LEGISLATURE OF NEBRASKA

ONE HUNDREDTH LEGISLATURE

SECOND SESSION

LEGISLATIVE BILL 308

FINAL READING

Introduced by Stuthman, 22; Burling, 33.

Read first time January 11, 2007

Committee: Health and Human Services

A BILL

FOR AN ACT relating to pharmacy; to amend sections 38-178, 38-2866, 71-448, and 71-7454, Revised Statutes Supplement, 2007; to adopt the Automated Medication Systems Act; to harmonize provisions; to change and eliminate restrictions on drug vending machines; to provide operative dates; to repeal the original sections; to outright repeal section 71-1,147.15, Reissue Revised Statutes of Nebraska, section 38-28,102, Revised Statutes Supplement, 2007, and section 9 of this legislative bill; and to declare an emergency.

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

Section 1. Sections 1 to 9 of this act shall be known and may be cited as the Automated Medication Systems Act.

Sec. 2. 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 before December 1, 2008, under the Uniform Licensing Law and on or after December 1, 2008, 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. Chart order does not include a prescription;

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

(5) Medical order means a prescription, a chart order, or

an order for pharmaceutical care issued by a practitioner;

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

(7) 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;

(8) 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 or pharmacy licensed under the Health Care Facility Licensure Act;

(9) 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;

(10) 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;

(11) 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

(12) 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. 3. Any automated machine that dispenses, delivers, or makes available, other than by administration, prescription medication directly to a patient or caregiver is prohibited.

Sec. 4. Any hospital 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 or pharmacy. At a minimum, the policies and procedures shall address the following:

(1) The description and location within the hospital or pharmacy of the automated medication system or equipment being used;

(2) The name of the individual or individuals 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 how and by whom the automated medication system is being utilized, including processes for filling, verifying, dispensing, and distributing medications;

(6) Staff education and training;

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

(8) Inoperability or emergency downtime procedures;

(9) Periodic system maintenance; and

(10) Medication security and controls.

Sec. 5. A prescription medication distribution machine:

(1) Is subject to the requirements of section 4 of this act; and

(2) May be operated only in a licensed pharmacy where a pharmacist dispenses medications to patients for self-administration pursuant to a prescription.

Sec. 6. (1) An automated medication distribution machine:

(a) Is subject to the requirements of section 4 of this act; and

(b) May be operated in a hospital for medication administration pursuant to a chart order 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 shall be excluded from the percent of total prescription drug sales revenue described in section 71-7454.

Sec. 7. A pharmacist providing pharmacist remote order entry shall:

(1) Be located within the United States;

(2) Maintain adequate security and privacy in accordance with state and federal laws, rules, and regulations;

(3) Be linked to one or more hospitals or pharmacies for which services are provided via computer link, video link, audio link, or facsimile transmission;

(4) Have access to each patient's medical information necessary to perform via computer link, video link, or facsimile transmission a prospective drug utilization review as specified before December 1, 2008, in section 71-1,147.35 and on or after December 1, 2008, in section 38-2869; and

(5) Be employed by or have a contractual agreement to provide such services with the hospital or pharmacy where the patient is located.

Sec. 8. 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. 9. Unless specifically limited by the Board of Pharmacy or the Department of Health and Human Services, a pharmacist may engage in the practice of telepharmacy.

Sec. 10. Section 38-178, Revised Statutes Supplement, 2007, is amended to read:

38-178 Except as otherwise provided in sections 38-1,119 to 38-1,123, a credential to practice a profession may be denied, refused renewal, or have other disciplinary measures taken against it in accordance with section 38-185 or 38-186 on any of the following grounds:

(1) Misrepresentation of material facts in procuring or attempting to procure a credential;

(2) Immoral or dishonorable conduct evidencing unfitness to practice the profession in this state;

(3) Abuse of, dependence on, or active addiction to alcohol, any controlled substance, or any mind-altering substance;

(4) Failure to comply with a treatment program or an aftercare program, including, but not limited to, a program entered into under the Licensee Assistance Program established pursuant to section 38-175;

