



THE COLLEGE OF
VETERINARIANS
OF ONTARIO

PROFESSIONAL PRACTICE STANDARD

Dispensing a Drug

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Introduction

Under the *Veterinarians Act* and regulations, a veterinarian licensed by the College of Veterinarians of Ontario is authorized to prescribe and dispense a drug. More specifically, the practice of dispensing requires appropriate knowledge and skill, and the use of professional judgment. In most circumstances, dispensing is coupled with the act of prescribing; however, there are acceptable instances when dispensing is an activity performed independently by a veterinarian. A veterinarian should acknowledge and manage the potential conflict of interest in assuming the dual role of prescriber and dispenser.

The professional practice of veterinary dispensing is informed and regulated by a broad legislative framework provincially and federally. This legislative framework sets out the requirements for the sale and dispensing of a drug, including labelling and record-keeping. The College *Professional Practice Standard: Extra-Label Drug Use*, *Professional Practice Standard: Management and Disposal of Controlled Drugs*, and *Professional Practice Standard: Use of Compounded Products in Veterinary Practice* describe specific expectations in the dispensing of a drug in an extra-label manner, a controlled drug, and a compounded product, respectively.

Definitions

Auxiliary: Auxiliary means a person involved in a veterinarian's practice of veterinary medicine, other than another veterinarian.

Client: Client means, with respect to a veterinarian, the owner of an animal(s), group of animals, or herd(s) that the veterinarian is treating, an authorized representative of the owner, or an individual who the veterinarian reasonably determines is acting in the interest of the animal.

Dispensing: The practice of dispensing means, with respect to a drug or substance, to distribute or provide the drug or substance and includes to sell or to give away the drug or substance but does not include the administration of the drug or substance, by injection, inhalation, ingestion or by any other means, to the body of an animal.¹

Drug: As per the *Drug and Pharmacies Regulation Act*, drug means any substance or preparation containing any substance (a) manufactured, sold or represented for use in (i) the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical or mental state or the symptoms thereof, in humans, animals or fowl, or (ii) restoring, correcting or modifying functions in humans, animals or fowl, (b) referred to in Schedule I, II, or III, (c) listed in a publication named by the regulations made under the *Drug and Pharmacies Regulation Act*, or (d) named in the regulations made under the *Drug and Pharmacies Regulation Act*.

Extra-Label Drug Use: Extra-label drug use (ELDU), also referred to as "off-label use", refers to the use or intended use of a drug approved by Health Canada in an animal in a manner not in accordance with the label or package insert with respect to species, indication, dose, duration, and route of administration. It also includes the use of all unapproved drugs, including unapproved bulk active pharmaceutical ingredients (APIs) and compounded drugs.²

Prescribing/Prescription: A direction from a member authorizing the dispensing of a drug or mixture of drugs to a client for a specified animal or group of animals.

Veterinarian: The term veterinarian in this document refers to a licensed member of the College of Veterinarians of Ontario, unless stated otherwise.

Withholding Time: Withholding time (also known as withdrawal time) means, in reference to a food producing animal that receives a drug or substance, the period of time for which the animal or the product(s) of the animal should be withheld or withdrawn from sale for consumption.

Practice Expectations

A veterinarian meets the *Professional Practice Standard: Dispensing a Drug* when the veterinarian:

(A) Expectations for Dispensing in All Circumstances

1. Respects the best interest(s) of the animal or group of animals and of the client in prescribing and/or dispensing a drug, acknowledging the overarching responsibilities of professionalism and balanced judgment, including the protection of public health.
2. Dispenses a drug only when working from an accredited veterinary facility.

¹ *Veterinarians Act*, R.R.O. 1990, Reg. 1093, s. 1.

