

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

LCB File No. R015-18

March 9, 2018

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

AUTHORITY: §§1 and 3-6, NRS 639.070; §2, NRS 639.070 and 639.170.

A REGULATION relating to pharmacy; establishing the requirements for a licensed veterinarian to obtain a certificate of registration from the State Board of Pharmacy to dispense controlled substances or dangerous drugs; revising the fees for a licensed veterinarian to dispense controlled substances or dangerous drugs; and providing other matters properly relating thereto.

Legislative Counsel’s Digest:

Existing law authorizes an exclusive list of persons, including practitioners, to possess and administer a controlled substance or dangerous drug in this State. (NRS 453.375, 454.213) Existing law authorizes the State Board of Pharmacy to adopt regulations governing the dispensing of poisons, drugs, chemicals and medicines. (NRS 639.070) Existing regulations require a practitioner who wishes to dispense controlled substances or dangerous drugs to obtain a certificate of registration from the Board to dispense controlled substances or dangerous drugs. (NAC 639.742) Further, existing law defines “practitioner” for purposes relating to pharmacy to include veterinarians. (NRS 639.0125) **Sections 1 and 3-6** of this regulation distinguish licensed veterinarians from other practitioners by establishing specific requirements: (1) for a licensed veterinarian to obtain and maintain a certificate of registration from the Board to dispense controlled substances or dangerous drugs; and (2) for a veterinary facility to comply with certain procedures relating to the dispensing of controlled substances or dangerous drugs. **Section 2** of this regulation decreases the fee for a licensed veterinarian to obtain a certificate of registration from the Board to dispense controlled substances or dangerous drugs.

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

1. A licensed veterinarian who wishes to dispense controlled substances or dangerous drugs 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 certificate of registration issued pursuant to this section:

(a) Entitles the licensed veterinarian to dispense controlled substances or dangerous drugs from any veterinary facility at which he or she engages in the practice of veterinary medicine.

(b) Must be renewed at the same time and in the same manner as certificates of registration by other practitioners.

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

2. A veterinary facility at which controlled substances or dangerous drugs are possessed, administered, prescribed or dispensed:

(a) Shall ensure that every veterinarian who practices at that veterinary facility registers and maintains a registration with the Drug Enforcement Administration of the United States Department of Justice and the Board.

(b) Except as otherwise provided in paragraph (c), may allow only veterinarians, veterinary technicians or veterinary technicians in training at that veterinary facility to prepare a prescription drug for dispensing.

(c) May allow veterinary assistants at that facility to prepare a prescription drug, other than a controlled substance or dangerous drug, for dispensing.

(d) Shall ensure that a prescription drug which is new for an animal is not dispensed unless a veterinarian or veterinary technician is at the veterinary facility or is otherwise available at the time the prescription drug is dispensed.

(e) Shall ensure that a notation is made in the medical record of the animal that contains:

(1) The name, strength and quantity of the prescription drug.

- (2) The date the prescription drug was prescribed and dispensed.*
 - (3) The directions for use.*
 - (4) The name, signature or initials of the veterinarian who prescribed the prescription drug.*
 - (5) The name, signature or initials of the veterinarian, veterinary technician or veterinary technician in training who prepared the prescription drug for dispensing.*
 - (6) The name, signature or initials of the veterinarian or veterinary technician who verified the prescription drug before the prescription drug was dispensed.*
- (f) Shall ensure that each vial or container which contains a prescription drug has affixed to the vial or container a label that contains:*
- (1) Except as otherwise provided in subsection 3, the name or unique identifier of the animal and the name of the owner of the animal for which the prescription drug is prescribed.*
 - (2) The name, strength and quantity of the prescription drug.*
 - (3) The date the prescription drug was dispensed.*
 - (4) The name of the veterinarian who prescribed the prescription drug.*
 - (5) The expiration date of the prescription drug.*
 - (6) A unique number identifying the prescription.*
 - (7) The directions for use.*
- (g) Shall maintain a stock of prescription drugs necessary to serve the foreseeable needs of the veterinary practice.*
- (h) Shall ensure that drugs which are inappropriate or unlawful to the practice of veterinary medicine are not ordered or maintained in the stock of prescription drugs of the veterinary facility.*

3. A label affixed to a vial or container that contains a prescription drug may contain a generic identifier for a group of animals of the same species in place of the name or unique identifier of one animal if:

(a) The group of animals identified on the label is owned by the same person;

(b) The prescription drug is dispensed for more than one of the animals in the group; and

(c) The directions for use of the prescription drug are the same for each animal in the group for which the prescription drug is dispensed.

