving an auto-</u>
 20 <u>mated dispensing device, including, but not limited to:</u>
- 21 (i) the identity of personnel who have accessed the contents of such 22 device;
 - (ii) the location of the device accessed;
- 24 (iii) the type of transaction, including a date and time stamp;
- 25 <u>(iv) the name, strength, dosage form and quantity of an accessed prod-</u>
 26 <u>uct;</u>
- 27 <u>(v) the name or other identifier of the patient for whom the</u> 28 <u>controlled substance was ordered; and</u>
- 29 (vi) reconciliation of all inventory activities.
- 8. Any losses of medication shall be reported in accordance with the requirements of the servicing pharmacy's licensing body.
- 9. Servicing pharmacies utilizing automated dispensing devices in licensed health care facilities for routine medication dispensing, for emergency medication kits or other similar approved use, shall be loaded by either a:
 - (a) pharmacy technician, pharmacy intern, or pharmacist; or
 - (b) licensed nurse.
- 10. Servicing pharmacies utilizing automated dispensing devices in licensed health care facilities for routine medication dispensing of controlled substances shall obtain a machine-specific federal Drug Enforcement Agency (DEA) registration number, and appropriate New York state licensing.
- 43 <u>11. Servicing pharmacies utilizing automated dispensing devices in</u> 44 <u>licensed health care facilities for routine medication dispensing shall</u> 45 <u>ensure that such device is continually monitored by video.</u>
 - § 3. This act shall take effect immediately.