LEGISLATURE OF NEBRASKA

ONE HUNDREDTH LEGISLATURE

FIRST SESSION

LEGISLATIVE BILL 308

Introduced by Stuthman, 22

Read first time January 11, 2007

Committee: Health and Human Services

A BILL

1 FOR AN A	ACT relating to pharmacy; to amend section 71-1,143.03,
2	Reissue Revised Statutes of Nebraska; to adopt the
3	Automated Medication System Act; to provide a penalty;
4	to harmonize provisions; to change and eliminate
5	restrictions on drug vending machines; to repeal the
6	original section; and to outright repeal sections
7	71-1,147.15 and 71-1,147.16, Revised Statutes Cumulative
8	Supplement, 2006.

9 Be it enacted by the people of the State of Nebraska,

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LB 308 LB 308 Section 1. Sections 1 to 14 of this act shall be known 1 2 and may be cited as the Automated Medication System Act. 3 Sec. 2. For purposes of the Automated Medication System 4 Act: 5 (1) Assisted living facility has the definition found in 6 section 71-406; 7 (2) Automated distribution machine means a type 8 of automated medication system that holds medication to be 9 administered by a person credentialed under the Uniform Licensing 10 Law to a patient; 11 (3) Automated medication system includes, but is not 12 limited to, prescription software or a mechanical system that 13 performs operations or activities, other than compounding or 14 administration, relative to storage and packaging for dispensing 15 or distribution of medications and that collects, controls, and maintains all transaction information. Automated medication system 16 17 does not include a medication vending machine or a medication 18 <u>kiosk;</u> 19 (4) Coordinating pharmacy means a licensed pharmacy which 20 is responsible for the practice of telepharmacy performed at 21 satellite pharmacies; (5) Intermediate care facility has the definition found 22 in section 71-420; 23 24 (6) Hospital has the definition found in section 71-419;

25 (7) Long-term care hospital has the definition found

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1	in section 71-422. Long-term care hospital does not include an
2	assisted living facility;
3	(8) Medical order has the definition found in section
4	<u>71-1,142;</u>
5	(9) Nursing facility has the definition found in section
6	<u>71-424;</u>
7	(10) Pharmacist care means the provision by a pharmacist
8	of medication therapy management, with or without the dispensing of
9	drugs or devices, intended to achieve outcomes related to the cure
10	or prevention of a disease, elimination or reduction of a patient's
11	symptoms, or arresting or slowing of a disease process;
12	(11) Pharmacist in charge has the definition found in
13	<u>section 71-1,142;</u>
13 14	<u>section 71-1,142;</u> (12) Pharmacist intern has the definition found in
14	(12) Pharmacist intern has the definition found in
14 15	(12) Pharmacist intern has the definition found in section 71-1,142;
14 15 16	(12) Pharmacist intern has the definition found in section 71-1,142; (13) Pharmacist remote order entry means the provision of
14 15 16 17	(12) Pharmacist intern has the definition found in section 71-1,142; (13) Pharmacist remote order entry means the provision of medication order review services or computer order entry services
14 15 16 17 18	(12) Pharmacist intern has the definition found in section 71-1,142; (13) Pharmacist remote order entry means the provision of medication order review services or computer order entry services by pharmacists licensed under the Uniform Licensing Law, pursuant
14 15 16 17 18 19	<pre>(12) Pharmacist intern has the definition found in section 71-1,142; (13) Pharmacist remote order entry means the provision of medication order review services or computer order entry services by pharmacists licensed under the Uniform Licensing Law, pursuant to medical orders in a hospital, pharmacy, long-term care hospital,</pre>
14 15 16 17 18 19 20	(12) Pharmacist intern has the definition found in section 71-1,142; (13) Pharmacist remote order entry means the provision of medication order review services or computer order entry services by pharmacists licensed under the Uniform Licensing Law, pursuant to medical orders in a hospital, pharmacy, long-term care hospital, nursing facility or skilled nursing facility licensed under the
14 15 16 17 18 19 20 21	(12) Pharmacist intern has the definition found in section 71-1,142; (13) Pharmacist remote order entry means the provision of medication order review services or computer order entry services by pharmacists licensed under the Uniform Licensing Law, pursuant to medical orders in a hospital, pharmacy, long-term care hospital, nursing facility or skilled nursing facility licensed under the Health Care Facility Licensure Act;
14 15 16 17 18 19 20 21 21 22	(12) Pharmacist intern has the definition found in section 71-1,142; (13) Pharmacist remote order entry means the provision of medication order review services or computer order entry services by pharmacists licensed under the Uniform Licensing Law, pursuant to medical orders in a hospital, pharmacy, long-term care hospital, nursing facility or skilled nursing facility licensed under the Health Care Facility Licensure Act; (14) Pharmacy technician has the definition found in

