College of Veterinarians of British Columbia

Guide to the Professional Practice Standard: Management and Disposal of Controlled Drugs[1]

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Introduction

This College's *Professional Practice Standard: Management and Disposal of Controlled Drugs* establishes the expectations a veterinarian must meet when controlled drugs are a part of the pharmaceutical inventory in a veterinary practice. Veterinarians are expected to implement strategies to mitigate the risk of loss, theft or diversion of controlled drugs.

Using a question-and-answer format, this Guide to the Professional Practice Standard addresses questions and offers suggestions on how to apply the Professional Practice Standard in situations that arise in veterinary practice.

Frequently Asked Questions – Inventory Management and Audits

What steps should be taken to ensure that new inventory is recorded accurately?

In 2013, Health Canada issued a letter to veterinary regulators across Canada entitled 'Correspondence to Veterinarians on Steps to Minimize the Loss and Theft of Controlled Substances within their Practices' with information on the Controlled Drugs and Substances Act (CDSA) and its regulations.

The notice describes the regulatory requirements and encourages veterinarians to adopt best practices which include the following:

- Examine and inspect shipping containers immediately upon receipt and document any anomalies such as tampering, improper or missing seals, etc.
- Physically inspect bottles and containers for missing seals, damage and any indications that the supply is less than ordered.
- If anomalies are identified, it may be necessary to complete a physical count of the shipment.

What is involved in doing an audit of controlled drugs?

An audit is a process used to reconcile records with actual inventory. Audits involve a physical check of current inventory against a review of documentation that shows how much stock has been added to and taken from the inventory. The designated registrant should provide a written protocol to guide staff, who are responsible for doing audits. Each audit should be documented and include

[1] This document was originally included in the 'Professional Practice Standard: Management and Disposal of Controlled Drugs' approved on September 9, 2017. On March 1, 2019 Council moved to establish the Guide as a document separate to and supportive of the Professional Practice Standard.

signatures of the auditor(s), date of the audit, and any explanatory notes. A Sample Controlled Drug Audit Form is provided under Resources at the end of this Guide.

Who should conduct audits?
Audits must be conducted by two staff, who are specifically identified by a designated registrant to manage controlled drugs. If possible, staff should alternate in the auditor role. In the situation of a single person practice, an exception will be made for the designated registrant to conduct the audit independently, provided the CVBC is notified.

When should controlled drugs be audited?
Mechanisms should be in place for both regular and random audits. Audits must be conducted on a regular basis; more frequent audits facilitate reconciliation. For best oversight of controlled drug inventory, the College strongly recommends **weekly drug audits**.

Situations may arise where additional audits will be necessary, such as:

- When discrepancies caused by process losses are identified in facilities that compound drugs.
- When shipments of controlled drugs appear to have been tampered with (e.g., seals are missing or altered, containers are damaged or inaccurate counts are found during the reconciliation process).
- When a break-in, robbery, fire or other physical damage or loss has occurred at the facility.

If a practice facility uses an electronic order processing system and an electronic controlled drug log, is an audit required?
Audits of controlled drug must be completed regardless of whether the records are paper-based or electronic.

A sample controlled drug audit log that incorporates the requirements can be found on the College's website (www.cvbc.ca) under 'For Registrants'.

Frequently Asked Questions – Security of Controlled Drugs

What steps should be considered to limit access to controlled drugs in a veterinary practice?
Access to controlled drugs should be limited to veterinarians and authorized auxiliary staff, who are educated about controlled drug policies and procedures. Additional procedures that limit access include:

- Keys to locked storage areas and/or cabinets are accessible only to authorized staff;
- Areas where controlled drugs are stored are not accessible to clients and clients are supervised if they have access to any space where controlled drugs are stored;
- Cabinets are locked at all times except when a controlled drug is being dispensed or new inventory is being placed in the storage area;
- When controlled drugs are transported, they are stored in a locked container and are not left unattended. A veterinarian working from an accredited mobile facility is encouraged to be aware of the need for additional security.

What design features should be incorporated into a storage cabinet to minimize risk of theft of controlled drugs?
If possible, veterinarians should ensure that controlled drugs are stored separately from other drugs. If this is not feasible, the controlled drugs should be contained in a locked container stored within the cabinet used to store drugs. The following is a list of design features for cabinets that help to minimize the risk of theft:

- Metal cabinets are preferred because cabinets made of wood or plastic/resins are less secure;
- Double locks provide additional security but the cabinet must have at least one lock;
- Hinges cannot be removed from the outside of the cabinet;
- All sides of the cabinet are enclosed (i.e., there is no access by removing a cabinet or drawer above or below).

Frequently Asked Questions – Documentation

What information is required in a controlled drug log?
A controlled drug dispensing log contains information about what controlled drugs, or compounded products made from a controlled drug(s), were used for which animals and must indicate:

- the date that a controlled substance is dispensed or administered
- the name and address of the client (client address can be substituted with a unique client identifier that allows for the client address to be readily accessed by practice facility staff and by the CVBC inspector)
- the patients name or ID
- drug identification number (D.I.N.)
- the strength/ concentration and the quantity of the controlled substance dispensed or administered,
- and the quantity of the controlled substance remaining after the controlled substance is dispensed or administered.

In addition to recording information on all dispensed controlled drugs or compounded products that included a controlled drug(s), an inventory log should be kept that documents inventory of any controlled drugs.

A sample controlled drug dispensing and inventory log that incorporates the requirements can be found on the College's website (www.cvbc.ca) under 'For Registrants'.

