APPROVED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R146-17

Effective May 16, 2018

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

AUTHORITY: §§1-13, NRS 639.070.

A REGULATION relating to pharmacy; defining the term "consignment" and certain related terms for purposes governing the purchase, transfer and dispensing of certain drugs; authorizing licensed veterinarians to engage in a consignment; establishing the procedures and requirements for a consignment; authorizing certain wholesalers to enter a consignment; authorizing certain pharmacies to enter a consignment; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law authorizes an exclusive list of persons, including veterinarians, 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) **Section 8** of this regulation: (1) authorizes a licensed veterinarian to engage in a consignment, which **section 4** of this regulation defines as a transaction wherein a veterinarian purchases an approved drug from a wholesaler, takes legal but not physical possession of the approved drug and prescribes the approved drug for dispensing by a pharmacy to a client; and (2) sets forth certain procedures and requirements for such a consignment. **Section 3** of this regulation defines the term "approved drug" as: (1) a controlled substance listed in schedule IV or V; or (2) a dangerous drug as defined in NRS 454.201. **Section 9** of this regulation sets forth the requirements for a wholesaler who enters into a consignment. **Section 10** of this regulation sets forth the requirements for a pharmacy that enters into a consignment.

Section 8 requires a veterinarian who prescribes an approved drug that will be consigned to a pharmacy for dispensing to counsel the client on any matters which will enhance therapy for the animal through the approved drug.

Existing law prohibits a registered pharmacist or an owner of a licensed pharmacy from offering, delivering or paying certain unearned compensation to any person for referring prescriptions, clients or customers to a pharmacist or pharmacy. (NRS 639.264) **Section 11** of this regulation provides that a remittance of payment to a veterinarian by a pharmacy, pursuant to a consignment, will not be considered unearned compensation as prohibited by existing law.

- **Section 1.** Chapter 639 of NAC is hereby amended by adding thereto the provisions set forth as sections 2 to 11, inclusive, of this regulation.
- Sec. 2. As used in sections 2 to 11, inclusive, of this regulation, unless the context otherwise requires, the words and terms defined in sections 3 to 7, inclusive, of this regulation have the meanings ascribed to them in those sections.
 - Sec. 3. "Approved drug" means:
 - 1. A controlled substance listed in schedule IV or V; or
- 2. A dangerous drug as defined in NRS 454.201, as amended by section 1.2 of Senate Bill No. 101, chapter 238, Statutes of Nevada 2017, at page 1250.
 - Sec. 4. "Consign," "consigned" or "consignment" means a transaction in which:
 - 1. A licensed veterinarian purchases an approved drug from a licensed wholesaler;
- 2. The licensed veterinarian takes legal possession but not physical possession of the approved drug;
 - 3. The licensed veterinarian prescribes the approved drug for a nonhuman animal;
- 4. The licensed wholesaler physically transfers the approved drug prescribed by the licensed veterinarian to a licensed pharmacy; and
- 5. The licensed pharmacy dispenses the approved drug prescribed by the licensed veterinarian through a mail order service to the client.
- Sec. 5. "Licensed pharmacy" means a pharmacy licensed by the Board pursuant to chapter 639 of NRS.
 - Sec. 6. "Licensed veterinarian" has the meaning ascribed to it in NRS 638.007.
- Sec. 7. "Licensed wholesaler" means a wholesaler licensed by the Board pursuant to chapter 639 of NRS.

- Sec. 8. 1. A licensed veterinarian may engage in a consignment with respect to an approved drug if:
- (a) The licensed veterinarian is a holder of a certificate of registration pursuant to NAC 639.742.
 - (b) The wholesaler is a licensed wholesaler.
 - (c) The pharmacy is a licensed pharmacy.
 - (d) The approved drug is not for human consumption.
- (e) The licensed veterinarian has established a veterinarian-client-patient relationship concerning the nonhuman animal for which the licensed veterinarian prescribes the approved drug.
- (f) The licensed veterinarian provides written notice to the client that the approved drug will be consigned to a licensed pharmacy for dispensing. Such a notice must include, without limitation:
 - (1) The name of the licensed pharmacy;
 - (2) The contact information of the licensed pharmacy; and
- (3) A statement that the client may request a written prescription and have the prescription filled at another location of the client's choosing.
 - (g) The client consents in writing to the consignment of the approved drug.
- 2. A licensed veterinarian who consigns an approved drug for dispensing shall keep complete and accurate records of each approved drug consigned pursuant to the requirements set forth in NRS 453.246 and 454.286 and NAC 639.745.
- 3. Upon prescribing an approved drug that will be consigned to a pharmacy for dispensing and after review of the medical record of the animal, a licensed veterinarian shall

counsel the client on any matters which will enhance therapy for the animal through the approved drug. The counseling must be in person if practicable, or by telephone or in writing if the client is not present. Additional information may be used to supplement counseling when appropriate, including, without limitation, leaflets, pictogram labels and video programs.

