Proposed Regulation of the Nevada State Board of Pharmacy

Workshop – July 14, 2022

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.

AUTNORITY: NRS 639.070, NRS 639.0727

A REGULATION relating to dispensing technicians in training and dispensing technicians; and providing other matters properly relating thereto.

Section 1. Chapter 639 of NAC is hereby amended by adding thereto the provisions set forth is sections 2 of this regulation.

Sec. 2.

1. ***An applicant for registration as a dispensing technician in training must:***
   (a) Be 18 years of age or older;
   (b) Be a high school graduate or the equivalent; and
   (c) Participate in training provided by a registered dispensing practitioner while on the job and acquire experience that is commensurate with the duties of his or her employment.
2. ***An applicant for registration as a dispensing technician in training must submit to the Board a complete and accurate application on a form provided by the Board, along with the requisite fee.***
3. ***The Board may deny an application for registration as a dispensing technician in training if the applicant has:***
   (a) Been convicted of any felony or a misdemeanor involving moral turpitude, dishonesty or the unlawful possession, sale or use of drugs; or
   (b) A history of drug abuse.
4. ***A person may perform the duties of a dispensing technician while the person is receiving the training and experience required by paragraph (c) of section 1 if he or she is registered with the Board.***
5. ***If the Board determines that the applicant meets the requirements of this chapter and chapter 639 of NRS for registration as a dispensing technician in training, the Board will issue a certificate or registration as a dispensing technician in training to the applicant.***
6. ***Registration as a dispensing technician in training expires on October 31 of each even-numbered year unless renewed before that date.***
7. ***The dispensing technician in training shall, within 10 days after changing or adding a new place of practice or changing or adding a registered dispensing practitioner for which they will receive***

training to perform the functions set forth in section 4 of NRS 639.742, notify the Board, on a form prescribed by the Board, of the change.

Sec. 3. NAC 639.7425 is hereby amended to read as follows:

1. Except as otherwise provided in NAC 639.7423, no person may *perform the duties of* ~~act as~~ a dispensing technician *until the person has been issued a certificate of registration as a dispensing technician* ~~unless the person is:~~

   ~~(a) A registered pharmaceutical technician; or~~

   ~~(b) Employed at a facility to which a certificate of registration has been issued pursuant to NAC 639.742. and the dispensing practitioner at that facility has registered the person as a dispensing technician.~~

2. ~~A dispensing practitioner may apply to the Board to register a person as a dispensing technician by submitting to the Board the fee required by NAC 639.744 and proof satisfactory to the Board that the person~~ *An applicant for registration as a dispensing technician must*:

   (a) *Be* ~~Is~~ 18 years of age or older;

   (b) *Be a high school graduate* ~~Has received a high school diploma~~ or its equivalent; *and*

   (c) Have complied with one of the following requirements:

      (1) The successful completion of at least 1,500 hours of training and experience as a registered dispensing technician in training providing the services set forth in section 4 of NAC 639.742. The training must be provided by a dispensing practitioner to which a certificate of registration has been issued pursuant to NAC 639.742. The applicant must provide with the application a form prescribed by the Board and completed by the registered dispensing practitioner from which the applicant received training, verifying the completion of such training and experience. The dispensing practitioner shall supervise the training and experience of the person by observing the work of the person. A dispensing technician in training may accumulate certified hours of training from each registered dispensing practitioner with whom they are employed and receiving training.

      (2) Active registration and in good standing as a registered pharmaceutical technician in this state.

3. *An applicant for registration as a dispensing technician must submit to the Board a complete and accurate application on a form provided by the Board, along with the requisite fee.*

4. *The Board may deny an application for registration as a dispensing technician if the applicant has:*

   ~~(c)~~ *(a)* ~~Has not~~ *B*een convicted of any felony or misdemeanor involving moral turpitude, dishonesty or the unlawful possession, sale or use of drugs; and

~~(d)~~ *(b)* ~~Does not have~~ *A* history of drug abuse.