² Extra-Label Drug Use (ELDU) in Animals, Health Canada

3. Dispenses a drug that is not past its expiry date or that will not likely expire before the intended course of therapy has ended.
4. Dispenses a drug for resale only where the drug is dispensed to another veterinarian or a pharmacist, who are licensed in Ontario, in reasonably limited quantities in order to address a temporary shortage experienced by that other veterinarian or pharmacist.
5. Provides a client with information regarding common side effects and any serious risks associated with the administration of a dispensed drug used in either a label or extra-label manner. Informs the client of the proper storage, handling, and the means of administration of a prescribed drug. Retains this information in the medical record.
6. Advises the client of appropriate withholding times when dispensing a drug for use in food-producing animals, which shall be at least as long as the withholding time recommended by the manufacturer of the drug or substance. Appropriate withholding time(s) must be legibly and conspicuously displayed on the label affixed to the container in which the drug is dispensed. In instances where the appropriate withholding time is not known, makes every effort to establish an appropriate withholding time. The Canadian Global Food Animal Residue Avoidance Database (www.cgfarad.usask.ca) should be consulted for its recommended residue avoidance information when a drug is used in an extra-label manner
7. Engages in informed and responsible dispensing of T-61 only to those individuals who are either auxiliaries operating under the specific direction of the veterinarian or individuals who are employed by agencies or organizations given the legal authority to obtain T-61 to euthanize animals, including wild animals, and who are known to the veterinarian to be competent in the humane administration of T-61, and aware of the advisability of administering sedation to the animal before administering T-61.
8. Disposes of a drug that is damaged or expired and unfit for dispensing, safely and securely and in accordance with any environmental requirements.
9. Understands that he or she may not return to stock, administer, re-sell, or re-dispense a drug that was previously sold or dispensed.
10. Ensures that a drug is stored appropriately to maintain safety and efficacy.

(B) Dispensing Within a Veterinarian-Client-Patient Relationship

11. (a) Dispenses a drug within an established Veterinarian-Client-Patient-Relationship (“VCPR”) where the veterinarian:
 - has been retained by the owner of the animal(s), groups of companion animals, or herd(s), an authorized representative of the owner, or an individual who the veterinarian reasonably determines is acting in the interest of the animal;
 - has advised the client that the veterinarian will only provide services in accordance with the standards of practice of the profession;

- has reached an agreement with the client as to the scope of the services to be provided by the veterinarian; and
- has obtained the consent of the client for each service to be provided.

(b) Understands that additional requirements for dispensing a drug are that the veterinarian:

- has recent and sufficient knowledge of the animal or group of animals by virtue of a history and inquiry and either physical examination of the animal or group of animals or medically appropriate and timely visits to the premises where the animal or group of animals is kept to reach at least a general or preliminary diagnosis;
- believes that the drug is prophylactically or therapeutically indicated for the animal or group of animals; and
- is readily available in case of adverse reactions to the drug.³

(C) Dispensing Without an Existing Veterinarian-Client-Patient Relationship

12. Understands that the requirements for a VCPR in section 11 do not apply when a veterinarian dispenses a drug pursuant to an oral or written prescription from another veterinarian who is licensed in Ontario (the prescribing veterinarian) when the following conditions are met:

- the drug being dispensed is not a controlled substance,
- it is not reasonably possible for the client to obtain the drug from the prescribing veterinarian or a pharmacy,
- it is necessary in the interests of the animal to administer or dispense the drug without the delay that would be associated with returning to the prescribing veterinarian,
- he or she makes a reasonable effort to discuss the matter with the prescribing veterinarian,
- he or she conducts a sufficient assessment of the animal's circumstances, which may not require a physical examination in every case, to ascertain that it is unlikely that there has been a material change in the circumstances since the prescription was given,
- the quantity of the drug dispensed is no more than would reasonably enable the client to return to the prescribing veterinarian for future prescriptions or quantities of the drug, and
- he or she makes a written record of the transaction.

³ In accordance with the College's policy on After Hours Care.

