

## LEGISLATIVE BILL 326

Approved by the Governor June 4, 2013

Introduced by Howard, 9; Gloor, 35.

FOR AN ACT relating to pharmacists; to amend sections 38-2845, 38-2847, 71-2444, 71-2445, 71-2446, 71-2447, 71-2448, 71-2449, and 71-2452, Reissue Revised Statutes of Nebraska; to define and redefine terms; to change provisions of the Pharmacy Practice Act and the Automated Medication Systems Act; to provide for licensure of long-term care automated pharmacies; to provide for a patient's choice of pharmacy; to harmonize provisions; and to repeal the original sections.

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

Section 1. Section 38-2845, Reissue Revised Statutes of Nebraska, is amended to read:

38-2845 Supervision means the immediate personal guidance and direction by the licensed a pharmacist on duty in the facility of the performance by a pharmacy technician of authorized activities or functions subject to verification by such pharmacist. Supervision of a pharmacy technician may occur by means of a real-time audiovisual communication system. ~~except that when a pharmacy technician performs authorized activities or functions to assist a pharmacist on duty in the facility when the prescribed drugs or devices will be administered by a licensed staff member or consultant or by a licensed physician assistant to persons who are patients or residents of a facility, the activities or functions of such pharmacy technician shall only be subject to verification by a pharmacist on duty in the facility.~~

Sec. 2. Section 38-2847, Reissue Revised Statutes of Nebraska, is amended to read:

38-2847 Verification means the confirmation by a supervising pharmacist of the accuracy and completeness of the acts, tasks, or functions undertaken by a pharmacy technician to assist the pharmacist in the practice of pharmacy. Verification shall occur by a pharmacist on duty in the facility, except that if a pharmacy technician performs authorized activities or functions to assist a pharmacist and the prescribed drugs or devices will be administered to persons who are patients or residents of a facility by a credentialed individual authorized to administer medications, verification may occur by means of a real-time audiovisual communication system.

Sec. 3. Section 71-2444, Reissue Revised Statutes of Nebraska, is amended to read:

71-2444 Sections 71-2444 to 71-2452 and sections 9 and 10 of this act shall be known and may be cited as the Automated Medication Systems Act.

Sec. 4. Section 71-2445, Reissue Revised Statutes of Nebraska, is amended to read:

71-2445 For purposes of the Automated Medication Systems Act:

(1) Automated medication distribution machine means a type of automated medication system that stores medication to be administered to a patient by a person credentialed under the Uniform Credentialing Act;

(2) Automated medication system means a mechanical system that performs operations or activities, other than compounding, administration, or other technologies, relative to storage and packaging for dispensing or distribution of medications and that collects, controls, and maintains all transaction information and includes, but is not limited to, a prescription medication distribution machine or an automated medication distribution machine. An automated medication system may only be used in conjunction with the provision of pharmacist care;

(3) Chart order means an order for a drug or device issued by a practitioner for a patient who is in the hospital where the chart is stored, ~~or~~ for a patient receiving detoxification treatment or maintenance treatment pursuant to section 28-412, or for a resident in a long-term care facility in which a long-term care automated pharmacy is located from which drugs will be dispensed. Chart order does not include a prescription;

(4) Hospital has the definition found in section 71-419;

(5) Long-term care automated pharmacy means a designated area in a long-term care facility where an automated medication system is located, that stores medications for dispensing pursuant to a medical order to residents in such long-term care facility, that is installed and operated by a pharmacy licensed under the Health Care Facility Licensure Act, and that is licensed under section 9 of this act;

~~(5)~~ (6) Long-term care facility means an intermediate care facility,

an intermediate care facility for the mentally retarded, a long-term care hospital, a mental health center, a nursing facility, or a skilled nursing facility, as such terms are defined in the Health Care Facility Licensure Act;

~~(6)~~ (7) Medical order means a prescription, a chart order, or an order for pharmaceutical care issued by a practitioner;

~~(7)~~ (8) Pharmacist means any person who is licensed by the State of Nebraska to practice pharmacy;

~~(8)~~ (9) Pharmacist care means the provision by a pharmacist of medication therapy management, with or without the dispensing of drugs or devices, intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process;

