PROPOSED REGULATION OF THE STATE BOARD OF PHARMACY

LCB FILE NO. R179-22I

The following document is the initial draft regulation proposed by the agency submitted on 08/03/2022

Proposed Regulation of the Nevada State Board of Pharmacy

Workshop – July 14, 2022

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

AUTHORITY: § 1, NRS 639.070; §§ 2-5, NRS 639.070 and 639.2655.

A REGULATION relating to pharmacy; requiring a license to distribute drugs through certain mechanical means; prescribing fees for such licensure; proscribing requirements governing the use of such mechanical means to distribute drugs; and providing other matters properly relating thereto.

Digest:

Existing law authorizes the State Board of Pharmacy to adopt regulations: (1) relating to the practice of pharmacy as necessary for the protection of the public; and (2) governing the dispensing, recordkeeping, storage and handling of drugs. Additionally, existing law authorizes the Board to charge and collect fees for any incidental service the Board provides. (NRS 639.070) Existing law further authorizes the use of computerized mechanical equipment to perform work that a pharmacist is authorized to perform by law in accordance with the regulations adopted by the Board. (NRS 639.2655)

Existing regulations authorize pharmacies and medical facilities to use mechanical devices to dispense drugs to a patient. (NAC 639.718, 639.720) **Section 3** of this regulation: allow a pharmacy operated by a governmental agency to locate an automated drug dispensing system at any location operated by the governmental agency.

Section 1. NAC 639.220 is hereby amended to read as follows:

639.220 1. The Board hereby adopts the following schedule of fees:

For the examination of an applicant for registration as a pharmacist	Actual cost of the examination
For the investigation or registration of an applicant as a registered pharmacist	$200
For the investigation, examination or registration of an applicant as a registered pharmacist by reciprocity	200
For the investigation or issuance of an original license to conduct a retail pharmacy	500
For the biennial renewal of a license to conduct a retail pharmacy	500
For the investigation or issuance of an original license to conduct an institutional pharmacy	500
For the biennial renewal of a license to conduct an institutional pharmacy	500
For the investigation or issuance of an original license to conduct a pharmacy in a correctional institution	500

For the biennial renewal of a license to conduct a pharmacy in a correctional institution 500

For the investigation or issuance of an original license to conduct a pharmacy in a recovery center or ambulatory surgical center licensed by the State Board of Health pursuant to NRS 449.0303..... 500

For the biennial renewal of a license to conduct a pharmacy in a recovery center or ambulatory surgical center licensed by the State Board of Health pursuant to NRS 449.0303. 500

For the issuance of an original or duplicate certificate of registration as a registered pharmacist 50

For the biennial renewal of registration as a registered pharmacist 200

For the reinstatement of a lapsed registration (in addition to the fees for renewal for the period of lapse) 100

For the initial registration of a pharmaceutical technician or pharmaceutical technician in training 50

For the biennial renewal of registration of a pharmaceutical technician or pharmaceutical technician in training..... 50

For the investigation or registration of an intern pharmacist 40

For the biennial renewal of registration as an intern pharmacist 40

For the investigation or registration of an advanced practice registered

nurse or a physician assistant to prescribe drugs that are not controlled substances 80

For the biennial renewal of registration of an advanced practice registered nurse or a physician assistant to prescribe drugs that are not controlled substances

.....

80

For authorization of a physician, advanced practice registered nurse, physician assistant, euthanasia technician, facility for treatment with narcotics, researcher, instructional user or any other authorized person, except a practitioner who is a medical intern or resident physician, to

prescribe or possess controlled substances 200

For the biennial renewal of authorization of a physician, advanced practice registered nurse, physician assistant, euthanasia technician, facility for treatment with narcotics, researcher, instructional user or any other authorized person, except a practitioner who is a medical intern or resident physician, to prescribe or possess controlled substances 200

For authorization of a practitioner who is a medical intern or resident physician to prescribe or possess controlled substances. 80

For the biennial renewal of authorization of a practitioner who is a medical intern or resident physician to prescribe or possess controlled substances.

.....

