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## **The Importance of Understanding what is Required of you when Administering, Distributing, Dispensing, or Prescribing Prescription Drugs**

Over these past few years the State Board of Veterinary Medicine (Board) has reviewed several cases and fielded multiple questions surrounding the subject of prescriptions—ranging from acts requiring registration as a wholesaler with the State Board of Pharmacy to the responsibilities of a licensed veterinarian when prescribing medication for a patient. After engaging in numerous discussions in the area of prescription drugs being administered, distributed, dispensed, or prescribed by licensed veterinarians, it is clear to the Board that there is potentially widespread misunderstanding and miscommunication of the legal requirements governing licensees when engaged in such acts.

Also, your Veterinary Practice Act, which is codified as Article 64 of Title 12 of the Colorado Revised Statutes, was reviewed this past legislative session by the General Assembly as part of the sunset review process that is periodically initiated after a number of years have passed in order to determine whether or not a regulatory program is still necessary for public safety, if it is working appropriately and adequately, and whether any amendments need to be made to further its mission. The process concluded with a continuation of the State Board of Veterinary Medicine for another 11 years, through September 1, 2022, and the Veterinary Practice Act was amended, with most amendments becoming effective July 1, 2011, including several related to the topic of this article. Also, the timing is such that the Pharmacy Practice Act, which is codified as Article 22 of Title 12 of the Colorado Revised Statutes, will be undergoing a sunset review during the legislative session in 2012.

This document is an attempt to provide guidance and clarity as a resource to those interested in better understanding their roles and responsibilities in navigating this area. It is important to first delve into the relevant requirements of the Veterinary Practice Act and the Rules of the State Board of Veterinary Medicine as well as Board Policies and Guidelines, then cover the implications of the Pharmacy Practice Act, review applicable U.S. Drug Enforcement Administration (DEA) registration requirements, and then finally review how the three separate but relevant sets of requirements work together in framing these issues.

### **Veterinary Practice Act, Board Rules, and Board Policies & Guidelines**

Section 12-64-103, C.R.S. of the Veterinary Practice Act is reserved for definitions and within that section are several relevant to this discussion.

- (5.1) “Dispense” means to provide a drug or device, other than by distribution, bearing a label stating the name of the veterinarian, the date dispensed, directions for use, all cautionary statements, withdrawal time, if appropriate, the identity of the animal, and the owner's name.
- (5.2) “Distribute” or “distribution” means to provide a drug or device in the manufacturer’s original package to the client-patient.



- (15.5) “Veterinarian-client-patient relationship” means that relationship established when: (a) the veterinarian has assumed the responsibility for making medical judgments regarding the health of an animal and the need for medical treatment, and the owner or other caretaker has agreed to follow the instruction of the veterinarian; (b) there is sufficient knowledge of an animal by the veterinarian to initiate at least a general or preliminary diagnosis of the medial condition of the animal, which means that the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal by virtue of an examination of the animal or by medically appropriate and timely visits to the premises where the animal is kept; and (c) the practicing veterinarian is readily available, or has arranged for emergency coverage, for follow-up evaluation in the event of adverse reactions or failure of the treatment regimen.

Section 12-64-104, C.R.S. of the Veterinary Practice Act is reserved for license requirements and exceptions. Subsection (1) reads: “No person may practice veterinary medicine in this state if the person is not a licensed veterinarian. No person may practice artificial insemination or ova transplantation of cattle or other animal species in this state except in accordance with section 12-64-105(9)(c). This article does not prohibit:”...

There has been an important change made this past legislative session to this section, particularly an amendment was made to paragraph (1)(f) and a subsection (2) was added.