4. The authorization to possess a prescription drug is not transferrable upon the sale or other transfer of the animal or animals for which the prescription drug was dispensed.

5. A veterinary facility which maintains a stock of controlled substances or dangerous drugs for administration or dispensing shall:

(a) Secure the stock of controlled substances or dangerous drugs in a locked container that is:

(1) Affixed to the structure and located within a locked room; or

(2) Located within a second locked container which is affixed to the structure.

(b) Ensure that only a veterinarian or a veterinary technician designated by the veterinarian has the keys or combination to unlock the two separate locks at the start of a business day or beginning of a shift, if the veterinary facility has veterinarians on successive shifts.

(c) Restrict access to the controlled substances or dangerous drugs to veterinarians or veterinary technicians only.

(d) Ensure that each veterinarian or veterinary technician who accesses the secure container which stores the controlled substances or dangerous drugs records in a log:

(1) The name of the veterinarian or veterinary technician who accessed the secure container and the date that he or she accessed the secure container.

(2) The name, strength and quantity of the controlled substance or dangerous drug removed from or placed into the secure container and the total amount of all quantities of that particular controlled substance or dangerous drug remaining inside the secure container.

(e) Ensure that a veterinarian who intends to destroy an unused portion of a controlled substance or dangerous drug records in a log the name and quantity of the controlled substance or dangerous drug that will be destroyed and the date and time that the controlled substance or dangerous drug will be destroyed. An entry made pursuant to this paragraph must be verified by an employee of the veterinary facility.

(f) Ensure that the purchasing, storage and recordkeeping of controlled substances or dangerous drugs comply with all applicable state and federal laws.

(g) Ensure that any controlled substance or dangerous drug is purchased by a veterinarian or with the knowledge of a veterinarian and that all controlled substances and dangerous drugs received by the veterinary facility are verified by a veterinarian or with the knowledge of the veterinarian.

(h) Maintain separate files for the records of the purchase of each controlled substance or listed in schedule II of controlled substances in NAC 453.520 and records of the dispensing of each controlled substance listed in schedule II of controlled substances in NAC 453.520.

6. Any record made pursuant to subsections 2 to 5, inclusive, must be maintained for at least 4 years and must be available for inspection by the Board or its representative or any authorized federal, state or local regulatory agency or law enforcement agency.

7. *A licensed veterinarian with a certificate of registration issued by the Board pursuant to subsection 1 and a veterinary facility at which controlled substances or dangerous drugs may be dispensed pursuant to this section are exempt from the provisions of NAC 639.7425 to 639.745, inclusive.*

8. *As used in this section:*

(a) *“Licensed veterinarian” has the meaning ascribed to it in NRS 638.007.*

(b) *“Prescription drug” has the meaning ascribed to it in NAC 638.0135.*

(c) *“Veterinarian facility” has the meaning ascribed to it in NAC 638.018.*

Sec. 2. 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.....	\$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 both300

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 both150

For the biennial renewal of authorization of a licensed veterinarian to dispense controlled substances or dangerous drugs, or both.....150

2. The penalty for failure to pay the renewal fee for any license, permit or certificate within the statutory period, as provided in subsection ~~4~~ 5 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. 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. 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.

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

639.742 1. ~~{A}~~ *Except as otherwise provided in section 1 of this regulation, a* practitioner who wishes to dispense controlled substances or dangerous drugs 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. A certificate of registration to dispense controlled substances or dangerous

drugs 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 section 1 of this regulation, if* a facility from which the practitioner intends to dispense dangerous drugs or controlled substances 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.