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(16) Prescription dispensing machine means a type of 1 2 automated medication system that is used to package, label, or 3 count medication to prepare for dispensing by a pharmacist; 4 (17) Repackaging machine means a type of automated 5 medication system that is used to repackage and label medications 6 from bulk to unit dose packages; 7 (18) Satellite pharmacy means a pharmacy staffed by a 8 pharmacist or pharmacy technician, which pharmacy is electronically 9 linked to a coordinating pharmacy via a computer system with a real-time online data base and a video and auditory communication 10 11 system; 12 (19) Skilled nursing facility has the definition found in 13 section 71-429; and 14 (20) Telepharmacy means the provision of pharmacist care, 15 by a pharmacist licensed under the Uniform Licensing Law and 16 located within the United States, which is accomplished through the use of telecommunications or other technologies to patients 17 18 or their agents who are at a distance and are located within the 19 United States and which follows all federal and state laws, rules, 20 and regulations with regard to privacy and security. 21 Sec. 3. (1) All events involving the contents of an 22 automated medication system shall be stored in a secure location 23 and may be recorded electronically. 24 (2) An automated medication system shall only be utilized

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25 in health care facilities licensed under the Health Care Facility

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Licensure Act and only in settings where there is an established 1 2 program of pharmacist care. 3 (3) An automated medication system may be utilized in conjunction with telepharmacy. 4 5 (4) Medication vending machines and medication kiosks are 6 prohibited under the Automated Medication System Act. 7 Sec. 4. Medications in an automated distribution machine 8 shall be stocked by a pharmacist, pharmacy technician, or 9 pharmacist intern. 10 Sec. 5. A pharmacist in charge shall be responsible 11 for the following activities relating to an automated medication 12 system: 13 (1) Implementing an ongoing quality assurance program; 14 (2) Establishing and ensuring compliance with all 15 policies and procedures relating to automated medication systems; 16 (3) Ensuring that access to medications, including, but 17 not limited to, access to controlled substances, complies with 18 state and federal laws, rules, and regulations; 19 (4) Ensuring that the automated medication system is 20 filled or stocked accurately and in accordance with established 21 policies and procedures; 22 (5) Ensuring that the automated medication system is in good working order and performs its designated tasks, including 23 24 ensuring that the correct strength, dosage, and quantity of 25 the prescribed medication are packaged, labeled, and dispensed

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correctly; (6) Ensuring that the automated medication system has adequate security safeguards relating to medication access and information access; and (7) Ensuring that all personnel utilizing or accessing the automated medication system have been appropriately trained. Sec. 6. Written policies and procedures for operation of an automated medication system shall address, at a minimum: (1) Operation of the automated medication system, including policies and procedures relating to access to the automated medication system that comply with state and federal laws, rules, and regulations; (2) Prevention of unauthorized access; (3) Maintenance of patient confidentiality; (4) Quality assurance procedures; (5) Procedures that will be followed if the automated medication system is unavailable at any time; and (6) Record-keeping procedures. Sec. 7. The stocking of all medications in a prescription dispensing machine or a repackaging machine shall be performed by a pharmacist, a pharmacy technician, or a pharmacist intern. If