- (1)(f)(I) Except as provided in subparagraph (II) of this paragraph (f) and subject to subsection (2) of this section, the owner of an animal and the owner’s employees from caring for and treating the animal belonging to such owner.
  - (II) Subparagraph (I) of this paragraph (f) does not apply in cases where the ownership of the animal was transferred for purposes of circumventing this article or where the primary reason for hiring the employee is to circumvent this article.
- (2)(a) Notwithstanding paragraph (f) of subsection (1) of this section and except as permitted by paragraph (j) of subsection (1) of this section, a person who is not a licensed veterinarian shall not administer, distribute, dispense, or prescribe prescription drugs. Except as provided in paragraph (b) of this subsection (2), a licensed veterinarian must have a veterinarian-client-patient relationship with the animal and its owner or other caretaker in order to administer, distribute, dispense, or prescribe prescription drugs to or for an animal.
  - (b)(I) In an emergency situation where a licensed veterinarian who has a veterinarian-client-patient relationship prescribes a prescription drug that the licensed veterinarian does not have in stock and is not available at a local pharmacy, another licensed veterinarian who does not have a veterinarian-client-patient relationship with the animal and owner or other caretaker may administer, distribute, or dispense the prescription drug to the animal based on the examining veterinarian’s expertise and veterinarian-client-patient relationship.
    - (II) The board shall adopt rules defining what constitutes an emergency situation under which this paragraph (b) would apply, including a requirement that failure to administer, distribute, or dispense the prescription drug threatens the health and well-being of the animal and requiring detailed records documenting the emergency circumstances that include at least the following:
      - (A) A requirement that the examining veterinarian with the veterinarian-client-patient relationship document the emergency and the immediate need for the prescription drug;
      - (B) A requirement that the examining veterinarian with the veterinarian-client-patient relationship document his or her efforts to obtain the prescription drug from a local pharmacy, including documentation of contact with at least one pharmacy in the general proximity of the examination location that does not have the prescription drug immediately available, and
      - (C) A requirement that the licensed veterinarian who administers, distributes, or dispenses the prescription drug document the date the prescription is administered, distributed, or dispensed.
    - (III) A veterinarian who administers, distributes, dispenses, or prescribes a prescription drug in accordance with this paragraph (b) is not subject to discipline pursuant to section 12-64-111(1)(aa) if the veterinarian satisfies the requirements of this paragraph (b) and the rules adopted by the board.

Section 12-64-111, C.R.S. of the Veterinary Practice Act is reserved for discipline of licensees. Subsection (1) reads: "Upon signed complaint by any complainant or upon its own motion, the board may proceed to a hearing in conformity with section 12-64-112. After a hearing, and by a concurrence of a majority of members, the board may revoke or suspend the license of, place on probation, or otherwise discipline or fine, any licensed veterinarian for any of the following reasons:"

There are two important paragraphs to highlight in this section of the Veterinary Practice Act that are relevant to this discussion.

- (1)(aa) Administering, dispensing, distributing, or prescribing any prescription drug other than in the course of a veterinarian-client-patient relationship, except in accordance with section 12-64-104(2)(b); and
- (dd) Engaging in any act prohibited in article 22 of this title.

A relevant Board Rule to this discussion can be located in Board Rule 6, which covers the "Veterinary Medical Ethics and Code of Conduct" section. There are three sections of this rule that apply directly to this topic.

- **6.07 VCPR.**

The veterinarian-client-patient relationship (VCPR) is the basis for veterinary care. To establish such a relationship, the veterinarian should have sufficient knowledge of the animal to understand its current health and render at least a preliminary diagnosis. This would require that the veterinarian is personally acquainted with the animal (herd, flock, litter, or large group) either through office or home visits.

- **6.08 Prescription Drugs.**

Veterinarians may only prescribe medication when they have a VCPR with the animal (herd, flock, litter, or large group). Under federal and state law, veterinarians may not sell, distribute, dispense or participate in or arrange for the sale of prescription medicines in any fashion except through a VCPR. Veterinarians are charged with knowledge of the Pharmacy Practice Act provisions that apply to their practice, as well as the laws and regulations of the Federal Food and Drug Administration. When a client requests a copy of a prescription for their animal under current treatment, the veterinarian must provide it to the client.

- **6.09 Medical Records.**

Medical records must be kept by veterinarians in all cases in which they have a VCPR. Records must also be kept in any other situation where a veterinarian has provided care or prescribed or dispensed drugs. Clients have a statutory right to copies of the medical records of their animals, and copies must be provided in a reasonable length of time.

There is also a relevant Board Guideline regarding prescription medications. While the header indicates it is effective June 2011, this particular guideline has been in place as written for more than five years. It reads as follows:

The Colorado State Board of Veterinary Medicine believes that the appropriate prescribing, dispensing, and administration of prescription and other medications is a crucial element in the treatment of animal patients. Veterinarians should only prescribe medications for animals with which they have a veterinarian-client-patient relationship. Veterinarians may dispense medications for the animals under their care. Should a client ask for a written prescription for an animal being seen by a veterinarian, the veterinarian should supply that written prescription, as it is a part of the animal's medical record, and the owner has a right to that record pursuant to C.R.S. 12-64-120 (2003). However, at any time, if supplying the prescription would compromise or risk the animal's health, the veterinarian should decline to provide it and inform the owner what is required in order to address the animal's health concerns.