3. Except as otherwise provided in NRS 639.23277 , ~~and~~ NAC 639.395 ~~##~~ *and section 1 of this regulation*, the dispensing practitioner and, if applicable, the owner or owners of the facility, 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;
- (f) All drugs are dispensed only to the patient personally at the facility;
- (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.

4. ~~With~~ *Except as otherwise provided in section 1 of this regulation, 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.

5. ~~A~~ *Except as otherwise provided in section 1 of this regulation, 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.

Sec. 4. NAC 639.7425 is hereby amended to read as follows:

639.7425 1. ~~No~~ *Except as otherwise provided in section 1 of this regulation, no* person may act 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:

- (a) Is 18 years of age or older;
- (b) Has received a high school diploma or its equivalent;
- (c) Has not been convicted of any felony or misdemeanor involving moral turpitude, dishonesty or the unlawful possession, sale or use of drugs; and
- (d) Does not have a history of drug abuse.

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 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 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.

7. 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.

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

639.7435 1. The registration of a dispensing technician is nontransferable 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 section 1 of this regulation, 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.

Sec. 6. NAC 639.745 is hereby amended to read as follows:

639.745 1. ~~Each~~ *Except as otherwise provided in section 1 of this regulation, each* practitioner who is registered with the Board to dispense controlled substances and dangerous drugs, including, without limitation, a dispensing practitioner, and who dispenses such products for use by the practitioner's patients outside his or her presence shall:

(a) Keep complete, accurate and readily retrievable records of each controlled substance and dangerous drug purchased and dispensed. The record for each such product dispensed to a patient must include:

- (1) The name of the patient and, if not readily available from the practitioner's records, the patient's address;
- (2) The name, strength and quantity of the prescribed controlled substance or dangerous drug;
- (3) The directions for use;
- (4) The date the prescription was issued; and
- (5) A unique identifying number.

(b) Maintain a separate file for the records concerning the purchase of each controlled substance listed in schedule II and a separate file for the records concerning the dispensing of each controlled substance listed in schedule II. Each prescription for a controlled substance or dangerous drug must be maintained in a separate file pursuant to the requirements set forth in NAC 453.480.

(c) Keep all controlled substances and dangerous drugs in a locked storage area. Access to the storage area must be restricted to the persons described in NRS 453.375.

(d) Ensure that each package or container in which a controlled substance is dispensed, except samples in the manufacturer's packages, is clearly labeled pursuant to the requirements set forth in NRS 639.2801.

(e) Ensure that the package or container in which a controlled substance or dangerous drug is dispensed complies with all state and federal packaging requirements.

(f) Be deemed to be a pharmacy as that term is used in NAC 639.926 and shall comply with that section.

2. ~~1A~~ *Except as otherwise provided in section 1 of this regulation, a* practitioner may dispense dangerous drugs or controlled substances only after the patient has been informed by the practitioner that the patient may request a written prescription and have it filled at another location of the patient's choosing.

3. A record regarding the dispensing of a controlled substance or dangerous drug made and kept pursuant to this section must be maintained on paper or in a computer. If the record is:

(a) Maintained on paper, the record must:

(1) Include all the information required to be on the prescription pursuant to NRS 639.2353 and NAC 453.440;

(2) Set forth on the front of the prescription a certification initialed and dated by the patient that the patient has been informed by the practitioner in accordance with subsection 2 and that the patient has agreed to have the practitioner dispense the controlled substance or dangerous drug; and

(3) Be serially numbered and kept in numerical order in a single file for all dispensing practitioners, including, without limitation, physician assistants and advanced practice registered nurses, practicing at the same location.

(b) Maintained in a computer, the record must:

(1) Include all the information required to be on the prescription pursuant to NRS 639.2353 and NAC 453.440;

(2) Contain a certification, either in the computer or a separate paper document, initialed and dated by the patient that the patient has been informed by the practitioner in accordance with subsection 2 and that the patient has agreed to have the practitioner dispense the controlled substance or dangerous drug; and

(3) Be searchable for any item required by paragraph (a) of subsection 1 to be included in the record.