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23 <u>stocking shall be verified by a pharmacist. An electronic or paper</u>
24 <u>record of medications stocked in a prescription dispensing machine</u>
25 or a repackaging machine shall be maintained for a period of five

performed by a pharmacy technician or a pharmacist intern, the

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1	years and shall include identification of the person stocking and
2	verifying the stocking of the prescription dispensing machine or
3	repackaging machine.
4	Sec. 8. <u>A pharmacy or hospital may use an automated</u>
5	medication system if the pharmacy or hospital develops and
6	maintains a policy and procedure manual that includes compliance
7	with a quality assurance program. An ongoing quality assurance
8	program shall be developed and implemented that monitors
9	performance of the system. The program shall be evidenced by
10	written policies and procedures developed by the pharmacist in
11	charge and include the following:
12	(1) The methods of ensuring accurate packaging and
13	loading of the automated medication system;
14	(2) Procedures for conducting quality control checks of
15	final dispensing for accuracy; and
16	(3) Manufacturers' schedules and recommendations for
17	maintenance of the automated medication system.
18	Sec. 9. <u>A pharmacist providing pharmacist remote order</u>
19	entry from within the United States shall:
20	(1) Maintain adequate security and privacy in accordance
21	with state and federal laws, rules, and regulations;
22	(2) Be linked to one or more hospitals, pharmacies,
23	long-term care hospitals, nursing facilities, or skilled nursing
24	facilities for which services are provided via computer link, video
25	link, audio link, or facsimile;

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1	(3) Have access to each patient's medical information
2	necessary to perform a prospective drug utilization review as
3	specified in section 71-1,147.35 via computer link, video link, or
4	facsimile; and
5	(4) Be employed by or have a contractual agreement to
6	provide such services with the hospital, pharmacy, long-term care
7	hospital, nursing facility, or skilled nursing facility where the
8	patient is located.
9	Sec. 10. (1) The pharmacist in charge of a coordinating
10	pharmacy shall apply to the Department of Health and Human Services
11	Regulation and Licensure for a satellite pharmacy license prior to
12	engaging in the practice of telepharmacy via a satellite pharmacy.
13	He or she may apply for a satellite pharmacy license when there
14	is no licensed pharmacy, except (a) a hospital having a retail
15	pharmacy license or (b) a nursing facility or skilled nursing
16	facility having a pharmacy license at the location of the nursing
17	facility or skilled nursing facility and such pharmacy dispenses
18	only to patients of such nursing facility or skilled nursing
19	facility, within twenty miles. An exception to the limit in this
20	subsection may be granted by the board when the coordinating
21	pharmacy has demonstrated a need to supervise additional satellite
22	pharmacies and has demonstrated that appropriate safeguards are in
23	place to assure proper supervision of each satellite pharmacy.
24	(2) A coordinating pharmacy shall not be granted a
25	license for and operate more than three satellite pharmacies which

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are open simultaneously. Such satellite pharmacies shall have no 1 2 more than one pharmacy technician at each site. 3 (3) A coordinating pharmacy shall comply with the Uniform Controlled Substances Act and federal laws, rules, and regulations 4 5 relating to controlled substance registration for each satellite 6 pharmacy if controlled substances are kept or maintained at each 7 site. 8 (4) A coordinating pharmacy may utilize a prescription 9 dispensing machine or other automated medication system at the 10 satellite pharmacy. 11 (5) A coordinating pharmacy shall notify the department 12 in writing within ten days after a change of location by, 13 discontinuance of service by, or closure of a satellite pharmacy 14 operated by the coordinating pharmacy. 15 (6) If the computer link or other telecommunication link 16 between the coordinating pharmacy and the satellite pharmacy is 17 disrupted, all dispensing activities at the satellite pharmacy 18 shall stop until the computer link or other telecommunication link 19 is reestablished. 20 Sec. 11. The pharmacist in charge of the coordinating 21 pharmacy: 22 (1) Is responsible for the practice of telepharmacy 23 performed at a satellite pharmacy, including the supervision of any 24 prescription dispensing machine or automated medication system; 25 (2) Shall ensure that the coordinating pharmacy has

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1 <u>sufficient pharmacists on duty for the safe operation and</u> 2 supervision of all satellite pharmacies;