Internet pharmacy sale of prescription medications is legal if the veterinarian involved has a valid client-patient relationship with the animal for which he is supplying the medications. In addition, he must have prescribed an appropriate medication for that animal, which is always the case whether by internet or other means. Veterinarians are authorized providers under the law and may procure, store, and dispense whatever medications they prescribe their patients. Whether or not internet business constitutes a "pharmacy" under state law is an issue for the Colorado State Board of Pharmacy to determine.

The sale of nonprescription drugs in Colorado is largely unregulated. Internet pharmacy sale of such medications is legal, as is sales of these medications in any animal supply store.

Clearly, Board Rule 6.08 and the above Board Guideline were written prior to the changes made to the Veterinary Practice Act, which now allows another licensed veterinarian who does not have a VCPR, in an emergency situation, to administer, distribute, or dispense a prescription drug. In response, the Board held a rulemaking hearing on November 3, 2011 in order to discuss amending this rule to be consistent with the recent change to the statute.

Note the last sentence in the same rule: a recurring question the Board has fielded is whether or not the licensed veterinarian is required to provide a prescription to the owner or other caretaker of a patient for use elsewhere, particularly to purchase their medication online. The rule clearly states that one must be provided to the client if a request is made for their animal and it is under current treatment. Where it gets a little messy is if the request is made for the licensed veterinarian to fax the prescription directly to an entity, particularly one based outside of Colorado. The rule only requires the licensed veterinarian to provide the prescription to the client, so a best practice here would be to do just that; provide the prescription directly to the client and he or she can then decide where to take it for purposes of dispensing or distribution of the medication. More than likely this will be further clarified in the above Board Guideline, which begins towards the bottom of page 3 of this piece and concludes at the top of this page, through an amendment process; of course the gender-specific language in this guideline will also be amended.

## **Pharmacy Practice Act**

Section 12-22-121(6)(a), C.R.S. allows licensed veterinarians to dispense to their own patients.

However, section 12-22-121(4), C.R.S. states that prescriptions shall only be dispensed from a Board-registered pharmacy, so going beyond what is allowed under 121(6)(a) would violate 121(4).

Also, section 12-22-802(1), C.R.S. requires a person or entity distributing a drug to register with the Board as a prescription drug wholesaler.

Currently, what this means is licensed veterinarians can compound and dispense prescriptions for their own patients under the Pharmacy Practice Act. However, they may not do so for animals being treated by other veterinarians. Prescription drugs obtained using a veterinary license cannot be dispensed or sold by another business, such as a supply store. In order to do this, the veterinarian must be registered with the Colorado State Board of Pharmacy as a wholesaler. In turn, the business must be registered with the Colorado State Board of Pharmacy as either a prescription drug outlet (pharmacy) or a wholesaler, depending on the type of business conducted.

Section 12-22-121(3)(b), C.R.S. states that a wholesaler may sell or deliver to a person responsible for the control of an animal a drug intended for veterinary use for that animal only if a licensed veterinarian has issued, prior to such sale or delivery, a written prescription order for the drug in the course of an existing, valid veterinarian-client-patient relationship.

What this requirement means is that a written prescription order must be on file at the veterinary wholesaler before a prescription drug product can be delivered, i.e. to a feedlot or dairy farm.

In the recent past, the Colorado State Board of Pharmacy has investigated matters in which animal supply stores (or similar entities) were dispensing prescription medications, but failed to have the proper registration to do so. In all of these cases, a veterinarian had allowed this business to use his/her veterinary license to obtain prescription drugs. The State Board of Pharmacy took action against these licensed veterinarians, including issuing heavy fines for illegal distribution of drugs, as well as against the business for failing to have the appropriate registration. In turn, the State Board of Veterinary Medicine took action against the licensed veterinarians for violating the Pharmacy Practice Act, which included additional fines.

### **U.S. Drug Enforcement Administration (DEA)**

Any licensed veterinarian planning to prescribe controlled substances in the state of Colorado is required to obtain a separate DEA registration (renewed every 3 years) after first obtaining a state- issued license (renewed every 2 years) to practice as a veterinarian. A separate DEA registration is required for each principal place of business or professional practice where controlled substances are stored, administered, or dispensed. If a licensed veterinarian will ONLY be prescribing from another location(s) situated in Colorado, then an additional registration is NOT necessary. Also, DEA regulations do not require a separate registration for every location within the same state where a controlled substance is administered so long as the drugs are returned to a registered location on a daily basis. In other words, a licensed veterinarian can carry controlled substances from his/her registered location to a secondary location to treat patients so long as the drugs are returned to the registered location at the end of the day. If, however, he/she is crossing state lines (i.e. is licensed with the state of Colorado and has a DEA registration in Ft. Collins but has a secondary practice location in Laramie, WY), then he/she must be dually licensed and registered in WY as well as in CO. These same requirements apply to any veterinarians operating out of a mobile unit, i.e. treating patients in a home setting or out at a farm or ranch. A licensed veterinarian utilizing controlled drugs out of a mobile unit can only prescribe and administer those drugs from the mobile unit. The controlled drugs must be returned, secured, and stored at the location that is registered with the DEA, which is required to be a fixed or stationary building.