13. Understands that his or her responsibilities when dispensing a drug outside of an existing VCPR include the responsibilities to:

- Confirm the identification of the client and establish and maintain an appropriate dispensing record for each client/patient as part of the medical record
- Obtain and confirm the accuracy and authenticity of the original prescription and refill information.
- Maintain the original prescription in the dispensing record
- Confirm the identity and registration of the prescribing veterinarian
- Immediately transcribe a prescription that is received over the telephone into writing, inclusive of the name of the prescribing veterinarian.
- Reject a prescription and not dispense any medications if the prescription is assessed to be invalid, not reasonable, or improper, and the situation cannot be clarified by the prescribing veterinarian.
- Inform the prescribing veterinarian that the prescription has been filled.

14. Understands that a further exception to the requirement for a VCPR includes where a veterinarian determines that there is an emergency situation and that an animal or animals require(s) immediate veterinary services.

(D) Controlled Substances

In addition to the requirements in paragraphs 1 through 11 above related to dispensing within a VCPR, the following requirements apply to the dispensing of a controlled substance:

15. Dispenses a controlled substance only within a VCPR and where the controlled substance is required for a condition for which the animal is receiving treatment from the veterinarian.

16. When dispensing a controlled substance, keeps a controlled substances register and enters the following information in it:

- The date the controlled substance is dispensed or administered,
- The name and address of the client,
- The name, strength and quantity of the controlled substance dispensed or administered, and
- The quantity of the controlled substance remaining in the veterinarian's inventory after the controlled substance is dispensed or administered.

17. Understands that he or she can mail any controlled substance or any drug referred to in Schedule 1 established under section 3 of Ontario Regulation 264/16 made under *the Drug and Pharmacies Regulation Act* only by registered mail or another method of delivery that allows for the controlled substance to be tracked and requires the person receiving the controlled substance or drug to sign for its receipt.

18. Does not allow any person, other than another member or an auxiliary acting upon the specific direction of the veterinarian, to dispense, administer, or have access to the controlled substances in the veterinarian's possession.

(E) Restricted Drugs

19. The following drugs may not be dispensed under any circumstances:

- Ketamine
- Sodium pentobarbital
- General anesthetics (For example, propofol, halothane, isoflurane)
- Injectable fentanyl

(F) Record-Keeping

20. Keeps an inventory of every drug that he or she purchases and, immediately upon receiving the drug, ensures that the following information is entered in the record:

- The date of purchase of the drug and if different, the date the member received the drug;
- The name, strength and quantity of the drug received;
- The name and address of the supplier from whom the drug was purchased;
- The purchase price; and
- In the case of a controlled substance, the signature of the member who made the purchase and the signature of the person who received it.

21. Understands that all drugs that are sold from an accredited veterinary facility must have a recorded audit trail. The sale of any prescription drug that is recorded by an invoice will require as part of the audit trail:

- A medical record of the appropriate dispensing, including the labeling, and
- A record of the prescription, either:
 - medical record entries if prescribed by a veterinarian in the same practice where the drug was sold, or
 - the original prescription from another veterinarian who is licensed in Ontario, or a record of the requisite information, in the case of an oral prescription.

22. When dispensing a drug, makes a written record, which may be the same as the medical record, showing:

- the name and address of the owner of the animal or group of animals for which the drug is prescribed;
- the name, strength and quantity of the prescribed drug;
- the Drug Identification Number (DIN);
- the directions for use if they are different than the directions for use on the manufacturer's label or if the manufacturer's label does not specify the directions for use;
- the date on which the drug is dispensed;
- the price charged; and
- the name of the prescribing veterinarian if the veterinarian prescribing the drug is not the same as the veterinarian dispensing the drug.

(G) Packaging

23. Dispenses a drug in a child resistant package prescribed by the *Food and Drug Regulations* made under the *Food and Drugs Act* unless,

- child resistant packaging is unobtainable through no fault of the veterinarian,
- a child resistant package is not suitable because of the amount or physical form of the drug,
- the client directs otherwise, or
- in the best interests of the client, it is advisable not to use child resistant packaging.