5. ***If the Board determines that the applicant meets the requirements of this chapter and chapter 639 of NRS for registration as a dispensing technician, the Board will issue a certificate of registration as a dispensing technician to the applicant.***
6. ***Registration as a dispensing technician expires October 31 of each even-numbered year unless renewed before that date.***
7. ***The registered dispensing practitioner where a dispensing technician in training is employed to receive the training and experience required by paragraph (1) of section (2)(c)***

~~3. Upon determining that a person for whom application for registration as a dispensing technician has been made by a dispensing practitioner satisfies the requirements of subsection 2, the Board will issue to the person a provisional registration as a dispensing technician for that practitioner.~~

~~4. A person acting as a dispensing technician pursuant to a provisional registration must complete at least 500 hours of training and experience provided by the dispensing practitioner relating to the skills that the person will be performing as a dispensing technician for that dispensing practitioner. Only that training and experience received by the person after the provisional registration is issued may be applied to satisfy the 500-hour requirement. In providing the training and experience, the dispensing practitioner shall supervise the training and experience of the person by observing the work of the person on a random basis at least three times each day during which the person is receiving training and experience.~~

~~5. A provisional registration issued to a person acting as a dispensing technician expires 12 months after it is issued or upon the expiration of the certificate of registration of the dispensing practitioner to whom the dispensing technician is registered, whichever is earlier. If a person acting as a dispensing technician pursuant to a provisional registration:~~

~~(a) Fails to complete the required 500 hours of training and experience before the expiration of the provisional registration, the person shall not act as a dispensing technician unless he or she is issued a new provisional registration pursuant to this section. Any hours of training and experience completed by the person while acting as a dispensing technician pursuant to a provisional registration that has expired may not be used to satisfy the 500-hour requirement for a new provisional registration.~~

~~(b) Completes the required 500 hours of training and experience before the expiration of the provisional registration, the dispensing practitioner~~ shall file with the Board a ***completed form prescribed by the Board*** ~~signed affidavit~~ certifying:

(1) The number of hours of training and experience successfully completed by the person.

(2) The specific training and experience received by the person.

(3) That the person is, in the opinion of the ***registered*** dispensing practitioner, competent to perform the duties of a dispensing technician.

~~6. The Board, upon receiving the affidavit of the dispensing practitioner pursuant to subsection 5, will issue to the person a certificate of registration as a dispensing technician for that practitioner.~~

8. A dispensing technician shall complete at least 1 hour of in-service training during the 2-year period immediately preceding the renewal of the registration of the dispensing technician. The training must be a jurisprudence program approved or presented by the Board that relates to the practice of pharmacy or the law concerning pharmacy in this State. The dispensing technician shall retain a copy of the certificate from the Board or approved program certifying the completion of such in-service training. The copy must be:

(a) Retained for at least 2 years; and

(b) Readily accessible to a member of the Board or a person conducting an inspection or investigation on behalf of the Board.

9. The dispensing technician shall, within 10 days after changing or adding a new place of practice or changing or adding a registered dispensing practitioner for which they will perform the functions set forth in section 4 or 5 of NAC 639.742, notify the Board, on a form prescribed by the Board, of the change.

Sec. 4. NAC 639.743 is hereby amended to read as follows:

1. Except as otherwise provided in NRS 639.23277 and NAC 639.395, a person to whom a dispensing practitioner is providing training and experience pursuant to ***paragraph (c)(1) of*** ~~sub~~section ~~4~~ ***2*** of NAC 639.7425 must not be allowed access to the room or cabinet in which drugs are stored unless accompanied by the dispensing practitioner. After the person has completed his or her training and experience and the Board ***has issued a certificate of registration as a dispensing technician to the person*** ~~has received an affidavit from the dispensing practitioner pursuant to subsection 5 of NAC 639.7425~~:

(a) The person may access the room or cabinet in which drugs are stored without being accompanied by the dispensing practitioner, so long as the dispensing practitioner is on-site at the facility; and

(b) The dispensing practitioner is not required to observe the work of the person.

2. A dispensing practitioner who allows a dispensing technician to perform any function described in subsection 4 or 5 of NAC 639.742 is responsible for the performance of that function by the dispensing technician. All such functions performed by a dispensing technician must be performed at the express direction and delegation of the dispensing practitioner. Each prescription with respect to which a dispensing technician performed such a function:

(a) Must be checked by the dispensing practitioner, and the dispensing practitioner shall indicate on the label of the prescription and in his or her record regarding the prescription that the dispensing practitioner has checked the work performed by the dispensing technician; and

(b) Must not be dispensed to the patient without the initials of the dispensing practitioner thereon. A prescription which has been so initialed must be handed to the patient only by the dispensing practitioner or an employee authorized by the dispensing practitioner.