There are many important regulations enforced by the DEA—too many to go through in this piece. I have provided a link to the DEA website in the “Resources” section at the end of this document; it would be best to review those regulations in their entirety, which include requirements on who should be registered, what the records must contain, who is responsible for signing Schedule II order forms, prescriptions, etc. However, there are common oversights that the DEA sees in clinic situations that are important enough to cover here. They include but are not limited to the following:

- (a) Multiple veterinarians ordering controlled substances under their own DEA numbers but storing them in a common cabinet and not taking responsibility for the records, or not knowing what drugs have been procured under their own DEA number;
- (b) A veterinarian’s DEA number being used to order stock for all veterinarians in the clinic to dispense or administer. It is important that the veterinarian whose DEA number is used is in agreement with such designation and is also fully aware of the requirements under the Code of Federal Regulations (CFR). Dispensing or administering is sometimes delegated to a technician or office staff under supervision, but if the DEA finds non-compliance, the registrant (licensed veterinarian) will be held accountable;
- (c) A Medical Director retires or relocates and someone else in the clinic calls the DEA to see what to do with the remaining drugs. Under the Controlled Substances Act (CSA), the drugs are tracked by registration number, and not by the money. As far as the DEA is concerned, the licensed veterinarian is the responsible entity and should responsibly transfer any drugs at a clinic to another DEA number at the facility prior to leaving. This should be accomplished by an “invoice” listing the DEA numbers of the “owner” and the “recipient,” both of their addresses, and the name, strength, and quantity of each drug transferred. The new “owner” must be able to show how he/she obtained all controlled substances. Again, the DEA does not

look at controlled substance ownership as a monetary consideration but rather tracks the drugs by the DEA number under which the drugs were procured; and

- (d) Whenever controlled substances are ordered by a DEA registrant, it is incumbent upon that registrant to take initial and biennial controlled substance inventories (CII and CIII-IV) and retain records of all controlled substances purchased, distributed, administered/dispensed, returned to the manufacturer or otherwise disposed of. If there is a theft or loss, it has to be reported to the DEA on the correct form (DEA106). The regulations cover what each of those reports must contain.

Please note that veterinarians as well as all other authorized licensed registrants (physicians, dentists, etc.) are referred to collectively in these regulations as “practitioners.”

### **Applying Three Sets of Requirements to your Veterinary Practice**

Prior to the recent statutory changes to the Veterinary Practice Act, a licensed veterinarian was required to establish a veterinarian-client-patient relationship in order to administer, distribute, dispense, or prescribe prescription drugs. The Veterinary Practice Act and Board Rules did not previously allow for this to occur outside of the established VCPR. However, the recent change in section 12-64-104(1)(f) and (2), C.R.S. now allows another licensed veterinarian who does not have a VCPR, in an emergency situation, to administer, distribute, or dispense a prescription drug. As a result, the Board held a rulemaking hearing on November 3, 2011 in order to discuss amending current rules and creating new rules to be consistent with recent changes to the statute, including this particular exemption. At the conclusion of the rulemaking hearing, the Board adopted revised rules and new rules, which will become effective December 30, 2011. This means that effective December 30, 2011, Rule 6 will be re-numbered to be Rule III. As a result, Rule 6.07 will become Rule III.A.7; Rule 6.08 will become Rule III.A.8; and Rule 6.09 will become Rule III.A.9. The Board will also discuss at their December 15, 2011 meeting further amendments to the Board Policies and Guidelines in adherence to these recent changes.

The Pharmacy Practice Act currently limits the ability of a licensed veterinarian to compound and dispense prescriptions to his or her patients; otherwise he or she would have to be operating as a Board-registered pharmacy. And according to the Pharmacy Practice Act, if a licensed veterinarian is distributing a prescription drug outside of such a relationship, then he or she is required to register with the State Board of Pharmacy as a prescription drug wholesaler. Unfortunately, a change was not made to the Pharmacy Practice Act that would also allow for the emergency exemption that is allowed under the Veterinary Practice for a licensed veterinarian to dispense or distribute a prescription drug to a non-patient. I have asked the Policy Analyst assigned in conducting a sunset review of the Pharmacy Practice Act to look into this matter as part of his process and to ensure that the Pharmacy Practice Act also clearly identifies this limited exemption in order to prevent the State Pharmacy Board from potentially disciplining licensed veterinarians who are in compliance with the new provisions of the Veterinary Practice Act.