80

For the investigation or issuance of an original license to engage in business as an authorized warehouse, medical products provider or medical products wholesaler 500

For the biennial renewal of a license to engage in business as an authorized warehouse, medical products provider or medical products wholesaler 500

For the investigation or issuance of an original license to a manufacturer or wholesaler 500

For the biennial renewal of a license for a manufacturer or wholesaler 500

For the reissuance of a license issued to a pharmacy, when no change of ownership is involved, but the license must be reissued because of a change in the information required thereon 50

For 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 both, for human consumption 300

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 both, for human consumption 300

For authorization of a licensed veterinarian to dispense controlled substances or dangerous drugs, or both, not for human consumption 150

For the biennial renewal of authorization of a licensed veterinarian to dispense controlled substances or dangerous drugs, or both, not for human consumption 150

For the investigation or issuance of an original license for an automated drug dispensing system.....500

For the biennial renewal of a license for an automated drug dispensing system.....500

For the investigation or issuance of an original license to a pharmacy authorizing the use of a mechanical device to furnish drugs and medications for administration to patients at a medical facility.....250

For the biennial renewal of a license to a pharmacy authorizing the use of a mechanical device to furnish drugs and medications for administration to patients at a medical facility.....250

2. The penalty for failure to pay the renewal fee for any license, permit or certificate within the statutory period, as provided in subsection 6 of NRS 639.170, is 50 percent of the renewal fee for each period of delinquency in addition to the renewal fee for each period of delinquency.

3. Any person who has been registered as a pharmacist in this State for at least 50 years is not required to pay the fee for the biennial renewal of a certificate of registration as a registered pharmacist.

4. The provisions of this section concerning the fee for the biennial renewal of the authorization to dispense controlled substances or dangerous drugs do not apply to an advanced practice registered nurse who is required to pay a fee pursuant to NAC 639.870.

5. A practitioner employed by or serving as an independent contractor of a health center:

(a) Which is a federally-qualified health center that provides health care primarily to medically underserved persons in a community; and

(b) Which is not a medical facility as defined in NRS 449.0151,

↪ is not required to pay a fee to the Board for a change of address or for an additional address at which the practitioner dispenses drugs.

6. A practitioner who is exempt from the payment of a fee pursuant to subsection shall notify the Board in writing of each change of address or additional address, or both.

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 639.715 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 ***automated drug dispensing system or other*** mechanical device except as otherwise provided in NAC 639.718 and 639.720.

Sec. 3. NAC 639.718 is hereby amended to read as follows:

639.718 1. Except as otherwise provided in this section, a pharmacy may use

an automated drug dispensing system to dispense a prescription drug to a patient *if the pharmacy obtains a license from the Board for the automated drug dispensing system pursuant to subsection 2.*

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 Board determines that the system dispenses prescription drugs accurately and other otherwise meets the requirements of this section and the fee prescribed by NAC 639.220 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 *automated drug dispensing system* must conform to all of the following provisions:

(a) The *system* must contain only prescription drugs:

(1) *Approved for use in the system by a registered pharmacist employed by the pharmacy;* 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 *system* must not contain*:*

(1) Controlled substances included in schedule II*; or*

(2) Controlled substances included in schedules III, IV and V, unless authorized by the Drug Enforcement Administration of the United States Department of Justice to dispense such substances.

(c) The *system* must*:*

(1) *Control and track access to the system for* stocking, cleaning, maintenance or any other purpose *to ensure that access to the system* can be obtained only by a *registered* pharmacist*,*

pharmaceutical technician, or intern pharmacist employed by the pharmacy *using user-based access technology.*

(2) *Be* secure from unauthorized access to and removal of prescription drugs*.*

(3) Be owned or leased by the pharmacy that holds the license for the system and operated under the supervision and control of that pharmacy.

(4) Monitor the temperature of the system or be able to have a device installed to monitor the temperature of the system. Such monitoring must include, without limitation, an alarm that records when the temperature of the system reaches a level outside the range compatible with the proper storage of a prescription drug and a method to notify the pharmacy of the temperature change.

(5) Create and maintain a complete, accurate and readily retrievable record of all transactions. The record must include, without limitation:

(I) The name, strength, quantity and form of dosage of each prescription drug stocked, inventoried, removed or dispensed from the system;

(II) Each day and time the system is accessed;

(III) An inventory of the prescription drugs stored in the system; and

(IV) The identity of each person who accesses the system.

