



THE COLLEGE OF
VETERINARIANS
OF ONTARIO

PROFESSIONAL PRACTICE STANDARD

Dispensing Drugs

TBD

Introduction

Under the *Veterinarians Act* and Regulations, veterinarians licensed by the College of Veterinarians of Ontario are authorized to engage in the practice of dispensing. 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 a procedure performed independently. A veterinarian should acknowledge and manage the inherent conflict of interest in assuming the dual role of prescriber and dispenser.

The professional practice of dispensing is informed and regulated by a broad legislative framework: the *Controlled Drugs and Substances Act*, the *Drug and Pharmacies Regulation Act*, the *Drug Interchangeability and Dispensing Fee Act*, the *Food and Drugs Act*, and the *Veterinarians Act* and the regulations thereunder. This legislative framework sets out the requirements for the sale and dispensing of drugs, including labelling and record-keeping. The College *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 controlled drugs and compounded products.

Definitions

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), often termed “off-label use”, refers to the actual or intended use of any drug, whether it is a prescription or an over-the-counter (OTC) drug, in an animal in a manner that is not in accordance with the label or the package insert of the drug approved by Health Canada. This includes the use of all drugs, (including unapproved bulk pharmaceutical substances and compounded drugs) that do not have a Canadian approved label.²

Prescription

A prescription is an evidence based or informed order by a veterinarian directing that a specific animal patient or group of animals, be administered a specified drug, via an appropriate route of administration, in a defined dosage for a limited time in order to treat or prevent an identified condition, disease, disorder or dysfunction.

Withholding Time

Withholding 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 of the animal should be withheld or withdrawn from sale for consumption.

Practice Expectations

A veterinarian meets the *Professional Practice Standard: Dispensing Drugs* when the veterinarian:

Expectations for Dispensing in All Circumstances

1. Respects the best interest(s) of the client and of the animal or group of animals in prescribing and/or dispensing a drug, acknowledging the overarching responsibilities of professionalism and balanced judgment.
2. Dispenses drugs only from an accredited veterinary facility from which the veterinarian practices veterinary medicine.
3. Advises the client of common side effects and any serious risks associated with the administration of the dispensed drug.

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

² CVMA Guidelines for the legitimate use of Compounded Drugs in Veterinary Practice

4. Advises the client of proper storage and handling of dispensed drugs.
5. Advises the client of appropriate withholding times when dispensing drugs 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.
6. Charges a reasonable fee for dispensing.
7. Dispenses drugs that are not past their expiry date or that will not likely expire before the prescribed course of therapy has ended.
8. 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.
9. Disposes of drugs that are damaged or expired and unfit for dispensing safely and securely and in accordance with any environmental requirements.
10. Engages in informed and responsible dispensing of drugs, other than narcotics or controlled substances, for use in free-ranging wildlife to those individuals who are employed by agencies or organizations given the legal authority to manage free-ranging wildlife.
11. 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 euthanasia, and aware of the advisability of administering sedation to the animal before administering the product.

Dispensing Within a Veterinarian-Client-Patient Relationship

12. (a) Dispenses drugs 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 drugs are that the veterinarian:

- has 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

Dispensing Without an Existing Veterinarian-Client-Patient Relationship

13. Understands that the requirements for a VCPR in section 12 do not apply when a veterinarian dispenses drugs pursuant to an oral or written prescription from another veterinarian who is licensed in Ontario 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.

14. Understands that his or her responsibilities when dispensing drugs 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 (this may already be documented in the medical 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.

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

- Confirm any substitutions of a specific medication for a generic medication with the prescribing veterinarian and client.
- Maintain a declining balance of refills.
- Forward available or remaining totals to other dispensing locations if requested by the client.
- Refuse to provide additional refills when a prescription is finished.