(5) Conviction of (a) a misdemeanor or felony under Nebraska law or federal law, or (b) a crime in any jurisdiction which, if committed within this state, would have constituted a misdemeanor or felony under Nebraska law and which has a rational connection with the fitness or capacity of the applicant or credential holder to practice the profession;

(6) Practice of the profession (a) fraudulently, (b) beyond its authorized scope, (c) with gross incompetence or gross negligence, or (d) in a pattern of incompetent or negligent conduct;

(7) Practice of the profession while the ability to practice is impaired by alcohol, controlled substances, drugs, mind-altering substances, physical disability, mental disability, or emotional disability;

(8) Physical or mental incapacity to practice the profession as evidenced by a legal judgment or a determination by other lawful means;

(9) Illness, deterioration, or disability that impairs the ability to practice the profession;

(10) Permitting, aiding, or abetting the practice of a profession or the performance of activities requiring a credential by a person not credentialed to do so;

(11) Having had his or her credential denied, refused renewal, limited, suspended, revoked, or disciplined in any manner similar to section 38-196 by another state or jurisdiction based

upon acts by the applicant or credential holder similar to acts described in this section;

(12) Use of untruthful, deceptive, or misleading statements in advertisements;

(13) Conviction of fraudulent or misleading advertising or conviction of a violation of the Uniform Deceptive Trade Practices Act;

(14) Distribution of intoxicating liquors, controlled substances, or drugs for any other than lawful purposes;

(15) Violations of the Uniform Credentialing Act or the rules and regulations relating to the particular profession;

(16) Unlawful invasion of the field of practice of any profession regulated by the Uniform Credentialing Act which the credential holder is not credentialed to practice;

(17) Violation of the Uniform Controlled Substances Act or any rules and regulations adopted pursuant to the act;

(18) Failure to file a report required by section 38-1,124 or 38-1,125;

(19) Failure to maintain the requirements necessary to obtain a credential;

(20) Violation of an order issued by the department;

(21) Violation of an assurance of compliance entered into under section 38-1,108;

(22) Failure to pay an administrative penalty; ~~or~~

(23) Unprofessional conduct as defined in section 38-179;

or~~.~~

(24) Violation of the Automated Medication Systems Act.

Sec. 11. Section 38-2866, Revised Statutes Supplement, 2007, is amended to read:

38-2866 Unless specifically limited by the board or the department, a pharmacist may (1) engage in the practice of pharmacy and telepharmacy as defined in section 2 of this act, (2) use automation in the practice of pharmacy and telepharmacy, (3) use the abbreviation R.P. or the title licensed pharmacist, ~~(3)~~ (4) enter into delegated dispensing agreements, and ~~(4)~~ (5) possess, without dispensing, prescription drugs and devices, including controlled substances, for purposes of administration.

Sec. 12. Section 71-448, Revised Statutes Supplement, 2007, is amended to read:

71-448 The Division of Public Health of the Department of Health and Human Services may take disciplinary action against a license issued under the Health Care Facility Licensure Act on any of the following grounds:

(1) Violation of any of the provisions of the Assisted-Living Facility Act, the Health Care Facility Licensure Act, the Nebraska Nursing Home Act, or the rules and regulations adopted and promulgated under such acts;

(2) Committing or permitting, aiding, or abetting the commission of any unlawful act;

(3) Conduct or practices detrimental to the health or

safety of a person residing in, served by, or employed at the health care facility or health care service;

(4) A report from an accreditation body or public agency sanctioning, modifying, terminating, or withdrawing the accreditation or certification of the health care facility or health care service;

(5) Failure to allow an agent or employee of the Department of Health and Human Services access to the health care facility or health care service for the purposes of inspection, investigation, or other information collection activities necessary to carry out the duties of the Department of Health and Human Services;

(6) Discrimination or retaliation against a person residing in, served by, or employed at the health care facility or health care service who has submitted a complaint or information to the Department of Health and Human Services;

(7) Discrimination or retaliation against a person residing in, served by, or employed at the health care facility or health care service who has presented a grievance or information to the office of the state long-term care ombudsman;

(8) Failure to allow a state long-term care ombudsman or an ombudsman advocate access to the health care facility or health care service for the purposes of investigation necessary to carry out the duties of the office of the state long-term care ombudsman as specified in the rules and regulations adopted and promulgated

by the Department of Health and Human Services;

(9) Violation of the Emergency Box Drug Act;

(10) Failure to file a report required by section 38-1,127;

(11) Violation of the Medication Aide Act; ~~or~~

(12) Failure to file a report of suspected abuse or neglect as required by sections 28-372 and 28-711; or~~.~~

(13) Violation of the Automated Medication Systems Act.

