Nevada State Board of Pharmacy

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February 1, 2018

NOTICE OF INTENT TO ACT UPON A REGULATION

Notice of Hearing for the Adoption and Amendment of
Regulations of the Nevada State Board of Pharmacy

The Nevada State Board of Pharmacy will hold a Public Hearing at 1:30 p.m., on Wednesday, March 7, 2018, at the Hyatt Place, 1790 East Plumb Lane, Reno, Nevada. The purpose of the hearing is to receive comments from all interested persons regarding the adoption and amendment of regulations that pertain to Chapters 453 and/or 639 of the Nevada Administrative Code.

The following information is provided pursuant to the requirements of NRS 233B.060:

Amendment of Nevada Administrative Code Chapter 639 to add a new section providing for the dispensing of certain drugs by veterinarians through consignment.
(LCB File No. R146-17)

1. The need for and the purpose of the proposed regulation or amendment.

The regulation will allow a licensed veterinarian to take legal ownership but not physical possession of a dangerous drug or Schedule IV or V controlled substance from a licensed wholesaler, prescribe the drug to a patient, and then consign to a licensed pharmacy for dispensing to the patient.

2. Either the terms or the substance of the regulations to be adopted and amended.

A copy of the proposed regulation amendment is attached to this notice.

3. The estimated economic effect of the regulation on the business which it is to regulate and on the public:

(a) Both adverse and beneficial effects.

There should be no adverse economic impact from this regulation on businesses or the public.

(b) Both immediate and long-term effects.

The Board anticipates that there will be no immediate or long-term economic effect on businesses or the public, or that any such effects will be negligible.

4. The estimated cost to the agency for enforcement of the proposed regulation.

There will be no additional or special costs incurred by the Board of Pharmacy for enforcement of this

regulation.

5. A description of and citation to any regulations of other state or local governmental agencies which the proposed regulation overlaps or duplicates and a statement explaining why the duplication or overlapping is necessary. If the proposed regulation overlaps or duplicates a federal regulation, the notice must include the name of the regulating federal agency.

The Board of Pharmacy is not aware of any similar regulations of any other state or local governmental agency that the proposed regulation overlaps or duplicates.

6. If the regulation is required pursuant to federal law, a citation and description of the federal law.

The regulation is not required by federal law.

7. If the regulation includes provisions which are more stringent than a federal regulation that regulates the same activity, a summary of such provisions.

The Board of Pharmacy is not aware of any similar federal regulation of the same activity in which the state regulation is more stringent.

8. Whether the proposed regulation establishes a new fee or increases an existing fee.

This regulation does not provide a new or increase of fees.

Persons wishing to comment upon the proposed action of the Board may appear at the scheduled public hearing or may address their comments, data, views, or arguments in written form to the Nevada State Board of Pharmacy, 431 West Plumb Lane, Reno, Nevada 89509, or at e-mail address: shunting@pharmacy.nv.gov. Written submissions must be received by the Board at least fourteen days before the scheduled public hearing. If no person who is directly affected by the proposed action appears to request time to make an oral presentation, the Board may proceed immediately to act upon any written submissions.

A copy of this notice and the regulation to be adopted and amended will be on file at the State Library, 100 Stewart Street, Carson City, Nevada, for inspection by members of the public during business hours. Additional copies of the notice and the regulation to be adopted and amended will be available in all counties in which an office of the agency is not maintained, at the main public library, for inspection and copying by members of the public during business hours. The text of each regulation will include the entire text of any section of the Nevada Administrative Code which is proposed for amendment or repeal. This notice and the text of the proposed regulation are also available in the State of Nevada Register of Administrative Regulations which is prepared and published monthly by the Legislative Counsel Bureau pursuant to NRS 233B.0653, and on the Internet at http://www.leg.state.nv.us. Copies of this notice and the proposed regulation will also be mailed to members of the public upon request. A reasonable fee may be charged for copies if it is deemed necessary.

Upon adoption of any regulation, the agency, if requested to do so by an interested person, either before adoption or within 30 days thereafter, will issue a concise statement of the principal reasons for and against its adoption, and incorporate therein its reason for overruling the consideration urged against its adoption.

This notice of hearing has been posted at the following locations:

Nevada State Board of Pharmacy
Reno, Nevada

Nevada State Board of Pharmacy
Las Vegas, Nevada

Mineral County Courthouse
Hawthorne, Nevada

Elko County Courthouse
Elko, Nevada

Washoe County Courthouse
Reno, Nevada

REVISED PROPOSED REGULATION OF

THE STATE BOARD OF PHARMACY

LCB File No. R146-17

February 1, 2018

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

AUTHORITY: §§1-15, 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 communicate certain information to a client. The communication must include elements of counseling provided in **sections 11 and 12** of this regulation. **Sections 11 and 12** also provide the duties related to the communication and counseling.

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 13** 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 13, inclusive, of this regulation.

Sec. 2. ***As used in sections 2 to 13, 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 communicate matters which will enhance therapy for the animal through the approved drug with the client. The communication must include appropriate elements for counseling with the client as provided in sections 11 and 12 of this regulation. The communication 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 13, 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 13, inclusive, of this regulation must, if as 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 13, 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 13, 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. *1. Except as otherwise provided in this section, a licensed veterinarian who prescribes an approved drug that will be consigned to a licensed pharmacy for dispensing shall provide a client with information about each approved drug prescribed that:*

(a) Has not been previously dispensed or prescribed to the client; or

(b) Has been previously dispensed or prescribed to the client, including, without limitation, an approved drug that is being refilled, if, in the professional judgment of the licensed veterinarian:

(1) The information would further or improve the drug therapy of the nonhuman animal; or

(2) A reasonable concern relating to the safety or efficacy of the drug therapy of the animal was raised by the review of the medical record of the animal conducted pursuant to subsection 3.

