

Chapter 639 of NAC

LCB File No. T013-07

**ADOPTED TEMPORARY REGULATION OF THE
STATE BOARD OF PHARMACY**

Filed with the Secretary of State on March 29, 2007

Section 1. NAC 639.720 shall be amended as follows:

1. Except as otherwise provided in subsections 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:***
 - (I) 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.

**NOTICE OF ADOPTION OF TEMPORARY REGULATION
LCB File No. T013-07**

The State Board of Pharmacy adopted temporary regulations assigned LCB File No. T013-07 which pertain to chapter 639 of the Nevada Administrative Code on February 23, 2007.

INFORMATIONAL STATEMENT

The informational statement required by NRS 233B.066 numerically conforms to the subsections of the statute as follows:

1. A DESCRIPTION OF HOW PUBLIC COMMENT WAS SOLICITED, A SUMMARY OF PUBLIC RESPONSE, AND AN EXPLANATION HOW OTHER INTERESTED PERSONS MAY OBTAIN A COPY OF THE SUMMARY.

Public comment was solicited through public notices posted in county courthouses and through mailings to interested parties.

There was no public response expressed relative to this proposed regulation.

2. THE NUMBER OF PERSONS WHO: (A) ATTENDED EACH HEARING; (B) TESTIFIED AT EACH HEARING; AND (C) SUBMITTED TO THE AGENCY WRITTEN STATEMENTS.

The number of persons who attended the hearing was 5.

The number of persons who testified at the hearing was 5.

The number of agency submitted statements was 0.

3. A DESCRIPTION OF HOW COMMENT WAS SOLICITED FROM AFFECTED BUSINESSES, A SUMMARY OF THEIR RESPONSE, AND AN EXPLANATION HOW OTHER INTERESTED PERSONS MAY OBTAIN A COPY OF THE SUMMARY.

Comments were solicited from affected businesses through posting of public notices in the county courthouses, by direct mailings to all interested persons who have requested notices of board of pharmacy meeting agendas and by direct mailings to professional and trade associations.

There was testimony and suggestions to be made to the language presented. Those suggestions were incorporated into the language passed by the Board.

All interested parties may obtain a summary of public response by written or verbal request to: Nevada State Board of Pharmacy, 555 Double Eagle Court, Suite 1100, Reno, Nevada, 89521.

4. IF THE REGULATION WAS ADOPTED WITHOUT CHANGING ANY PART OF THE PROPOSED REGULATION, A SUMMARY OF THE REASONS FOR ADOPTING THE REGULATION WITHOUT CHANGE.

The proposed regulation was adopted with amendments or changes suggested through comments received from the public.

5. THE ESTIMATED ECONOMIC EFFECT OF THE REGULATION ON THE BUSINESS WHICH IT IS TO REGULATE AND ON THE PUBLIC. THESE MUST BE STATED SEPARATELY, AND IN EACH CASE MUST INCLUDE:

A) BOTH ADVERSE AND BENEFICIAL EFFECTS.

This regulation should have no economic impact on affected businesses or on the public.

B) BOTH IMMEDIATE AND LONG-TERM EFFECTS.

This regulation will have no immediate or long-term economic effects on business or the public.

6. THE ESTIMATED COST TO THE AGENCY FOR ENFORCEMENT OF THE PROPOSED REGULATION.

There will be no additional or special costs incurred by the board for enforcement of this regulation.

7. A DESCRIPTION OF ANY REGULATIONS OF OTHER STATE OR GOVERNMENT AGENCIES WHICH THE PROPOSED REGULATION OVERLAPS OR DUPLICATES AND A STATEMENT EXPLAINING WHY THE DUPLICATION OR OVERLAPPING IS NECESSARY. IF THE REGULATION OVERLAPS OR DUPLICATES A FEDERAL REGULATION, THE NAME OF THE REGULATING FEDERAL AGENCY.

The Board of Pharmacy is not aware of any similar regulations of other state or government agencies that the proposed regulation overlaps or duplicates.

8. IF THE REGULATION INCLUDES PROVISIONS WHICH ARE MORE STRINGENT THAN A FEDERAL REGULATION WHICH REGULATES THE SAME ACTIVITY, A SUMMARY OF SUCH PROVISIONS.

The Board of Pharmacy is not aware of any similar regulations of the same activity in which the federal regulation is more stringent.

9. IF THE REGULATION PROVIDES A NEW FEE OR INCREASES AN EXISTING FEE, THE TOTAL ANNUAL AMOUNT THE AGENCY EXPECTS TO COLLECT AND THE MANNER IN WHICH THE MONEY WILL BE USED.

This regulation does not provide a new or increase of fees.