(6) Authorize access only to patients who previously *have* indicated to the pharmacy *their desire to have their* prescription drugs *dispensed* by the *system.*

(7) Provide a method to identify the patient and *dispense* a prescription drug

only to the patient or to an authorized agent of the patient.

(8) Dispense 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 *system.*

(9) Record the date and time that the patient removes the prescription drugs from the *system.*

(10) Inform a patient:

(I) If the patient is using the *system* 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 *or through the user-based access technology described in subparagraph (14).*

(II) If the patient is using the *system* at the time that the pharmacy is closed,

that the patient may discuss questions and concerns regarding the prescription drug *through the user-based access technology described in subparagraph (14).*

(III) That the patient may choose not to purchase the prescription drug from the system at any time before the system dispenses the prescription drug.

(11) Dispense all prescription drugs in containers labeled in conformance with NRS 639.2801.

(12) Be installed in such a place and manner that a person is unable to remove the system from its location and any attempts to obtain access to the system without authorization are visible to the pharmacist of the pharmacy, either through the system being in view of the pharmacist or by real-time audio-visual communication technology or audio-visual recording technology.

(13) Be located in a:

(I) Pharmacy;

(II) Medical facility, as defined in NRS 449.0151, other than a mobile unit; or

(III) Practice site of one or more practitioners of medicine.

(IV) An automated drug dispensing system operated by a pharmacy owned by the Division of Public and Behavioral Health of the Department of Health and Human Services or county health department, may be located at any site operated by the government agency.

(14) Be equipped with user-based access technology that includes, without limitation, an audio-visual function that allows the patient to communicate, in real time, with a registered pharmacist who has access to any patient record necessary for counseling the patient in compliance with NAC 639.707 and 639.708.

4. A pharmacy that dispenses prescription drugs by an automated drug dispensing system pursuant to this section shall maintain a written policy that sets forth:

(a) The duties of all persons who are authorized to access the system; and

(b) The procedures for:

(1) Maintaining the security of the prescription drugs stored in the system during the maintenance and repair of the system;

(2) The preparation of an inventory of the prescription drugs stored in the system; and

(3) Stocking the system with prescription drugs.

5. A pharmacy that dispenses prescription drugs through an automated drug dispensing system pursuant to this section shall comply with all applicable federal and state recordkeeping requirements and shall maintain those records in a readily retrievable manner separate from other pharmacy records.

6. Prescription drugs stored in an automated drug dispensing system pursuant to this section shall be deemed part of the inventory and the responsibility of the pharmacy that holds the license for the system. Prescription drugs dispensed from the system shall be deemed to have been dispensed by that pharmacy.

7. The Board may prohibit a pharmacy from using *an automated drug dispensing system* to furnish a prescription drug to a patient if the Board determines that the *system* or the pharmacy's use of the *system* does not comply with this section.

8. The provisions of this section do not prohibit the use of *an automated drug dispensing system* 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 *system* is otherwise authorized to use the *system* pursuant to this section.

9. As used in this section:

(a) "Automated drug dispensing system" means a system that performs operations, other than compounding or administration, related to the storage and dispensing of drugs.

(b) "User-based access technology" means software or hardware that restricts access to an automated drug dispensing system to authorized users by requiring two-factor authentication. Authentication factors may include, without limitation, knowledge, hardware tokens or biometric information.

Sec. 4. NAC 639.720 is hereby amended to read as follows:

639.720 1. Except as otherwise provided in *this section,* a mechanical device*, other than an automated drug dispensing system licensed pursuant to*

NAC 639.718, may be used to furnish drugs and medicines for administration to registered patients in a medical facility *if the pharmacy which supplies drugs and medicines to the medical facility has obtained a license from the Board for a mechanical device pursuant to subsection 4. A license is not required for a mechanical device that meets the requirements of this section and is located inside a hospital licensed pursuant to chapter 449 of NRS.*

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. 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.

4. ***The Board will issue a license for*** a mechanical device ***if the Board determines that the mechanical device meets the requirements of this section and the fee required by NAC 639.220***

is paid. A license 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 NAC 639.486; 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

(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) 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 unique code which identifies that person.

(d) 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.

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

Sec. 5. 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 ***an automated drug dispensing system,*** a mechanical device or mechanical counting device governed by NAC 639.718, 639.720 or 639.725.