2. The information provided by the licensed veterinarian pursuant to subsection 1 may include, without limitation:

(a) The name and a description of the approved drug;

(b) The form of dosage, dose, route of administration and duration of drug therapy;

(c) The intended use of the approved drug and expected responses from that use;

(d) Any special directions and precautions for the preparation, administration and use of the approved drug by the client for the animal;

(e) Any common severe side effects, interactions and contraindications that may occur, recommendations to avoid such side effects, interactions or contraindications, and the action required if they occur;

(f) Techniques for the client to monitor the drug therapy;

(g) Proper storage of the approved drug;

(h) Information about refilling the prescription;

(i) Actions to be taken in the event of a missed dose;

(j) Any relevant information contained in the record of medication of the animal; and

(k) Any other information which, in the professional judgment of the licensed veterinarian, is necessary to ensure the safe and effective use of the approved drug by the client for the animal.

3. The licensed veterinarian shall review the medical record of the animal before prescribing an approved drug that will be consigned to a pharmacy for dispensing to determine its therapeutic appropriateness and, in making that determination, may consider, without limitation:

(a) Overutilization of the approved drug and drug abuse;

(b) Underutilization of the approved drug;

(c) Therapeutic duplications, contraindications and any warning labels or other information included with the approved drug;

(d) Interactions between the approved drug and any:

(1) Other drugs which the client is administering to the animal or has recently administered;

(2) Diseases which the animal has, including any stages of that disease; and

(3) Allergies that the animal may have; and

(e) Incorrect dosage or duration of treatment.

4. A licensed veterinarian is not required to counsel a client pursuant to this section if the client refuses to accept counseling.

5. Except as otherwise provided in subsection 6, the licensed veterinarian shall, at the time that counseling is provided or refused:

(a) Initial a written document that is maintained by the licensed veterinarian to record whether counseling was provided to or refused by a client; or

(b) Enter initials onto a record in a computerized system used by the licensed veterinarian for recording information concerning prescriptions to indicate whether counseling was provided to or refused by a client.

6. The licensed veterinarian is not required to comply with the provisions of subsection 5 if the prescribed approved drug that will be consigned to a pharmacy for dispensing is being refilled.

Sec. 12. *To facilitate counseling regarding the prescription of an approved drug that will be consigned to a pharmacy for dispensing, a licensed veterinarian shall:*

1. Maintain a record of medication for each nonhuman animal and the client to whom a prescription has been consigned pursuant to sections 2 to 13, inclusive, of this regulation, dispensed or prescribed by the licensed veterinarian. The record must:

(a) Be retrievable for use by the licensed veterinarian;

(b) Be maintained for at least 2 years after the most recent entry;

(c) List all prescriptions consigned pursuant to sections 2 to 13, inclusive, of this regulation, dispensed or prescribed for the animal to the client by the licensed veterinarian; and

(d) Include all the data required to be placed on the prescription.

2. Make a reasonable effort to obtain and retain in the record of medication the:

(a) Telephone number or numbers, if any, of the client;

(b) Age, sex, weight and breed of the animal;

(c) History of the animal, including allergies, reactions to particular drugs and any medications or medical devices administered to the animal by the client; and

(d) Any comments relevant to the drug therapy of the animal, including, without limitation, any other information which is specific to the animal or approved drug.

3. Ensure that the licensed veterinarian is available by telephone during business hours and, if the licensed veterinarian routinely consigns, pursuant to sections 2 to 13, inclusive, of this regulation, dispenses or prescribes prescriptions outside of the trade area covered by local telephone service, provide a toll-free telephone number.

4. Include with each prescription of an approved drug to be consigned pursuant to sections 2 to 13, inclusive, of this regulation:

(a) The local, and if applicable toll-free, telephone numbers of the licensed veterinarian;

(b) The hours during which the client may contact the licensed veterinarian by telephone; and

(c) A written notice in substantially the following form:

> *Written information about this prescription has been provided for you. Please read this information before you administer this medication to an animal. If you have questions concerning this prescription, a licensed veterinarian is available between the hours of .... and .... to answer your questions.*

5. Maintain the confidentiality of each medical record of an animal, including prescriptions, pursuant to NAC 638.0475. A licensed veterinarian shall not divulge the contents of the medical record of an animal, except as authorized by NAC 638.0475.

6. Make available to a licensed veterinarian, upon request, all information relating to a prescription of an approved drug which was consigned pursuant to sections 2 to 13, inclusive, of this regulation, to a client of that licensed veterinarian by the prescribing licensed veterinarian.

7. Ensure that counseling is conducted in a confidential manner to prevent disclosure of information to any person other than the client.

Sec. 13. ***If a licensed pharmacy remits payment to a licensed veterinarian when dispensing an approved drug consigned pursuant to sections 2 to 13, inclusive, of this regulation, the payment must not be considered unearned compensation as prohibited by NRS 639.264.***

Sec. 14. 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. 15. 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.