ADOPTED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R038-07

Effective October 31, 2007

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

AUTHORITY: §§1-3, NRS 639.070 and 639.2655.

A REGULATION relating to pharmacies; authorizing a pharmacy to use a mechanical device to furnish a prescription drug to a patient under certain circumstances; and providing other matters properly relating thereto.

Section 1. Chapter 639 of NAC is hereby amended by adding thereto a new section to read as follows:

1. Except as otherwise provided in this section, a pharmacy may use a mechanical device to furnish a prescription drug to a patient. The device must conform to all of the following provisions:

(a) The device must contain only prescription drugs:

(1) For which counseling is not required pursuant to NAC 639.707; and

(2) For which the prescriptions have been processed, verified and completed in the same manner as prescriptions for drugs that are delivered manually by the pharmacy, including the provision of printed medication guides and any other information required pursuant to NAC 639.707.

(b) The device must not contain controlled substances included in schedule II.

(c) The device must be designed to ensure that the device:

(1) Is located such that access to the device:

(I) For stocking, cleaning, maintenance or any other purpose can be obtained only by a pharmacist or a member of the staff of the pharmacy from within a secured area of the pharmacy; and

(II) Is secure from unauthorized access to and removal of prescription drugs from the device.

(2) Records the name of each person at the pharmacy who authorizes access to the device.

(3) Cannot be used by a patient:

(I) Outside the physical location of the pharmacy.

(II) Unless the patient previously has indicated to the pharmacy that he desires that his prescription drugs be furnished by the mechanical device.

(4) Provides a method to identify the patient and furnishes a prescription drug only to the patient or to an authorized agent of the patient.

(5) Can furnish one, any combination or all of the prescription drugs available to a patient at the option of the patient at the time that the patient removes the prescription drugs from the device.

(6) Records the date and time that the patient removes the prescription drugs from the device.

(7) Informs a patient:

(I) That a prescription drug is not available to be furnished by the device if the pharmacist wishes to counsel the patient regarding the prescription drug.

(II) If he is using the device at the time that the pharmacy is open, that the patient may discuss questions and concerns regarding the prescription drug with a pharmacist at the pharmacy.

(III) If he is using the device at the time that the pharmacy is closed, that the patient may discuss questions and concerns regarding the prescription drug using a toll-free telephone number at which a pharmacist at a pharmacy licensed by the Board will respond at all hours when the pharmacy at which the device is located is closed. A pharmacist who responds to questions or concerns pursuant to this sub-subparagraph must have access by computer to the same information regarding the patient that a pharmacist would have using the computer system of the pharmacy at which the device is located.

2. A pharmacy shall not use a mechanical device to furnish a prescription drug to a patient until the pharmacy has notified the Board in writing of:

(a) The type of device that will be used; and

(b) The anticipated date that the device will first be used.

3. The Board may prohibit a pharmacy from using a mechanical device to furnish a prescription drug to a patient if the Board determines that the device or the pharmacy's use of the device does not comply with this section.

4. The provisions of this section do not prohibit the use of a mechanical device to furnish a drug or device that is approved by the Food and Drug Administration for sale over the counter without a prescription if the pharmacy using the mechanical device is otherwise authorized to use the mechanical device pursuant to this section.

Sec. 2. NAC 639.715 is hereby amended to read as follows:

639.715 No drug, controlled substance, medicine, chemical or poison, as those terms are defined in chapters 453, 454 and 639 of NRS, may be sold or offered for sale or dispensed by means of any mechanical device except as ***otherwise*** provided in NAC 639.720 ~~[.]~~ ***and section 1 of this regulation.***

Sec. 3. NAC 639.940 is hereby amended to read as follows:

639.940 As used in NAC 639.940 to 639.943, inclusive, "computerized system to fill prescriptions" means an automated device operated by a computer which is used to prepare and package specified dosage units of drugs for dispensing to patients or ultimate users. The term does not include a mechanical device or mechanical counting device governed by NAC 639.720 or 639.725 ~~[.]~~ ***or section 1 of this regulation.***

NOTICE OF ADOPTION OF PROPOSED REGULATION
LCB File No. R038-07

The State Board of Pharmacy adopted regulations assigned LCB File No. R038-07 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.

The number of persons who attended the hearing was __2__.
The number of persons who testified at the hearing was __2__.
The number of agency submitted statements was __0__.

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 amended slightly as a result of testimony offered at the hearing.

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.

Enforcement of the regulation will be performed during annual inspections of all pharmacies. There will be no additional cost incurred by the board.

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.