Sec. 5. NAC 639.7435 is hereby amended to read as follows:

1. The registration of a dispensing technician is ~~non~~transferable~~. and limited to the dispensing practitioner to whom the dispensing technician is registered. The registration of a dispensing technician expires at the same time that the certificate of registration of the dispensing practitioner expires. If a dispensing practitioner and the dispensing technician registered to that practitioner leave the facility at which they are registered, and the dispensing technician continues his or her employment with that practitioner at a different site, the dispensing practitioner shall, as soon as practicable, notify the Board of the change of address of employment of the dispensing technician.~~

~~2. If a dispensing technician no longer works as a dispensing technician for the dispensing practitioner to whom the dispensing technician is registered, the registration of the dispensing technician terminates. Except as otherwise provided in NAC 639.7423, if that person is subsequently employed by another dispensing practitioner to work as a dispensing technician, the employing dispensing practitioner must, before the person may act as a dispensing technician for that practitioner:~~

~~(a) Register the person with the Board, showing the site of employment and the name of the dispensing practitioner; and~~

~~(b) Ensure that the person receives an additional 200 hours of training and experience provided by the dispensing practitioner. The additional training and experience must be provided in accordance with subsection 4 of NAC 639.7425. Except as otherwise provided in NRS 639.23277 and NAC 639.395, the dispensing practitioner shall not allow the person to be registered as a dispensing technician to enter the room or cabinet in which drugs are stored or perform any function described in subsection 4 or 5 of NAC 639.742 without the dispensing practitioner observing the act by the person to be registered as a dispensing technician until that person has completed the 200 additional hours of training and experience~~.

2. The dispensing technician shall, within 10 days, after changing or adding a new place of practice or changing or adding a registered dispensing practitioner for which they will perform the functions set forth in section 4 or 5 of NAC 639.742, notify the Board, on a form prescribed by the Board, of the change.

Sec. 6. NAC 639.744 is hereby amended to read as follows:

1. ~~A dispensing practitioner shall pay to the Board a fee of $40 for each dispensing technician whom that practitioner registers:~~

~~(a) At the time of application by the dispensing practitioner for initial registration of the person as a dispensing technician; and~~

~~(b) With the practitioner's renewal thereafter as a part of and in addition to the practitioner's renewal of his or her registration as a dispensing practitioner.~~

~~2.~~ A dispensing practitioner may ~~register~~ ***employ*** more than one ***registered*** dispensing technician at a time, except that only one of those dispensing technicians, including, without limitation, a dispensing technician staffing a remote site or satellite consultation site, may be designated and allowed to perform the functions described in subsection 4 or 5 of NAC 639.742 at one time. A dispensing practitioner shall make and maintain a document on which must be recorded for each day the name of the dispensing technician so designated and allowed to perform the functions described in subsection 4 or 5 of NAC 639.742, and maintain the record for not less than 2 years.

Sec. 7. 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.....**$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**, *dispensing technician, or dispensing technician in training*.....50**

For the biennial renewal of registration of a pharmaceutical technician**, ~~or~~** pharmaceutical technician in training**, *dispensing technician, or dispensing 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.....**1,000**

For the biennial renewal of a license for a manufacturer or wholesaler.....**1,000**

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, 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 at a location off the premises of the pharmacy ……250

For the biennial renewal of a license to a pharmacy authorizing the use of a mechanical device at a location off the premises of the pharmacy ……250

PROPOSED REGULATION OF THE 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: §§1-3, NRS 639.070.

A REGULATION relating to pharmacy; establishing the requirements for a group of practitioners practicing at a reproductive healthcare center to obtain a certificate of registration from the State Board of Pharmacy to maintain a single inventory of certain dangerous drugs received at a site of practice; prescribing the procedure for renewing such a certificate; prescribing certain powers and duties of the dispensing practitioners; 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. An oncology group practice ***or a group of practitioners practicing at a reproductive healthcare center*** that wishes to maintain a single inventory of dangerous drugs, excluding compounded drug products, received at a site of practice in lieu of maintaining separate inventories for each dispensing practitioner of the oncology group practice ***or a group of practitioners practicing at a reproductive healthcare center*** must apply to the Board on an application provided by the Board for a certificate of registration and submit the fee prescribed in NAC 639.220 for authorization of a practitioner, other than a licensed veterinarian, to dispense dangerous drugs. An oncology group practice ***or a group of practitioners practicing at a reproductive healthcare center*** must submit a separate application and fee for each site of practice at which the oncology group practice ***or a group of practitioners practicing at a reproductive healthcare center*** wishes to maintain a single inventory of dangerous drugs, excluding compounded drug products.