3 (3) Shall ensure, through the use of a video and auditory 4 communication system, that a pharmacy technician at the satellite 5 pharmacy has accurately and correctly prepared any prescription for 6 dispensing according to the prescription; and

7 <u>(4) Is responsible for the supervision and training of</u> 8 pharmacy technicians at satellite pharmacies who shall be subject 9 to all rules and regulations of the Department of Health and Human 10 <u>Services Regulation and Licensure, excluding rules and regulations</u> 11 <u>establishing the permissible ratio of pharmacy technicians to</u> 12 <u>pharmacist.</u>

All patient counseling at the satellite pharmacy must be performed by a pharmacist located at the coordinating pharmacy via audio and video communication system or by a pharmacist at the satellite pharmacy.

17 Sec. 12. A pharmacy technician at a satellite pharmacy 18 may not receive oral prescriptions from a practitioner. For written 19 prescriptions or refill authorizations, the pharmacy technician 20 shall either transmit the prescription or refill authorization 21 to the coordinating pharmacy or process the prescription or 22 refill authorization so that the pharmacist at the coordinating 23 pharmacy may perform a prospective drug utilization review prior to disp<u>ensing.</u> 24

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Sec. 13. A pharmacy may operate an automated distribution

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machine in a long-term care hospital, hospital, nursing facility, 1 2 or skilled nursing facility under the following conditions: 3 (1) The pharmacy shall maintain registration with the Drug Enforcement Administration of the United States Department 4 5 of Justice for each long-term care hospital, hospital, nursing 6 facility, or skilled nursing facility at which the pharmacy 7 maintains an automated distribution machine; 8 (2) Drugs placed in an automated distribution machine in 9 a long-term care hospital, hospital, nursing facility, or skilled 10 nursing facility shall be under the control of the pharmacy 11 providing dispensing services to the long-term care hospital, 12 hospital, nursing facility, or skilled nursing facility. The 13 pharmacy shall have on-line communication with and control of 14 the automated distribution machine, and access to any drug for 15 a patient or resident of the long-term care hospital, hospital, nursing facility, or skilled nursing facility shall be controlled 16 17 by the pharmacy; 18 (3) Removal of individual doses of drugs from an 19 automated distribution machine for dispensing to a patient or 20 resident of a long-term care hospital, hospital, nursing facility, 21 or skilled nursing facility shall only be made pursuant to a 22 valid medical order issued by a practitioner. A drug shall not be 23 dispensed to a patient or resident of a long-term care hospital, 24 hospital, nursing facility, or skilled nursing facility from an

25 automated distribution machine until a pharmacist has reviewed the

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1	medical order and electronically authorized access to such drug
2	for that particular patient or resident in accordance with the
3	medical order. The pharmacist in charge of the pharmacy providing
4	dispensing services shall ensure that a pharmacist who has online
5	access to the system is available at all times to review a
6	medical order as needed and to authorize administration of the drug
7	pursuant to the medical order reviewed;
8	(4) Drugs placed in an automated distribution machine
9	shall be in the manufacturer's sealed original packaging or in
10	containers repackaged in compliance with state and federal laws,
11	rules, and regulations relating to repackaging, labeling, and
12	record keeping;
13	(5) Prior to the removal of drugs from the pharmacy,
14	a delivery record shall be generated for all drugs to be placed
15	in an automated distribution machine which shall include: Date,
16	the name of the drug, the form and strength of dosage, and the
17	quantity; name of the long-term care hospital, hospital, nursing
18	facility, or skilled nursing facility; a unique identifier for
19	the specific device receiving the drugs; and the initials of the
20	pharmacist checking the medical order of drugs to be removed from
21	the pharmacy;
22	(6) At the direction of the pharmacist in charge, drugs
23	may be loaded in the automated distribution machine in a long-term
24	care hospital, hospital, nursing facility, or skilled nursing
25	facility by a pharmacist, a pharmacist intern, or a pharmacy

