ADOPTED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R043-07

Effective October 31, 2007

EXPLANATION – Matter in ***italics*** is new; matter in brackets **[**~~omitted material~~**]** is material to be omitted.

AUTHORITY: §1, NRS 639.070 and 639.2655.

A REGULATION relating to pharmacy; authorizing the use of mechanical devices to furnish drugs directly to patients in emergency rooms under certain circumstances; and providing other matters properly relating thereto.

Section 1. NAC 639.720 is hereby amended to read as follows:

639.720 1. Except as otherwise provided in **[**~~subsection 4,~~**]** ***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]~~ ***the device*** 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]~~ ***subsection 1*** 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 furnish drugs and medicines for a patient receiving treatment in the emergency room of a hospital. The device must conform to all 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 furnished; or

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

(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 registered pharmacists employed by the hospital or the pharmacy that supplies the hospital.

(c) Use of the device to furnish a drug or medicine 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 drug or medicine that is furnished to the patient;

(IV) Personally verifies the correctness of the prescription for the drug or medicine before he furnishes it to the patient; and

(V) Has offered to the patient the choice of being provided a prescription that may be filled at a pharmacy, which offer first must be declined by the patient before the prescription is transmitted to the mechanical device to fill and furnish the prescription; or

(2) By the patient where:

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

(II) The patient is notified by the device that he may choose not to purchase the drug or medicine from the device at any time before the device furnishes the drug or medicine.

(d) Each container of a drug or medicine 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 to the device, the device 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 dispensing to a patient;

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

(III) If a drug or medicine is removed for dispensing 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 unique code which identifies that person.

(f) The device must be located in such a place and manner that a person is unable to remove it from the hospital, and that attempts to obtain access to the device without authorization are visible to employees of the hospital.

(g) Before the device is used to furnish a drug or medicine directly to a patient pursuant to paragraph (c), the manufacturer of the device must appear before the Board for its approval of that use of the device and submit evidence satisfactory to the Board that the device:

(1) Furnishes drugs and medicines accurately; and

(2) Otherwise satisfies the provisions of this subsection.

7. As used in this section, "medical facility" has the meaning ascribed to it in NRS 449.0151.

NOTICE OF ADOPTION OF PROPOSED REGULATION
LCB File No. R043-07

The State Board of Pharmacy adopted regulations assigned LCB File No. R043-07 which pertain to chapter 639 of the Nevada Administrative Code.

INFORMATIONAL STATEMENT

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.

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

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 no response from affected businesses relative to this proposed regulation.

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 minor changes.

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.