24. (a) Ensures that all labels on the container in which a drug is dispensed include the following information, whether on the dispensing label or the manufacturer's label:

- the name, strength and quantity of the drug;
- the date the drug is dispensed;
- the name and address of the dispensing veterinarian, and the prescribing veterinarian, if dispensing occurs outside a veterinarian-client-patient relationship;
- the identity of the animal or group of animals for which it is dispensed;
- The Drug Identification Number (DIN);
- the name of the owner of the animal or animals;
- the prescribed directions for use (dose, route of administration, frequency, and duration).
- minimal withholding time (where applicable) as prescribed;
- storage precautions;
- any toxic warnings or other precautions appearing on the original label; and
- any other information required by legislation.

(b) Marks the label on the container in which a drug is dispensed with the words "Veterinary Use Only" on both inner and outer package labels.

(c) If drugs are dispensed in a container, each container must be labeled. If a case containing multiple containers is dispensed, the case must be labelled.

25. Where the product is supplied in its original packaging and already includes some or all of the information in section 24 which remains legible following application of the dispensing label, it is not necessary to repeat this same information on the dispensing label. If it is not feasible to include all of the information on the label due to the size of the packaging it must be included on a separate sheet or via a weblink.

Legislative Authority

Food and Drugs Act and Regulations (Federal)

Feeds Act and Regulations (Federal)

Controlled Drugs and Substances Act and Regulations (Federal)

Drug and Pharmacies Regulation Act and Regulations (Provincial)

Drug Interchangeability and Dispensing Fee Act (Provincial)

Veterinarians Act (Provincial)

Regulation 1093, s. 1, 18, 23-33 (Veterinarians Act) (Provincial)

Guide to the Standard

A separate *Guide to the Professional Practice Standard: Dispensing a Drug* has been developed by the College. See the Resources tab on the College website at www.cvo.org.

Other References:

Policy on Extra-Label Drug Use in Food Producing Animals, Health Canada, 2015.

http://www.hc-sc.gc.ca/dhp-mps/vet/label-etiquet/pol_eldu-umdde-eng.php

Position Statement: Extra-label Drug Use (ELDU), Canadian Veterinary Medical Association, 2015. <http://www.canadianveterinarians.net/documents/extra-label-drug-use-eldu>

Canadian gFARAD Website:

<https://cgfarad.usask.ca/home.html>

Veterinary Oversight of Antimicrobial Use – A Pan-Canadian Framework of Professional Standards for Veterinarians, Canadian Veterinary Medical Association,

<https://www.canadianveterinarians.net/documents/pan-canadian-framework>

The following can be found on the College's website at www.cvo.org:

Professional Practice Standard: Prescribing a Drug

Guide to the Professional Practice Standard: Prescribing a Drug

Professional Practice Standard: Extra-Label Drug Use

Guide to the Professional Practice Standard: Extra-Label Drug Use

Professional Practice Standard: Management and Disposal of Controlled Drugs

Guide to the Professional Practice Standard: Management and Disposal of Controlled Drugs

Professional Practice Standard: Use of Compounded Drugs in Veterinary Practice

Guide to the Professional Practice Standard: Use of Compounded Drugs in Veterinary Practice

Professional Practice Standard: Informed Client Consent

Guide to the Professional Practice Standard: Informed Client Consent

Professional Practice Standard: Medical Records

Guide to the Professional Practice Standard: Medical Records

Professional Practice Standard: Veterinarian Client Patient Relationship

Guide to the Professional Practice Standard: Veterinarian Client Patient Relationship

College publications contain practice parameters and standards which should be considered by all Ontario veterinarians in the care of their patients and in the practice of the profession. College publications are developed in consultation with the profession and describe current professional expectations. It is important to note that these College publications may be used by the College or other bodies in determining whether appropriate standards of practice and professional responsibilities have been maintained. The College encourages you to refer to the website (www.cvo.org) to ensure you are referring to the most recent version of any document.