ADOPTED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R017-03

Effective October 21, 2003

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

AUTHORITY: §§1-3, NRS 639.070.

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

639.720 1. ~~[A]~~ ***Except as otherwise provided in subsection 4, 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 ~~[supportive personnel,]~~ ***pharmaceutical technicians, pharmaceutical technicians in training,*** intern pharmacists, registered pharmacists, licensed practical nurses ~~[or]~~ **,** registered nurses ~~[employed]~~ ***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.

~~[(3) It prepares a permanent record of any waste of a controlled substance which must be witnessed by a person other than the person who obtains access to the device pursuant to paragraph (g) of subsection 1 of NAC 639.486. The person who witnesses the preparation of the record of waste must include his name in the record.]~~

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

Sec. 2. NAC 639.035 is hereby repealed.

Sec. 3. This regulation becomes effective on October 1, 2003, or upon filing with the Secretary of State, whichever occurs later.

TEXT OF REPEALED SECTION

639.035 "Supportive personnel" interpreted. For the purposes of NRS 639.0152, "supportive personnel" includes:

1. Pharmaceutical technicians; and
2. Pharmaceutical technicians in training.

NOTICE OF ADOPTION OF PROPOSED REGULATION
LCB File No. R017-03

The State Board of Pharmacy adopted regulations assigned LCB File No. R017-03 which pertain to chapter 639 of the Nevada Administrative Code on September 11, 2003.

Notice date: 8/11/2003 **Date of adoption by agency:** 9/11/2003
Hearing date: 9/11/2003 **Filing date:** 10/21/2003

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.

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 without change as no testimony was offered.

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 cost 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.