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1	technician adequately trained in the proper loading of the system;
2	(7) At the time of stocking the automated distribution
3	machine, the delivery record for all drugs in the automated
4	distribution machine which are listed in Schedule II, III, IV, or
5	V of section 28-405 shall be signed by a registered nurse or other
6	person authorized to administer drugs from that specific automated
7	distribution machine, to attest to accurate counts of drugs stocked
8	in the automated distribution machine. The delivery record shall be
9	returned to the pharmacy and maintained in chronological order for
10	a period of five years after the date of delivery. The delivery
11	record and required signatures may be generated or maintained
12	electronically if the system being used can record an electronic
13	signature which is a unique identifier and restricted to the
14	individual receiving the drugs and if such record is maintained in
15	a read-only format which cannot be altered after the information
16	is recorded. The electronic record shall be readily retrievable and
17	maintained for a period of five years, and the system used shall be
18	capable of producing a printout of the record upon request;
19	(8) At the time of stocking any controlled substance
20	listed in Schedule II, III, IV, or V of section 28-405 in an
21	automated distribution machine, the person stocking the automated
22	distribution machine shall verify that the count of that drug

24 noted shall be recorded on the delivery record and immediately

in the automated distribution machine is correct. Any discrepancy

25 reported to the pharmacist in charge who shall be responsible for

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1 reconciliation of the discrepancy or the proper reporting of a
2 loss;

3 (9) The pharmacy providing dispensing services shall 4 <u>conduct an audit at least monthly to review distribution and</u> 5 <u>administration of controlled substances listed in Schedule II,</u> 6 <u>III, IV, or V from each automated distribution machine. The</u> 7 <u>pharmacist in charge or a pharmacist, pharmacist intern, or</u> 8 <u>pharmacy technician designated by the pharmacist in charge shall</u> 9 conduct the audit;

10 (10) An exact count of all controlled substances in 11 each automated distribution machine shall be performed through a 12 blind-count inventory at least every seven days by two individuals 13 who shall be a pharmacist, a pharmacist intern, a pharmacy 14 technician, a registered nurse, or a physician. For purposes 15 of this subdivision, blind-count inventory means an accounting 16 in which two individuals perform an inventory in which neither 17 individual has access to the automated distribution machine's 18 expected count at the time the inventory is performed;

19 <u>(11) Each automated distribution machine shall be</u> 20 inspected monthly by a pharmacist, a pharmacist intern, or a 21 pharmacy technician to verify proper storage, proper location of 22 drugs within the automated distribution machine, expiration dates, 23 the security of drugs, and the validity of access codes;</u>

24 (12) Personnel allowed access to an automated
 25 distribution machine shall have a unique identifier which records

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1 <u>the identity of the person accessing the automated distribution</u> 2 <u>machine;</u>

3 (13) A nurse may remove a medication from the list of 4 approved emergency box drugs under the Emergency Box Drug Act from 5 the automated distribution machine prior to a medical order being 6 reviewed by the pharmacist. An order for any emergency box drug 7 so removed shall be reviewed by the pharmacist within twenty-four 8 hours after such removal; and

9 <u>(14) The inventory which is transferred from a pharmacy</u> 10 <u>to an automated distribution machine in a long-term care hospital,</u> 11 <u>hospital, nursing facility, or skilled nursing facility shall</u> 12 <u>be excluded from the count as required by the Wholesale Drug</u> 13 <u>Distributor Licensing Act.</u>

Sec. 14. Any person who violates the Automated Medication
System Act shall be guilty of a Class II misdemeanor.

16 Sec. 15. Section 71-1,143.03, Reissue Revised Statutes of 17 Nebraska, is amended to read:

18 71-1,143.03 Unless specifically limited by the board or 19 the department, a pharmacist may (1) engage in the practice of 20 pharmacy and telepharmacy as defined in section 2 of this act, 21 (2) use the abbreviation R.P. or the title licensed pharmacist, 22 (3) enter into delegated dispensing agreements, and (4) possess, 23 without dispensing, prescription drugs and devices, including 24 controlled substances, for purposes of administration.

25 Sec. 16. Original section 71-1,143.03, Reissue Revised

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1 Statutes of Nebraska, is repealed.

2 Sec. 17. The following sections are outright repealed: 3 Sections 71-1,147.15 and 71-1,147.16, Revised Statutes Cumulative

4 Supplement, 2006.