~~(9)~~ (10) Pharmacist remote order entry means entering an order into a computer system or drug utilization review by a pharmacist licensed to practice pharmacy in the State of Nebraska and located within the United States, pursuant to medical orders in a hospital, long-term care facility, or pharmacy licensed under the Health Care Facility Licensure Act;

~~(10)~~ (11) Practice of pharmacy means (a) the interpretation, evaluation, and implementation of a medical order, (b) the dispensing of drugs and devices, (c) drug product selection, (d) the administration of drugs or devices, (e) drug utilization review, (f) patient counseling, (g) the provision of pharmaceutical care, and (h) the responsibility for compounding and labeling of dispensed or repackaged drugs and devices, proper and safe storage of drugs and devices, and maintenance of proper records. The active practice of pharmacy means the performance of the functions set out in this subdivision by a pharmacist as his or her principal or ordinary occupation;

~~(11)~~ (12) Practitioner means a certified registered nurse anesthetist, a certified nurse midwife, a dentist, an optometrist, a nurse practitioner, a physician assistant, a physician, a podiatrist, or a veterinarian;

~~(12)~~ (13) Prescription means an order for a drug or device issued by a practitioner for a specific patient, for emergency use, or for use in immunizations. Prescription does not include a chart order;

~~(13)~~ (14) Prescription medication distribution machine means a type of automated medication system that packages, labels, or counts medication in preparation for dispensing of medications by a pharmacist pursuant to a prescription; and

~~(14)~~ (15) Telepharmacy means the provision of pharmacist care, by a pharmacist located within the United States, using telecommunications, remote order entry, or other automations and technologies to deliver care to patients or their agents who are located at sites other than where the pharmacist is located.

Sec. 5. Section 71-2446, Reissue Revised Statutes of Nebraska, is amended to read:

71-2446 Any automated machine that dispenses, delivers, or makes available, other than by administration, prescription medication directly to a patient or caregiver without the provision of pharmacist care is prohibited.

Sec. 6. Section 71-2447, Reissue Revised Statutes of Nebraska, is amended to read:

71-2447 Any hospital, long-term care facility, or pharmacy that uses an automated medication system shall develop, maintain, and comply with policies and procedures developed in consultation with the pharmacist responsible for pharmacist care for that hospital, long-term care facility, or pharmacy. At a minimum, the policies and procedures shall address the following:

(1) The description and location within the hospital, long-term care facility, or pharmacy of the automated medication system or equipment being used;

(2) The name of the ~~individual or individuals~~ pharmacist responsible for implementation of and compliance with the policies and procedures;

(3) Medication access and information access procedures;

(4) Security of inventory and confidentiality of records in compliance with state and federal laws, rules, and regulations;

(5) A description of the process used by a pharmacist or pharmacy technician for filling an automated medication system;

~~(5)~~ (6) A description of how and by whom the automated medication system is being utilized, including processes for ~~filling~~, verifying, dispensing, and distributing medications;

~~(6)~~ (7) Staff education and training;

~~(7)~~ (8) Quality assurance and quality improvement programs and processes;

~~(8)~~ (9) Inoperability or emergency downtime procedures;

- ~~(9)~~ (10) Periodic system maintenance; and  
~~(10)~~ (11) Medication security and controls.

Sec. 7. Section 71-2448, Reissue Revised Statutes of Nebraska, is amended to read:

71-2448 A prescription medication distribution machine:

(1) Is subject to the requirements of section 71-2447 and, if it is in a long-term care automated pharmacy, is subject to section 9 of this act;  
 and

(2) May be operated only (a) in a licensed pharmacy where a pharmacist dispenses medications to patients for self-administration pursuant to a prescription or (b) in a long-term care automated pharmacy subject to section 9 of this act.

Sec. 8. Section 71-2449, Reissue Revised Statutes of Nebraska, is amended to read:

71-2449 (1) An automated medication distribution machine:

(a) Is subject to the requirements of section 71-2447 and, if it is in a long-term care automated pharmacy, is subject to section 9 of this act;  
 and

(b) May be operated in a hospital or long-term care facility for medication administration pursuant to a chart order or prescription by a licensed health care professional.

(2) Drugs placed in an automated medication distribution machine shall be in the manufacturer's original packaging or in containers repackaged in compliance with state and federal laws, rules, and regulations relating to repackaging, labeling, and record keeping.

(3) The inventory which is transferred to an automated medication distribution machine in a hospital or long-term care facility shall be excluded from the percent of total prescription drug sales revenue described in section 71-7454.