15. Informs and educates a client to whom the veterinarian has dispensed drugs.

16. Understands that further exceptions to the requirement that a VCPR must be established before a veterinarian can provide veterinary services (inclusive of dispensing drugs) include where a veterinarian determines that there is an emergency situation and that an animal or animals require(s) immediate veterinary services or cases where a veterinarian dispenses non-controlled substances to individuals, agencies, or organizations that treat free-ranging wildlife (whom they may regard as clients).

Controlled Substances

In addition to the requirements in paragraphs 1 through 12 above, the following requirements apply to the dispensing of controlled substances:

17. Dispenses controlled substances only when the animal is under his or her professional treatment and the controlled substance is required for a condition for which the animal is receiving treatment from the veterinarian.

18. 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.

19. Understands that he or she can mail a controlled substance or drug referred to in Schedule 1 established under section 3 of Ontario Regulation 58/11 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.

20. Protects controlled substances in his or her possession from loss and theft and reports any loss or theft of controlled substances in his or her possession to a police officer immediately upon discovery of the loss or theft, and to the Minister of Health for the Government of Canada within 10 days of discovering the loss or theft.

21. 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.

Record-Keeping

22. Keeps an inventory of every drug that he or she purchases and, immediately upon receiving the drug, enters the following information 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.

23. 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.

24. 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.

Packaging

25. Dispenses drugs in child resistant packages 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 recipient directs otherwise, or
- in the best interests of the recipient, it is advisable not to use child resistant packaging.

26. Marks the label on the container in which drugs are dispensed with,

- the name, strength and quantity of the drug;
- the date the drug is dispensed;
- the name and address of the dispensing veterinarian;
- the identity of the animal or group of animals for which it is dispensed;

- the name of the owner of the animal or animals; and
- the prescribed directions for use (dose, route of administration, frequency, and duration).

Additional Considerations Related to Dispensing Antimicrobials

27. Dispenses antimicrobials in a manner consistent with prudent use of antimicrobials that sustains the clinical efficacy of antimicrobials by optimizing drug use, choice, dosing, duration, and route of administration, while minimizing the emergence of resistance and other adverse effects.

28. Marks the label on the container in which antimicrobial drugs are dispensed with the words “Veterinary Use Only” on the main panel of both inner and outer package labels, immediately following or preceding the proprietary or brand name, proper name or common name, in type not less than one half as large as the largest type on the label. Each unit of drug dispensed must be labeled. If units of medication are dispensed by the bottle, each bottle must have a label. If units are dispensed in a case lot, each case must display the label.

29. The following information must be included on labels on the containers in which antimicrobial drugs are dispensed. Where the product is supplied in its original packaging and already includes some of this information which remains legible following application of the dispensing label, it is not necessary to repeat this 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. The information provided must include:

- the name of the client;
- the names of the facility and the veterinarian prescribing the drug;
- the names of the facility and the veterinarian dispensing the drug;
- identification of the animal or group of animals;
- the name of the drug dispensed and its concentration;
- the Drug Identification Number (DIN);
- the quantity of the drug dispensed;
- directions for use in the identified animal or group of animals, including dose, route of administration, frequency, and duration as prescribed;
- minimal withdrawal 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.

Legislative Authority

Food and Drugs 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)

Animals for Research Act (Provincial)

Ontario Society for the Prevention of Cruelty to Animals Act (Provincial)

Fish and Wildlife Conservation Act (Provincial)

Veterinarians Act (Provincial)

Regulation 1093 made under the *Veterinarians Act*, s. 18, 25, 27(1), 27(3), 28, 31, 33(1), 33(1.1), 33(2) (*Veterinarians Act*)

Guide to the Standard

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

Other References:

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 Products in Veterinary Practice

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

Professional Practice Standard: Informed Client Consent

Guide to the Professional Practice Standard: Informed Client Consent

Position Statement: Veterinarian Client Patient Relationship

Professional Practice Standard: Medical Records

Guide to the Professional Practice Standard: Medical Records

Professional Practice Standard: Prescribing

Other References:

Canadian gFARAD Website:

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