Sec. 13. Section 71-7454, Revised Statutes Supplement, 2007, is amended to read:

71-7454 (1) No wholesale drug distributor, manufacturer, or pharmacy shall knowingly purchase or receive any prescription drug from any source other than a person or entity licensed under the Wholesale Drug Distributor Licensing Act except transfers for emergency medical reasons and except as provided in subsection (3) of section 6 of this act, the gross dollar value of which shall not exceed five percent of the total prescription drug sales revenue of the transferor or transferee holder of a pharmacy license or practitioner as defined in section 38-2838 during the immediately preceding calendar year, and except as otherwise provided in the act.

(2) A wholesale drug distributor may receive returns or exchanges of prescription drugs from a pharmacy, chain pharmacy warehouse, health care practitioner facility as defined in section 71-414, or hospital as defined in section 71-419 pursuant to

the terms and conditions agreed upon between such wholesale drug distributor and such pharmacy, chain pharmacy warehouse, health care practitioner facility, or hospital. Such returns and exchanges shall not be subject to sections 71-7455 to 71-7457. A wholesale drug distributor shall not receive from a pharmacy, chain pharmacy warehouse, health care practitioner facility, or hospital an amount or quantity of a prescription drug greater than the amount or quantity that was originally sold by the wholesale drug distributor to such pharmacy, chain pharmacy warehouse, health care practitioner facility, or hospital.

(3) A manufacturer or wholesale drug distributor shall furnish prescription drugs only to persons licensed by the department and shall verify such licensure before furnishing prescription drugs to a person not known to the manufacturer or wholesale drug distributor.

(4) Prescription drugs furnished by a manufacturer or wholesale drug distributor shall be delivered only to the premises listed on the license, except that a manufacturer or wholesale drug distributor may furnish prescription drugs to a person licensed by the department or his or her agent at the premises of the manufacturer or wholesale drug distributor if:

(a) The identity and authorization of the recipient is properly established; and

(b) This method of receipt is employed only to meet the prescription drug needs of a particular patient of the person

licensed by the department.

(5) Prescription drugs may be furnished to a hospital pharmacy receiving area. Receipt of such drugs shall be acknowledged by written receipt signed by a pharmacist or other authorized personnel. The receipt shall contain the time of delivery and the type and quantity of the prescription drug received. Any discrepancy between the signed receipt and the type and quantity of prescription drug actually received shall be reported by the receiving authorized pharmacy personnel to the delivering manufacturer or wholesale drug distributor by the next business day after the delivery to the pharmacy receiving area.

(6) A manufacturer or wholesale drug distributor shall only accept payment or allow the use of credit to establish an account for the purchase of prescription drugs from the owner or owners of record, the chief executive officer, or the chief financial officer listed on the license of a person or entity legally authorized to receive prescription drugs. Any account established for the purchase of prescription drugs shall bear the name of such licensee.

Sec. 14. Sections 10, 11, 15, and 17 of this act become operative on December 1, 2008. The other sections of this act become operative on their effective date.

Sec. 15. Original sections 38-178 and 38-2866, Revised Statutes Supplement, 2007, are repealed.

Sec. 16. Original sections 71-448 and 71-7454, Revised

Statutes Supplement, 2007, are repealed.

Sec. 17. The following sections are outright repealed: Section 38-28,102, Revised Statutes Supplement, 2007, and section 9 of this legislative bill.

Sec. 18. The following section is outright repealed: Section 71-1,147.15, Reissue Revised Statutes of Nebraska.

Sec. 19. Since an emergency exists, this act takes effect when passed and approved according to law.