2. Upon receipt of a fee and approval of an application, the Board will issue a certificate of registration to an oncology group practice ***or a group of practitioners practicing at a reproductive healthcare center***.

3. To renew a certificate of registration, an oncology group practice ***or a group of practitioners practicing at a reproductive healthcare center*** must submit to the Board another completed application and the fee prescribed in NAC 639.220 for biennial renewal of authorization of a practitioner, other than a licensed veterinarian, to dispense dangerous drugs.

4. A certificate of registration issued pursuant to this section:

(a) Entitles the oncology group practice ***or a group of practitioners practicing at a***

reproductive healthcare center to maintain a single inventory of dangerous drugs, excluding compounded drug products, at the site of practice for which the oncology group practice ***or a group of practitioners practicing at a reproductive healthcare center*** received certification.

(b) Is a revocable privilege, and no holder of such a certificate of registration acquires any vested right therein or thereunder.

5. An oncology group practice ***or a group of practitioners practicing at a reproductive healthcare center*** registered pursuant to this section shall provide written notice to the Board of the addition to or removal of a dispensing practitioner from the oncology group practice ***or a group of practitioners practicing at a reproductive healthcare center*** not later than 15 days after the addition or removal, as applicable.

6. A dispensing practitioner of an oncology group practice ***or a group of practitioners practicing at a reproductive healthcare center*** registered pursuant to this section:

(a) May dispense any dangerous drug accounted for in the single inventory of the oncology group practice ***or a group of practitioners practicing at a reproductive healthcare center***.

(b) Shall ensure that he or she complies with the requirements prescribed by NAC 639.745, including, without limitation, maintaining separate records of each dangerous drug dispensed by him or her.

7. As used in this section:

(a) "Compounded" has the meaning ascribed to "compound" and "compounding" in NAC 639.6625.

(b) "Drug product" has the meaning ascribed to it in NAC 639.6631.

Sec. 2. NAC 639.010 is hereby amended to read as follows:

639.010 As used in this chapter, unless the context otherwise requires:

1. "Board" means the State Board of Pharmacy.

2. "Controlled substances" has the meaning ascribed to it in NRS 0.031.

3. "Dangerous drug" has the meaning ascribed to it in NRS 454.201.

4. "Direct supervision" means the direction given by a supervising pharmacist who is:

(a) On the premises of the pharmacy or telepharmacy at all times when the person he or she is supervising is working at the pharmacy or telepharmacy or at a remote site or satellite consultation site; and

(b) Aware of the activities of that person related to the preparation and dispensing of medications, including the maintenance of appropriate records.

5. "Dispensing practitioner" means:

(a) A practitioner to whom the Board has issued a certificate of registration pursuant to NAC 639.742 to dispense controlled substances or dangerous drugs, or both, for human consumption; or

(b) A licensed veterinarian to whom the Board has issued a certificate of registration pursuant to NAC 639.7423 to dispense controlled substances or dangerous drugs, or both, not for human consumption.

6. "Executive Secretary" means the Executive Secretary employed by the Board pursuant to NRS 639.040.

7. "Federally-qualified health center" has the meaning ascribed to it in 42 U.S.C. § 1396d(l)(2)(B).

8. "Federally-qualified health center vehicle" means a vehicle that meets the requirements of paragraph (c) of subsection 1 of section 3 of LCB File No.R004-19.

9. "Licensed veterinarian" has the meaning ascribed to it in NRS 638.007.

10. "Oncology group practice ***or a group of practitioners practicing at a reproductive***

healthcare center" means two or more dispensing practitioners who practice oncology ***or at a reproductive healthcare center*** in a group practice.

11. "Pharmaceutical technician" means a person who performs technical services in a pharmacy under the direct supervision of a pharmacist and is registered with the Board pursuant to NAC 639.240.

~~[11.]~~ 12. "Pharmaceutical technician in training" means a person who is registered with the Board pursuant to NAC 639.242 in order to obtain the training and experience required to be a pharmaceutical technician pursuant to subparagraph (3) of paragraph (c) of subsection 2 of NAC 639.240, or who is enrolled in a program of training for pharmaceutical technicians that is approved by the Board.

~~[12.]~~ 13. "Practitioner" has the meaning ascribed to it in NRS 639.0125.

~~[13.]~~ 14. "Prescription drug" means a drug or medicine as defined in NRS 639.007 which:

(a) May be dispensed only upon a prescription order that is issued by a practitioner; and

(b) Is labeled with the symbol "Rx only" pursuant to federal law or regulation.

