

**PROPOSED REGULATION OF THE  
STATE BOARD OF PHARMACY**

**LCB File No. R013-21**

October 28, 2021

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

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

A REGULATION relating to pharmacy; establishing certain fees relating to the use of an automated drug dispensing system or a mechanical device at certain locations; authorizing a pharmacy to dispense prescription drugs to a patient using an automated drug dispensing system under certain circumstances; and providing other matters properly relating thereto.

**Legislative Counsel’s Digest:**

Existing law authorizes the State Board of Pharmacy to adopt regulations relating to the practice of pharmacy as necessary for the protection of the public. Existing law authorizes the Board to adopt regulations 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 allows a pharmacist to use 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)

Under existing regulations, the Board has adopted a schedule of fees for certain applications, licenses and registrations. (NAC 639.220) **Section 1** of this regulation adds fees for the licensing of an automated drug dispensing system and the certification of certain mechanical devices to the schedule of fees. **Section 1** also makes a conforming change by removing a reference to a previously deleted fee.

Existing regulations authorize pharmacies and medical facilities to use mechanical devices to dispense drugs to a patient. (NAC 639.718, 639.720) **Section 2** of this regulation establishes certain requirements that a pharmacy must follow to use an automated drug dispensing system. **Section 2** requires an automated drug dispensing system to track who uses the system, what drugs are in the system, the temperature of the system and other information to ensure that the drugs in the system are safely stored and only dispensed to a person authorized to receive the dispensed drug. **Section 2** of this regulation further requires the Board to issue a license to a pharmacy for an automated drug dispensing system upon approval of an application for a license by the Board and payment of the requisite fee.

**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 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, ambulatory surgical center, facility for treatment with narcotics, researcher, instructional user or any other authorized person to prescribe or possess controlled substances .....	200

For the biennial renewal of authorization of a physician, advanced practice registered nurse, physician assistant, euthanasia technician, ambulatory surgical center, facility for treatment with narcotics, researcher, instructional user or any other authorized person to prescribe or possess controlled substances.....	200
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
<i>For the investigation or issuance of an original license for an automated drug dispensing system.....</i>	<i>500</i>
<i>For the biennial renewal of a license for an automated drug dispensing system .....</i>	<i>500</i>
<i>For the investigation or issuance of an original certificate to a pharmacy authorizing the use of a mechanical device at a location off the premises of the pharmacy.....</i>	<i>250</i>
<i>For the biennial renewal of a certificate to a pharmacy authorizing the use of a mechanical device at a location off the premises of the pharmacy.....</i>	<i>250</i>

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 health center:~~

~~—(a) Which is a federally qualified health center as defined in 42 U.S.C. § 1396d(l)(2)(B), as that section existed on March 1, 2000, 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 the fee for the collective certification of advanced practice registered nurses in the employ of a public or nonprofit agency as set forth in subsection 1.~~

~~—6.1~~ A practitioner employed by or serving as an independent contractor of a health center:

(a) Which is a federally qualified health center as defined in 42 U.S.C. § 1396d(l)(2)(B), as that section existed on March 1, 2000, 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.

~~{7.}~~ 6. A practitioner who is exempt from the payment of a fee pursuant to subsection 6 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~~{5.}~~, unless the system uses 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; and*

~~(2)~~ (3) 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~~ *system* must not contain :

(1) ~~controlled~~ *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 ~~device~~ *system* must: ~~be designed to ensure that the device:~~

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

~~(I) For~~ *Control and track access to the system for* stocking, cleaning, maintenance or any other purpose *so that access to the system* can be obtained only by a pharmacist or a member of the staff of the pharmacy from within a secured area of the pharmacy *using user-based access technology.* ~~;~~ *and*

~~(II) Is~~

(2) *Be* 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~~

*(3) Be owned or leased by the pharmacy who obtained the license for the automated drug dispensing 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, including, 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) Restrict access to a patient **who** previously has indicated to the pharmacy that the patient desires that his or her prescription drugs be ~~{furnished}~~ **dispensed** by the ~~{mechanical device}~~ system.*

~~{(4) Provides}~~ *(7) Provide* a method to identify the patient and ~~{furnishes}~~ **dispense** a prescription drug only to the patient or to an authorized agent of the patient.

~~{(5) Can furnish}~~ (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 ~~{device}~~ *system*.

~~{(6) Records}~~ (9) *Record* the date and time that the patient removes the prescription drugs from the ~~{device}~~ *system*.

~~{(7) Informs}~~ (10) *Inform* a patient:

(I) That a prescription drug is not available to be ~~{furnished}~~ *dispensed* by the ~~{device}~~ *system* if the pharmacist wishes to counsel the patient regarding the prescription drug.

(II) If the patient is using the ~~{device}~~ *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 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.*

(III) If the patient is using the ~~{device}~~ *system* 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.}~~ *through 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.*

*(IV) 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 device 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 subsections 1 to 14, inclusive, or 16 of NRS 449.0151; or*

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

*(14) Be approved for use by the Board upon determination that the system:*

*(I) Dispenses prescription drugs accurately; and*

*(II) Otherwise satisfies the provisions of this section.*

~~{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.}~~

*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 was issued the license for the system. Prescription drugs dispensed from the system shall be considered to have been dispensed by that pharmacy.*

~~{3.}~~ 7. The Board may prohibit a pharmacy from using a ~~{mechanical device}~~ system to furnish a prescription drug to a patient if the Board determines that the ~~{device}~~ system or the pharmacy's use of the ~~{device}~~ system does not comply with this section.

~~{4.}~~ 8. The provisions of this section do not prohibit the use of a ~~{mechanical device}~~ 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 ~~{mechanical device}~~ system is otherwise authorized to use the ~~{mechanical device}~~ 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 the system to authorized users by requiring two-factor authentication. Authentication factors may include, without limitation, knowledge, hardware tokens or biometric information.*