It has also come to my attention that the Policy Analyst conducting the sunset review of the Pharmacy Practice Act is considering amending the Pharmacy Practice Act to allow licensed veterinarians to call in a prescription order to a distributor (wholesaler) as long as the licensed veterinarian provides a written prescription order within 72 hours of the verbal request. Currently, the requirement is for a licensed veterinarian to submit all prescription orders to distributors in writing. Understandably, several veterinarians have expressed to the Policy Analyst concerns with this requirement because there are times when a veterinarian is in a remote location and needs medication to treat sick animals and is unable to submit a written prescription order at that time.

A DEA registration to prescribe controlled substances in the state of Colorado can only be issued to a veterinarian licensed to practice in the state of Colorado. If a veterinarian is unable to obtain a Colorado license to practice veterinary medicine or such license is revoked or rescinded, then the DEA cannot issue a registration to that individual. In other words, you have to first obtain a license to practice veterinary medicine in the state of Colorado before you are eligible to apply for your DEA registration. If a DEA registrant loses his/her state licensure

privileges to prescribe controlled substances then the DEA must also rescind or revoke the federal authority to prescribe controlled substances. Also, if the State Board of Veterinary Medicine at any time restricts a licensee's ability to administer, distribute, dispense, or prescribe prescription drugs, then the DEA will follow suit so far as controlled substances are regarded.

Last but not least, a violation of any laws or regulations enforced by the DEA or any violation of the Pharmacy Practice Act is also considered a violation of the Veterinary Practice Act. That is why it is imperative for a licensed veterinarian to not only keep current with requirements enforced by the State Board of Veterinary Medicine, but those enforced by the State Board of Pharmacy and the Drug Enforcement Administration as well.

## Resources

The Policy Analyst's sunset report regarding the Pharmacy Practice Act will be issued on October 15, 2011. You may visit the following website of the Office of Policy, Research and Regulatory Reform after that date in order to review his recommendations for amendments to the Pharmacy Practice Act: [www.dora.state.co.us/opr](http://www.dora.state.co.us/opr).

In order to review this year's sunset bill amending the Veterinary Practice Act, please visit [www.leg.state.co.us/clics/clics2011a/csl.nsf/billcontainers/26B89AA74EAC4F518725781E00835AC5/\\$FILE/091\\_enr.pdf](http://www.leg.state.co.us/clics/clics2011a/csl.nsf/billcontainers/26B89AA74EAC4F518725781E00835AC5/$FILE/091_enr.pdf).

A current copy of the Veterinary Practice Act (which does not yet include the recent changes through sunset) may be reviewed at [www.dora.state.co.us/veterinarians/forms/Statute.pdf](http://www.dora.state.co.us/veterinarians/forms/Statute.pdf). A new version to include the recent amendments passed this legislative session will be posted in the near future.

The current Board Rules (amendments and new rules adopted on November 3, 2011 and effective December 30, 2011 will be posted in the near future) are located at [www.dora.state.co.us/veterinarians/rules](http://www.dora.state.co.us/veterinarians/rules).

Board Policies and Guidelines (proposed amendments to be discussed at a meeting of the Board on December 15, 2011) are located at [www.dora.state.co.us/veterinarians/forms/Policies.pdf](http://www.dora.state.co.us/veterinarians/forms/Policies.pdf).

Please periodically check the following link to see when and where a rulemaking hearing is noticed, including the process for providing written and verbal testimony for consideration: [www.dora.state.co.us/veterinarians/rulemaking](http://www.dora.state.co.us/veterinarians/rulemaking).

You may review current State Board of Pharmacy statutes, rules, and policies at [www.dora.state.co.us/pharmacy/statutesrulespolicies](http://www.dora.state.co.us/pharmacy/statutesrulespolicies).

In order to access the Code of Federal Regulations and the Controlled Substances Act with the Drug Enforcement Administration's Office of Diversion Control, please visit [www.deadiversion.usdoj.gov/21cfr](http://www.deadiversion.usdoj.gov/21cfr). It is important to note that the CSA is the law and the CFR spells out how the law is to be enacted. So, from a "user friendly" standpoint, it would be easier to follow the CFR, which is the first link provided on this page.

Thank you for your attention to this lengthy but important discussion. If you have any questions or concerns regarding this information, please feel free to contact me directly at 303-894-7761 or at [maulid.miskell@dora.state.co.us](mailto:maulid.miskell@dora.state.co.us).

For the State Board of Veterinary Medicine

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