~~[14.]~~ 15. "Public or nonprofit agency" means a health center as defined in 42 U.S.C. § 254b(a) which:

(a) Provides health care primarily to medically underserved persons in a community;

(b) Is receiving a grant issued pursuant to 42 U.S.C. § 254b or, although qualified to receive such a grant directly from the Federal Government, is receiving money from such a grant under a contract with the recipient of that grant; and

(c) Is not a medical facility as defined in NRS 449.0151.

~~[15.]~~ 16. "Surgical center for ambulatory patients" has the meaning ascribed to it in NRS 449.019.

Sec. 3. NAC 639.742 is hereby amended to read as follows:

639.742 1. Except as otherwise provided in NAC 639.7423, a practitioner who wishes to dispense controlled substances or dangerous drugs, or both, for human consumption must apply to the Board on an application provided by the Board for a certificate of registration to dispense controlled substances or dangerous drugs. A practitioner must submit a separate application for each site of practice, including, without limitation, a telepharmacy, remote site or satellite consultation site, from which the practitioner wishes to dispense controlled substances or dangerous drugs, or both, for human consumption. A certificate of registration to dispense controlled substances or dangerous drugs, or both, for human consumption is a revocable privilege, and no holder of such a certificate of registration acquires any vested right therein or thereunder.

2. Except as otherwise provided in NAC 639.7423, and section 3 of LCB File No. R004-19,

3. If a facility from which the practitioner intends to dispense dangerous drugs or controlled substances, or both, for human consumption is not wholly owned and operated by the practitioner, the owner or owners of the facility must also submit an application to the Board on a form provided by the Board.

4. Except as otherwise provided in this section and NRS 639.23277 and NAC 639.395, 639.648 and 639.7423, the dispensing practitioner and, if applicable, the owner or owners of the facility and any federally-qualified health center vehicle, shall ensure that:

(a) All drugs are ordered by the dispensing practitioner;

(b) All drugs are received and accounted for by the dispensing practitioner;

(c) All drugs are stored in a secure, locked room or cabinet to which the dispensing practitioner has the only key or lock combination;

(d) All drugs are dispensed in accordance with NAC 639.745;

(e) No prescription is dispensed to a patient unless the dispensing practitioner is on-site at the

facility or federally-qualified health center vehicle, as applicable;

(f) All drugs are dispensed only to the patient personally at the facility or federally-qualified health center vehicle, as applicable;

(g) The price of each drug dispensed to a patient is separately itemized on any bill or statement provided to the patient;

(h) All drugs are dispensed only for medically necessary purposes and according to prevailing standards of care for practitioners practicing in the specialty claimed or practiced by the dispensing practitioner; and

(i) The certificate for each dispensing technician employed at the facility is displayed in the room or cabinet in which drugs are stored.

5. Except as otherwise provided in NAC 639.648 and 639.7423, with regard to the filling and dispensing of a prescription at a facility, only the dispensing practitioner or a dispensing technician may:

(a) Enter the room or cabinet in which drugs are stored;

(b) Remove drugs from stock;

(c) Count, pour or reconstitute drugs;

(d) Place drugs into containers;

(e) Produce and affix appropriate labels to containers that contain or will contain drugs;

(f) Fill containers for later use in dispensing drugs; or

(g) Package or repackage drugs.

6. Except as otherwise provided in NAC 639.7423, a dispensing practitioner may compound drug products if he or she complies with the provisions of NAC 639.661 to 639.690, inclusive, as if:

(a) He or she were a pharmacist;

(b) His or her practice site was a pharmacy; and

(c) Any dispensing technician involved in the compounding was a pharmaceutical technician.

7. Except as otherwise provided in subsection 6 of section 1 of this regulation, the dispensing practitioners of an oncology group practice ***or a group of practitioners practicing at a reproductive healthcare center*** registered pursuant to section 1 of this regulation are jointly responsible for ensuring that the requirements prescribed by subsection 3 are met.

PROPOSED REGULATION OF THE STATE BOARD OF PHARMACY

Workshop – July 14, 2022

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:§ 1, NRS 639.070; § 2, NRS 639.0727

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

1. Except as otherwise provided in this section, one or more registered dispensing practitioners practicing at a reproductive healthcare center may use an automated drug dispensing system and maintain a shared inventory in the automated drug dispensing system to dispense a prescription drug to a patient if the reproductive healthcare center obtained a license from the Board for the automated drug dispensing system.

