PROPOSED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB FILE NO. R146-17I

The following document is the initial draft regulation proposed

by the agency submitted on 12/12/2017

639 Proposed Regulation of the Nevada State Board of Pharmacy

Workshop December 6, 2017

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

A REGULATION relating to dispensing of dangerous drugs by veterinarians; and providing other matters properly relating thereto.

Section. 1. Chapter 639 of NAC is hereby amended by adding thereto the provisions set forth as section 2 through 6, inclusive, of this regulation.

Sec. 2. ***"Consign" or "consignment" means a transaction whereby:***

1. A veterinarian purchases a dangerous drug from a wholesaler;

2. The veterinarian takes legal possession but not physical possession of the dangerous drug;

3. The veterinarian prescribes the dangerous drug for a nonhuman patient;

4. The wholesaler transfers the dangerous drug to a pharmacy; and

5. The pharmacy dispenses the dangerous drug to the patient through mail order.

Sec. 3. ***1. A veterinarian may consign a dangerous drug to a pharmacy for dispensing if:***

(a) The veterinarian is registered by the Board pursuant to NAC 639.742.

(b) The wholesaler is licensed by the Board pursuant to NRS 639.233.

(c) The pharmacy is licensed by the Board pursuant to NRS 639.230.

(d) The dangerous drug is not for human consumption.

(e) The veterinarian has a veterinarian-client-patient relationship.

(f) The veterinarian directly informs the client by separate written notice that the dangerous drug will be consigned to a pharmacy. The notice must include:

(1) The name of the pharmacy;

(2) The contact information of the pharmacy; and

(3) A statement that the client may request a written prescription and have it filled at another location of the client's choosing.

(g) The client consents in writing to the consignment of the dangerous drug.

2. A veterinarian who consigns a dangerous drug to a pharmacy is responsible for maintaining records regarding the prescription and dispensing of the dangerous drug in accordance with the provisions of chapter 630 of NRS and NAC.

3. The veterinarian must counsel the client in accordance with NRS 639.266, NAC 639.707 and 639.708.

4. A veterinarian shall not consign a controlled substance listed in schedule I, II or III.

5. As used in this section, "veterinarian-client-patient relationship" has the meaning scribed to it in NAC 638.0197.

Sec. 4. *1. A wholesaler may be consigned a dangerous drug if the wholesaler is licensed by the Board pursuant to NRS 639.230.*

2. A wholesaler from outside the State applying for a license pursuant to this Section shall, as required by the Board, successfully complete an on-site inspection by a representative of the Board and reimburse the Board for all costs of the inspection.

Sec. 5. *1. A pharmacy may be consigned a dangerous drug if the pharmacy is licensed by the Board pursuant to NRS 639.233.*

2. A pharmacy from outside the State applying for a license pursuant to this Section shall, as required by the Board, successfully complete an on-site inspection by a representative of the Board and reimburse the Board for all costs of the inspection.

Sec. 6. *The remittance of payment to a veterinarian by a pharmacy when dispensing a drug under consignment in compliance with sections 2-5 of this regulation shall not be considered unearned compensation for purposes of NRS 639.264.*

Sec. 7. NAC 639.7105 is hereby amended to read as follows:

NAC 639.7105 Except as otherwise provided in NAC 639.711 *or section 3 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 electronically by a practitioner to a pharmacy.

2. A practitioner shall not transmit a prescription electronically to a pharmacy unless:

(a) The practitioner is the only person who will have access to the prescription until it is received by the pharmacy;

(b) The patient:

(1) Consents to the transmission of the prescription electronically; and

(2) Approves the pharmacy where the prescription will be transmitted; and

(c) All requirements of 21 C.F.R. Part 1311 are satisfied.

3. 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.

4. In addition to the requirements set forth in subsection 3 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.

5. 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.

6. 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.

7. A prescription that is transmitted and complies with the provisions of this section shall be deemed an original prescription.

8. The Board may suspend the privilege of a practitioner to transmit prescriptions electronically if the Board reasonably suspects that the practitioner has transmitted a prescription electronically that is:

(a) Unlawful;

(b) Fraudulent; or

(c) Not for a legitimate medical purpose.

Sec. 8. NAC 639.742 is hereby amended to read as follows:

NAC 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 3 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. ***Except as otherwise provided in section 3 of this regulation, w***~~W~~ith 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.