Conforming Amendment to Page 5:

For the biennial renewal of authorization of a practitioner, other than a licensed veterinarian, to dispense controlled substances or dangerous drugs, or both, for human consumption for each location where the practitioner will dispense controlled substances or dangerous drugs, or 300 both, for human consumption For authorization of a licensed veterinarian to dispense controlled 150 substances or dangerous drugs, or both, not for human consumption For the biennial renewal of authorization of a licensed veterinarian to dispense controlled substances or dangerous drugs, or both, not for 150 human consumption For the investigation or issuance of an original license for an *500* automated drug dispensing system For the biennial renewal of a license for an automated drug dispensing *500* system For the investigation or issuance of an original [certificate] license to a pharmacy authorizing the use of a mechanical device at a location *250* off the premises of the pharmacy For the biennial renewal of a *[certificate]* license to a pharmacy authorizing the use of a mechanical device at a location off the premises of the 250 pharmacy

> --5--LCB Draft of Proposed Regulation R013-21

Conforming Amendment to Page 7:

- [7.] 6. A practitioner who is exempt from the payment of a fee pursuant to subsection [6] 5 shall notify the Board in writing of each change of address or additional address, or both.
- [8.] 7. In addition to any other fees paid by an applicant for a certificate, license or permit issued pursuant to chapter 639 of NRS, the Board may require that the applicant pay actual costs of inspection incurred by the Board.
 - **Sec. 2.** NAC 639.718 is hereby amended to read as follows:
- 639.718 1. Except as otherwise provided in this section, a pharmacy may use [a mechanical device to furnish] an automated drug dispensing system to dispense a prescription drug to a patient if the pharmacy obtained a license from the Board for the automated drug dispensing system.
- 2. The Board will provide to a pharmacy an application for a license for an automated drug dispensing system upon request. The Board will issue a license for an automated drug dispensing system if the application for a license is approved and the requisite fee is paid. A license must be:
 - (a) Issued for each automated drug dispensing system at a designated location; and
 - (b) Posted on the system so that the license is visible to the public.
- 3. The [device] automated drug dispensing system must conform to all of the following provisions:
 - (a) The **[device]** system must contain only prescription drugs:
- (1) Approved for use in the system by a registered pharmacist employed by the pharmacy;

 [(1)] (2) For which counseling is not required pursuant to NAC 639.707[;], unless the system uses user-based access technology that includes, without limitation, an audio-visual

--7--LCB Draft of Proposed Regulation R013-21

Conforming Amendments to NAC 639.720:

- 1. Except as otherwise provided in [subsections 4 and 6] this section, a mechanical device may be used to furnish drugs and medicines for administration to registered patients in a medical facility by obtaining a license from the Board for the mechanical device in conformance with subsection 4. A license shall not be required for a mechanical device in a hospital that meets the requirements of this section.
 - 2. The *mechanical* 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 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, 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.
- 3. [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. The Board will issue a license for mechanical device if the application for a license is approved and the requisite fee is paid. A license [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 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 <u>NAC 639.486</u>; or
 - (b) As a written record.
- 6. A mechanical device may be used to furnish drugs and medicines for *administration to* 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

(c) [Use of the device to furnish a drug or medicine to a patient must be:

- (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.
- (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 drug or medicine that is furnished to the patient;
- (IV) Personally verifies the correctness of the prescription for the drug or medicine before he or she 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 or she 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 <u>NRS</u> 639.2801.]
 - (d) (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] administration to a patient;
 - (II) The day and time access to the device is obtained;
- (III) If a drug or medicine is removed for [dispensing] 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 unique code which identifies that person.
- (e) [(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.