2. The Board will provide to a reproductive healthcare center 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 automated drug dispensing system must conform to all the following provisions:

a. The system must contain only dangerous drugs, excluding compounded drug products, for treatment in reproductive health care:

i. Approved for use in the system by a registered dispensing practitioner;

ii. 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 function that allows the patient to communicate, in real time, with the registered dispensing practitioner who prescribed the drug who has access to any

patient record necessary for counseling the patient in compliance with NAC 639.707 and 639.708 or unless the dispensing practitioner is available at the site when dispensing of the drug occurs for counseling the patient in compliance with NAC 639.707 and 639.708; and

iii. For which the prescription has been processed, verified, and completed in the same manner as prescriptions for drugs that are delivered manually by a dispensing practitioner pursuant to NAC 639.742, except for section 3(e), and NAC 639.745.

b. The system must not contain:

i. Controlled substances included in schedules II, III, IV and V.

c. The system must:

i. 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 registered dispensing practitioner practicing at the reproductive healthcare center.

ii. Be secure from unauthorized access to and removal of prescription drugs.

iii. Be owned or leased by the reproductive healthcare center who obtained the license for the automated drug dispensing system and operated under the supervision and control of that reproductive healthcare center.

iv. 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 reproductive healthcare center of the temperature change.

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

1. The name, strength, quantify and form of dosage of each prescription drug stocked, inventoried, removed or dispensed from the system;

2. *Each day and time the system in accessed;*

3. *An inventory of the prescription drugs stored in the system; and*

4. *The identify of each person who accesses the system.*

vi. *Restrict access to a patient who indicated to the dispensing practitioner who prescribed the drug that the patient desires that his or her prescription drugs be dispensed by the system.*

vii. *Provide a method to identify the patient and dispense a prescription drug only to the patient or to an authorized agent of the patient.*

viii. *Dispense one, any combination or all 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.*

ix. *Record the date and time that the patient removes the prescription drugs from the system.*

x. *Inform a patient:*

1. *If the patient is using the system at the time that the reproductive healthcare center is open, that the patient may discuss questions and concerns regarding the prescription with the dispensing practitioner in person if available or through user-based access technology that includes, without limitation, an audio-visual function that allows the patient to communicate, in real time, with the dispensing practitioner who has access to any patient record necessary for counseling the patient in compliance with NAC 639.707 and 639.708.*

2. *If the patient is using the system at the time that the reproductive healthcare center is closed that the patient may discuss questions and concerns regarding the prescription drug through user-based access technology that includes, without limitation, an audio-visual function that*

allows the patient to communicate, in real time, with the dispensing practitioner who has access to any patient record necessary for counseling the patient in compliance with NAC 639.707 and 639.708.

3. ***That the patient may choose not to purchase the prescription drug from the system at any time before the system dispenses the prescription drug.***

xi. ***Dispense all prescription drugs in containers labeled in conformance with NRS 639.2801.***

xii. ***Be installed at the reproductive healthcare center in such a place and manner that a person is unable to remove the system from its location or obtain access to the device without authorization. The system must be monitored by real-time audio-visual recording technology.***

xiii. ***Be approved for use by the Board upon determination that the system:***

1. ***Dispenses prescription drugs accurately; and***
2. ***Otherwise satisfies the provisions of this section.***

4. ***A registered dispensing practitioner 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 procedure for:***

i. ***Maintaining the security of the prescription drugs stored in the system during the maintenance and repair of the system;***

ii. ***The preparation of an inventory of the prescription drugs stored in the system; and***

iii. ***Stocking the system with prescription drugs.***

5. ***A registered dispensing practitioner practicing at the reproductive healthcare center 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 medical records.***

6. ***Prescription drugs stored in an automated drug dispensing system pursuant to this section shall be deemed part of the inventory of the dispensing practitioner and the responsibility of the dispensing practitioner that use the automated drug dispensing system at the reproductive healthcare center that was issued the license for the system.***
7. ***The Board may prohibit the reproductive healthcare center from using a system to furnish a prescription drug to a patient if the Board determines that the system or that one or more dispensing practitioners' use of the system does not comply with this section.***
8. ***The provisions of this section do not prohibit the use of a 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 reproductive healthcare center using the system is otherwise authorized to use the system pursuant to this section.***
9. ***As used in this section***
    a. ***"Reproductive healthcare center" means a health facility owned and operated by a non-profit corporation principally engaged in providing family planning services and reproductive healthcare, including the testing, diagnosis, treatment of, or medication to prevent a sexually transmitted infection or other infection of the urogenital system.***