LCB File No. T023-03

ADOPTED TEMPORARY REGULATION OF THE STATE BOARD OF PHARMACY

Filed with the Secretary of State on March 28, 2003

USE OF MECHANICAL DISPENSING DEVICES IN FACILITIES FOR INTERMEDIATE CARE AND FACILITIES FOR SKILLED NURSING REGULATIONS

Section 1. NAC 639.720 shall be amended as follows:

NAC 639.720 Mechanical devices: Exemption for floor stock of drugs in medical facilities.

1. 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, intern pharmacists, registered pharmacists, licensed practical nurses ~~[or]~~, registered nurses ***or other healthcare personnel licensed to prescribe or administer prescription drugs and*** 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. For each mechanical device to which it is supplying drugs and medicines, a pharmacy which supplies drugs and medicines to a medical facility which are furnished by a mechanical device pursuant to subsection1 shall notify the board in writing of:

(a) A description of the mechanical device, including the name of the manufacturer of the device; and

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

The mechanical device may not be stocked with drugs and medicines and may not be used to dispense drugs and medicines until the pharmacy has notified the board as required by this subsection and the board has issued the pharmacy a certificate that authorizes the use of the mechanical device at the facility where the device will be located.

4. Any medical facility using a mechanical device pursuant to this section must make a record of any waste of a controlled substance according to NAC 639.486 either:

(a) In the mechanical device if the mechanical device can permanently make and keep such a record and allows for the recordation of the witnessing of the waste; or

(b) On a paper record made and maintained pursuant to NAC 639.486.

~~[3.]~~ ***5.*** As used in this section, "medical facility" has the meaning ascribed to it in NRS 449.0151.

Section 2. A pharmacy which supplies drugs and medicines to a medical facility which are furnished by a mechanical device pursuant to subsection 1 at the time of the passage of Section 1 of this regulation shall have until July 1, 2003 within which to notify the board of each mechanical device as required by subsection 3 of Section 1.

NOTICE OF ADOPTION OF TEMPORARY REGULATION
LCB File No. T023-03

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.