Proposed Regulation of the Nevada State Board of Pharmacy

Workshop – March 4, 2021

Explanation – Language in ***blue italics*** is new; language in ***red text*** [~~*omitted material*~~] is language to be omitted, and language in ***green text*** indicates prior Board-approved amendments that are in the process of being codified.

AUTHORITY: NRS 639.070; NRS639.170; NRS 639.2655

A REGULATION relating to the use of a mechanical device to furnish a prescription drug to a patient; and providing other matters properly relating thereto.

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

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.....	$180
For the investigation, examination or registration of an applicant as a registered pharmacist by reciprocity.....	180
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.....	180
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.....	40
For the biennial renewal of registration of a pharmaceutical technician or pharmaceutical technician in training.....	40
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.....	80
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.....	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 each location where the practitioner will dispense controlled substances or dangerous drugs, or both.....	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 each location where the practitioner will dispense controlled substances or dangerous drugs, or both.....	300
For authorization of a licensed veterinarian to dispense controlled substances or dangerous drugs, or both.....	150
For the biennial renewal of authorization of a licensed veterinarian to dispense controlled substances or dangerous drugs, or both.....	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 certificate to a pharmacy authorizing the use of a mechanical device at a location off the premises of the pharmacy	***250***
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	***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 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,

Ê 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. 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,

Ê 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. 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.

Section. 2. NAC 639.718 is hereby amended to read as follows:

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 applies for and obtains a license from the Board. Each application for such a license must be made on a form furnished by the Board. Upon approval of the application by the Board and the payment of the required fee, the Board shall issue a license to the applicant. Each license must be issued for a specific system at a designated location, posted on the system and visible to the public***. The ~~***device***~~ ***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 utilizes user-based access technology that includes a real-time audiovisual function that links the patient to a registered pharmacist who has access to the electronic health records necessary for patient counseling***; 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 controlled substances included in schedule II***, or controlled substances in schedules III-V unless authorized by the federal Drug Enforcement Administration 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*~~ ***Control and track access to the device utilizing user-based access technology***~~*:*~~

~~*(I) F*~~for stocking, cleaning, maintenance or any other purpose ~~*can be obtained*~~ only by a ***registered*** pharmacist***, pharmaceutical technician, or intern pharmacist employed by the pharmacy*** ~~*or a member of the staff of the pharmacy from within a secured area of the pharmacy*~~; ~~*and*~~

~~*(II) Is*~~ ***(2) Be secure from unauthorized access to and removal of prescription drugs*** ~~*from the device;*~~

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

(4) Include a programmable device for monitoring temperature which includes an alarm that records when the temperature falls outside the range compatible with the proper storage of the drugs and a notification to the pharmacy.

(~~2~~5) ***Create and maintain a complete, accurate, and readily retrievable r~~~~R~~~~***ecord~~~~s~~~~ of all transactions that includes all users accessing the system and all drugs added to, or removed from, the system, including:*** ~~*the name of each person at the pharmacy who authorizes access to the device.*~~

(I) The name, strength, quantify and form of dosage of the drug which is stocked, inventoried, removed or dispensed from the system.

(II) The day and time access to the system is obtained

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

(IV) The identity of the person who obtained access to the system.

~~*(3) Cannot be used by a patient:*~~

~~*(I) Outside the physical location of the pharmacy.*~~

~~*(II) Unless the*~~ ***(6) Restrict access only to a*** patient ***that*** 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~~7) Provide~~s~~ 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~~8) ~~*Can furnish*~~ ***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~~9) Record~~s~~ the date and time that the patient removes the prescription drugs from the ~~*device*~~ ***system***.

(~~7~~10) Inform~~s~~ 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 the use of user-based access technology that includes a real-time audiovisual function that links the patient to a registered pharmacist who has access to the electronic health records necessary for patient counseling***.

(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 the use of user-based access technology that includes a real-time audiovisual function that links the patient to a registered pharmacist who has access to the electronic health records necessary for patient counseling*.

(IV) That he or she may choose not to purchase the drug from the system at any time before the system dispenses the drug.

(11) Dispense all drugs in a container 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 that attempts to obtain access to the device without authorization are visible to the pharmacist of the pharmacy in person or by real-time audiovisual function or audiovisual recording.

(12) Be located in a:

(I) Pharmacy;

(II) Medical facility licensed pursuant to subsections 1-14 or 16 of NRS 449.0151; or

(II) Practice site location of one or more practitioners.

2. A pharmacy which dispenses drugs by a system pursuant to this section shall maintain a written policy which sets forth:

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

(b) The procedure for:

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

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

(3) Stocking the system with drugs.

~~*2*~~*3. ~~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.*~~

The Board will not approve a license pursuant to this section until the manufacturer of the system appears before the Board for its approval of that use of the system and submits evidence satisfactory to the Board that the system:

(a) Dispenses drugs accurately; and

(b) Otherwise satisfies the provisions of this section.

4. A pharmacy which dispenses drugs by a 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.

5. Drugs stored in a system pursuant to this section shall be deemed part of the inventory and the responsibility of the pharmacy issued the license for the system, and drugs dispensed from the system shall be considered to have been dispensed by that pharmacy

~~*4*~~*6*. 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.

~~5~~*7.* 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 ~~*mechanical device*~~ *system* pursuant to this section.

8. As used in this section:

(a) "Automated drug dispensing system" means a system that performs operations, other than compounding or administration, relative to the storage and dispensing of drugs. An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.

(b) "Electronic health record" has the meaning ascribed to it in 42 U.S.C. § 17921(5); and

(c) "User-based access technology" means a secure system restricting access to authorized users by requiring two-factor authentication, including, without limitation, knowledge factor, hard token, or biometric information.

Section. 3. NAC 639.720is hereby amended to read as follows:

1. Except as otherwise provided in subsections 4 and 6, 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 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.

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. A 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 NAC 639.486; or

(b) As a written record.

6. A mechanical device may be used to furnish drugs and medicines for 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) Use of the device to furnish a drug or medicine to a patient must be:

(1) 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 NRS 639.2801.

(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 to a patient;

(II) The day and time access to the device is obtained;

(III) If a drug or medicine is removed for dispensing 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.

(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.