LCB File No. R043-07

PROPOSED REGULATION OF THE STATE BOARD OF PHARMACY

(This proposed regulation was previously adopted as T013-07)

Section 1. NAC 639.720 shall be amended as follows:

1. Except as otherwise provided in subsection***s*** 4 ***and 6***, a mechanical device may be used to furnish drugs and medicines for administration to registered patients in a medical facility. The device must conform to all of the following provisions:

(a) All drugs and medicines stocked in the device must be approved for use in the device by a registered pharmacist employed by the:

(1) Medical facility in which the drug or medicine is administered; or

(2) Pharmacy that supplies the medical facility in which the drug or medicine is administered.

(b) Access to the device must be:

(1) Limited to pharmaceutical technicians, pharmaceutical technicians in training, intern pharmacists, registered pharmacists, licensed practical nurses, registered nurses or other practitioners who are:

(I) Authorized by law to prescribe or administer controlled substances, poisons, or dangerous drugs and devices; and

(II) Employed by the medical facility or pharmacy that supplies the medical facility.

(2) Monitored and controlled by the pharmacy which supplies the medical facility or the registered pharmacist who is employed by the medical facility.

(c) Each container of a drug or medicine stored in the device must be labeled in a manner which includes the information required pursuant to subsection 2 of NAC 639.476.

(d) The device must be designed in such a manner that:

(1) Each time a person obtains access to the device, it automatically prepares a record which is readily retrievable and which includes:

(I) The name, strength, quantity and form of dosage of the drug or medicine which is stocked, inventoried or removed for administration to a patient;

(II) The day and time access to the device is obtained;

(III) If a drug or medicine is removed for administration to a patient, the name of the patient;

(IV) An inventory of the drugs and medicines stored in the device; and

(V) The name of the person who obtained access to the device.

(2) Access to the device may be obtained only by a person with the use of a code which identifies that person.

2. A pharmacy which supplies drugs and medicines to a medical facility which are furnished by a mechanical device pursuant to subsection 1 shall maintain a written policy which sets forth:

(a) The duties of all persons who are authorized to obtain access to the device; and

(b) The procedure for:

(1) Maintaining the security of the drugs and medicines stored in the device during the maintenance and repair of the device;

(2) The preparation of an inventory of the drugs and medicines stored in the device; and

(3) Stocking the device with drugs and medicines.

3. A pharmacy which supplies drugs or medicines to a medical facility which uses a mechanical device to furnish drugs or medicines for administration to patients pursuant to subsection 1 shall provide written notice to the Board. The notice must include:

(a) A description of each mechanical device used by the medical facility to furnish drugs or medicines for administration to patients, including, without limitation, the name of the manufacturer of the device; and

(b) The address of the medical facility at which the mechanical device is located.

4. A pharmacy shall not stock a mechanical device with drugs or medicines and a mechanical device must not be used to furnish drugs or medicines for administration to patients until:

(a) The pharmacy has notified the Board as required by subsection 3; and

(b) The Board has issued a certificate to the pharmacy that authorizes the use of the mechanical device at the medical facility at which the mechanical device is located.

5. Each medical facility that uses a mechanical device pursuant to this section must make and maintain a record of any waste of a controlled substance in the manner provided in NAC 639.486. The record of any waste of a controlled substance may be prepared:

(a) By the mechanical device if the mechanical device is capable of making and maintaining such a record and documenting the record of the waste being witnessed by another person as provided in paragraph (g) of subsection 1 of NAC 639.486; or

(b) As a written record.

6. A mechanical device may be used to dispense drugs and medicines for a patient of or at an emergency department of a hospital. The device must conform to all of the following provisions:

(a) All drugs and medicines stocked in the device must be approved for use in the device by a registered pharmacist employed by or contracted with the:

(1) Hospital in which the drug or medicine is dispensed; or

(2) Pharmacy that supplies the hospital in which the drug or medicine is dispensed.

(b) Access to the device for the purposes of stocking, inventory, and monitoring must be limited to pharmaceutical technicians, pharmaceutical technicians in training, intern pharmacists, or pharmacists employed by the hospital or the pharmacy that supplies the hospital.

(c) Use of the device for the purposes of dispensing to a patient must be:

(1) By a practitioner who:

(I) Is authorized by law to prescribe controlled substances or dangerous drugs;

(II) Is employed by or who has privileges at the hospital;

(III) Prescribed the controlled substance, poison, or dangerous drug that will be dispensed to the patient;

(IV) Personally verifies the correctness of the prescription before he dispenses it to the patient;

(V)Has offered to the patient the option of being provided a prescription that could be filled at a pharmacy, which offer must first be declined by the patient before the prescription can be transmitted to the mechanical device for the purposes of filling and dispensing the prescription; or

(2) By the patient where:

(I) The device requires from the patient a unique identifier known only to the patient to allow access to be gained to the device; and

(II) The patient is notified by the device that he may opt not to purchase the drug from the device at any time prior to the device's dispensing of the prescription.

(d) Each container of a drug dispensed by the device is labeled pursuant to NRS 639.2801.

(e) The device must be designed in such a manner that:

(1) Each time a person obtains access into the device, it automatically prepares a record that is readily retrievable and that includes:

(I) The name, strength, quantity and form of dosage of the drug or medicine which is stocked, inventoried or removed for dispensing to a patient;

(II) The day and time access to the device is obtained;

(III) If a drug or medicine is removed for administration to a patient, the name of the patient;

(IV) An inventory of the drugs and medicines stored in the device; and

(V) The identity of the person who obtained access to the device.

(2) Access to the device may be obtained only by a person with the use of a unique identifier which identifies that person.

(f) The device is placed in such a place and manner that it cannot be removed from the hospital and that attempted unauthorized access to the device would be visible to employees of the hospital.

(g) Where the device will dispense a prescription directly to a patient pursuant to subsection (c) of this section, then prior to the use of the device the manufacturer of the device must have appeared before the board for approval for the particular use of the device and satisfied the board through studies, testing, demonstration or other means that the device dispenses prescriptions accurately to a patient and that the device satisfies the other conditions of this section.

~~[6.]~~ ***7.*** As used in this section, "medical facility" has the meaning ascribed to it in NRS 449.0151.