Sec. 9. (1) In order for an automated medication system to be operated in a long-term care facility, a pharmacist in charge of a pharmacy licensed under the Health Care Facility Licensure Act and located in Nebraska shall annually license the long-term care automated pharmacy in which the automated medication system is located.

(2) The pharmacist in charge of a licensed pharmacy shall submit an application for licensure or renewal of licensure to the Division of Public Health of the Department of Health and Human Services with a fee in the amount of the fee the pharmacy pays for licensure or renewal. The application shall include:

(a) The name and location of the licensed pharmacy;

(b) If controlled substances are stored in the automated medication system, the federal Drug Enforcement Administration registration number of the licensed pharmacy. After the long-term care automated pharmacy is registered with the federal Drug Enforcement Administration, the pharmacist in charge of the licensed pharmacy shall provide the federal Drug Enforcement Administration registration number of the long-term care automated pharmacy to the division and any application for renewal shall include such registration number;

(c) The location of the long-term care automated pharmacy; and

(d) The name of the pharmacist in charge of the licensed pharmacy.

(3) As part of the application process, the division shall conduct an inspection by a pharmacy inspector as provided in section 38-28,101 of the long-term care automated pharmacy. The division shall also conduct inspections of the operation of the long-term care automated pharmacy as necessary.

(4) The division shall license a long-term care automated pharmacy which meets the licensure requirements of the Automated Medication Systems Act.

(5) A pharmacist in charge of a licensed pharmacy shall apply for a separate license for each location at which it operates one or more long-term care automated pharmacies. The licensed pharmacy shall be the provider pharmacy for the long-term care automated pharmacy.

(6) The pharmacist in charge of the licensed pharmacy operating a long-term care automated pharmacy shall:

(a) Identify a pharmacist responsible for the operation, supervision, policies, and procedures of the long-term care automated pharmacy;

(b) Implement the policies and procedures developed to comply with section 71-2447;

(c) Assure compliance with the drug storage and record-keeping requirements of the Pharmacy Practice Act;

(d) Assure compliance with the labeling requirements of subsection (8) of this section;

(e) Develop and implement policies for the verification of drugs by a pharmacist prior to being loaded into the automated medication system or for the verification of drugs by a pharmacist prior to being released for administration to a resident;

(f) Develop and implement policies for inventory, security, and accountability for controlled substances; and

(g) Assure that each medical order is reviewed by a pharmacist prior to the release of the drugs by the automated medication system. Emergency doses may be taken from an automated medication system prior to review by a pharmacist if the licensed pharmacy develops and implements policies for emergency doses.

(7) Supervision by a pharmacist is sufficient for compliance with the requirement of subdivision (6)(a) of this section if the pharmacist in the licensed pharmacy monitors the automated medication system electronically and keeps records of compliance with such requirement for five years.

(8) Each drug dispensed from a long-term care automated pharmacy shall be in a package with a label containing the following information:

(a) The name and address of the long-term care automated pharmacy;

(b) The prescription number;

(c) The name, strength, and dosage form of the drug;

(d) The name of the resident;

(e) The name of the practitioner who prescribed the drug;

(f) The date of filling; and

(g) Directions for use.

(9) A prescription is required for any controlled substance dispensed from a long-term care automated pharmacy.

(10) The inventory which is transferred to a long-term care automated pharmacy shall be excluded from the percent of total prescription drug sales revenue described in section 71-7454.

Sec. 10. Unless otherwise allowed by state or federal law or regulation, the management of a long-term care facility at which an automated medication system is located shall not require a resident of the facility to obtain medication through the automated medication system and shall not restrict or impair the ability of a resident of the facility to obtain medications from the pharmacy of the resident's choice.

Sec. 11. Section 71-2452, Reissue Revised Statutes of Nebraska, is amended to read:

71-2452 Any person who violates the Automated Medication Systems Act may be subject to disciplinary action by the Division of Public Health of the Department of Health and Human Services under the Health Care Facility Licensure Act, the Uniform Licensing Law, or the Uniform Credentialing Act.

Sec. 12. Original sections 38-2845, 38-2847, 71-2444, 71-2445, 71-2446, 71-2447, 71-2448, 71-2449, and 71-2452, Reissue Revised Statutes of Nebraska, are repealed.