- 4. As used in this section, "veterinarian-client-patient relationship" has the meaning ascribed to it in NAC 638.0197.
- Sec. 9. 1. A licensed wholesaler may sell an approved drug to a licensed veterinarian for consignment pursuant to sections 2 to 11, inclusive, of this regulation if the wholesaler is licensed by the Board pursuant to NRS 639.233.
- 2. In addition to any other requirements for obtaining a license as a wholesaler pursuant to this chapter and chapter 639 of NRS, a wholesaler who applies for such a license and who proposes to engage in a consignment pursuant to sections 2 to 11, inclusive, of this regulation must, if required by the Board:
 - (a) Successfully complete an on-site inspection by a representative of the Board; and
 - (b) Reimburse the Board for all costs of such an inspection.
- Sec. 10. 1. A licensed pharmacy may be consigned an approved drug pursuant to sections 2 to 11, inclusive, of this regulation if the pharmacy is licensed by the Board pursuant to NRS 639.231.
- 2. In addition to any other requirements for obtaining a license as a pharmacy pursuant to this chapter and chapter 639 of NRS, a pharmacy who applies for a license to operate a pharmacy and who proposes to engage in a consignment pursuant to sections 2 to 11, inclusive, of this regulation must, if required by the Board:
 - (a) Successfully complete an on-site inspection by a representative of the Board; and

- (b) Reimburse the Board for all costs of the inspection.
- Sec. 11. If a licensed pharmacy remits payment to a licensed veterinarian when dispensing an approved drug consigned pursuant to sections 2 to 11, inclusive, of this regulation, the payment must not be considered unearned compensation as prohibited by NRS 639.264.
 - **Sec. 12.** NAC 639.7105 is hereby amended to read as follows:
- 639.7105 Except as otherwise provided in NAC 639.711 [:] and section 8 of this regulation:
- 1. A prescription for a dangerous drug or a controlled substance listed in schedule II, III, IV or V may be transmitted to a pharmacy electronically by a practitioner or, if the prescription is for a dangerous drug, the designated agent of the practitioner, if the patient:
 - (a) Consents to the transmission of the prescription electronically; and
 - (b) Approves the pharmacy where the prescription will be transmitted.
- 2. A practitioner shall not transmit a prescription for a controlled substance to a pharmacy electronically unless:
- (a) The practitioner is the only person who will have access to the prescription until it is received by the pharmacy; and
 - (b) All requirements of 21 C.F.R. Part 1311 are satisfied.
- 3. The designated agent of a practitioner shall not transmit a prescription for a dangerous drug to a pharmacy electronically unless:
 - (a) The practitioner prescribes the dangerous drug;

- (b) The designated agent receives training from the practitioner regarding the electronic transmission of prescriptions and the practitioner keeps written documentation of such training at his or her office; and
- (c) The practitioner documents in the medical record of the patient for whom the prescription is being transmitted electronically the intention of the practitioner to prescribe the dangerous drug and to have his or her designated agent transmit the prescription electronically.
- 4. If the designated agent of a practitioner transmits a prescription electronically to a pharmacy, the practitioner shall review the electronic prescription file not later than 24 hours after the electronic transmission.
- 5. In addition to the requirements set forth in NRS 639.2353 and 639.2589, a prescription that is transmitted electronically to a pharmacy must include:
 - (a) The telephone number of the prescribing practitioner;
 - (b) The time and date of the transmission; and
 - (c) The name of the pharmacy to which the prescription is sent.
- 6. In addition to the requirements set forth in subsection 5 and NRS 639.2353 and 639.2589, a prescription for a controlled substance that is transmitted electronically to a pharmacy must include:
- (a) The registration number from the Drug Enforcement Administration of the prescribing practitioner; and
- (b) If the technological capability exists to require such information to be transmitted electronically:
 - (1) The Nevada controlled substance registration number of the prescribing practitioner;
 - (2) The indication for use or the diagnosis code; and

- (3) The date of the last physical examination of the patient.
- 7. A pharmacist who receives a prescription that is transmitted electronically shall keep a paper or electronic copy of the prescription for at least 2 years after the pharmacist receives the prescription. The copy of the prescription that is kept must be readily accessible to:
- (a) Personnel of the pharmacy who are authorized to access records of prescriptions kept by the pharmacy; and
 - (b) Members, employees, agents and designees of the Board.
- 8. A pharmacist shall not dispense a prescription that is transmitted electronically until the pharmacist determines that the prescription complies with the requirements of state and federal law
- 9. A prescription that is transmitted and complies with the provisions of this section shall be deemed an original prescription.
- 10. The Board may suspend the privilege of a practitioner to transmit prescriptions electronically or take any other appropriate action if the Board reasonably suspects that the practitioner or the designated agent of the practitioner has transmitted a prescription electronically that is:
 - (a) Unlawful;
 - (b) Fraudulent; or
 - (c) Not for a legitimate medical purpose.
 - **Sec. 13.** NAC 639.742 is hereby amended to read as follows:
- 639.742 1. 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. 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 8 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 8 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 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.