What documentation is required when a discrepancy is identified during an audit?
After any audit, if a discrepancy is found, the documentation in the log should include a description of the details of any investigation and the nature of any corrective actions taken (e.g., changes to policy, practice or procedures) including reports to police and Health Canada.

Frequently Asked Questions – Investigation and Reporting

Does Health Canada have established allowable loss limits to determine what amount of controlled drug loss must be reported?

Health Canada recognizes that small losses may occur when preparing a dose for a patient. Operational losses that are reasonable for production practices of your scale do not need to be reported to Health Canada. It is common practice to allow for losses due to withdrawal of controlled drugs in liquid form of up to 0.2 ml. Health Canada recommends that a physical inventory count be performed on a regular basis in order to adjust your logged inventory accordingly.

When must a discrepancy be reported and to which agencies?
Health Canada, Office of Controlled Substances, Compliance Division, requires veterinarians to immediately report to local police any shortages of a controlled drug or targeted substance that cannot be reconciled. The *Narcotic Control Regulations, Food and Drug Regulations, and the Benzodiazepines and Other Targeted Substances Regulations* require any loss or theft of these drugs must be reported to Health Canada, using the required form, within ten (10) days of the practitioner's discovery of the shortage, loss or theft.

Frequently Asked Questions – Disposal of Controlled Drugs

Under what circumstances may a veterinarian need to dispose of controlled drugs?
A veterinarian may decide to dispose of a controlled drug when:

- Doses intended for use were not administered or dispensed;
- Unused stock is expired or no longer needed;
- Drugs are returned by clients;
- Stock is damaged.

Are veterinarians required to obtain permission to destroy controlled drugs?
No, veterinarians are no longer required to receive pre-authorization from Health Canada, Office of Controlled Substances, for the local destruction of unserviceable controlled drugs and narcotics.

What steps must a veterinarian take to destroy controlled drugs?
Before destroying any controlled drug, a veterinarian is expected to:

- Use an appropriate method to denature the controlled drug(s).
- Ensure that the method of destruction is in compliance with all applicable federal, provincial and municipal environmental legislation.
- Have another health professional witness the destruction (i.e., veterinarian, registered veterinary technician, nurse, pharmacist.)
- Record on the inventory list/controlled drug log the date of destruction (the list should identify product destroyed from inventory and product destroyed that was returned by clients separately)
- Have the veterinarian and witness sign and date the list.

What methods can a veterinarian use to destroy a controlled drug?
Health Canada provides the following information to practitioners regarding denaturing controlled drugs as a method of destruction:

- Drugs must be destroyed in a way that will alter or denature the drugs to such an extent as to make them non-recoverable and their consumption rendered impossible or improbable.
- Alteration can be accomplished by mixing crushed tablets, capsules, liquids and transdermals with an inert substance, such as kitty litter. When there is no liquid in the mix, water or soap can be used to bind the mixture. Bleach is not recommended to bind the mixture as it may produce an exothermic reaction.
- Denatured mixtures may be placed in a bio-hazard container and destroyed by a company specializing in destruction of bio-medical products (usually incineration).

Alternatively, drugs that have been denatured can be delivered to a pharmacist who has agreed to accept them for disposal.

Background

The term 'controlled drug' is defined in Schedule D Accreditation Standards to mean: *Any substance listed in Schedule I-V of the Controlled Drugs and Substances Act, such as narcotics, controlled drugs, and targeted substances*. For more information on controlled drugs, please refer to the *Controlled Drugs and Substances Act* and Regulations at the following website: http://laws-lois.justice.gc.ca/eng/acts/c-38.8/.

A veterinarian may distinguish between a controlled drug and a prescription drug by referring to the provincial Drug Schedules Regulation that is available from the website of the College of Pharmacists of British Columbia at http://www.bcpharmacists.org/drug-distribution. This same website can be used to access information about the provincial Controlled Prescription Program.

The general requirements to maintain controlled drugs in a veterinary facility or practice are mentioned in the CVBC bylaws, Schedule D Accreditation Standards, Preface to Section 09 – Pharmacy Area:

> *Controlled, narcotics and other drugs as directed by the College in the interest of the public must be kept in a locked cabinet designed and constructed to ensure reasonable security of the drugs. There must be reasonable measures in place to ensure that no person other than a registrant or a person designated by, and acting upon the specific direction of, a registrant to dispense or have access to drug cabinet keys (or equivalent) or a controlled drug or narcotic. There must be measures in place to protect controlled drugs and narcotics from loss and theft and to report any loss, theft of controlled drugs and substances or forgery of records to the police and within ten days to the Compliance, Monitoring and Liaison Division of the Office of Controlled Substances of Health Canada.*

The bylaws, Schedule D Accreditation Standards, Standard 78, Guideline (b), (c) and (d) speaks to the veterinarians' and to the designated registrants' responsibility to properly manage controlled drugs in a facility or practice.

> *The facility must be capable of ensuring that all drugs are prepared, maintained, dispensed or administered, destroyed/disposed of in accordance with patient, staff and public safety.*
>
> ***GUIDELINES***
> *(a) The pharmacy area must not be accessible to the public.*

(b) There must be a secure and locked container or enclosure designed and constructed so as to ensure restricted access to controlled drugs and narcotics.
(c) The facility must have a controlled drug log containing but not limited to: date dispensed, owner's name and address, patients name or ID, drug identification, strength/concentration and quantity of drug dispensed and quantity of drug remaining after dispensing.
(d) A separate storage area must be available for holding expired drugs pending disposal or return to manufacturer.
(e) There must be a readily accessible sink with hot and cold running water.
(f) The facility must have a secure area for storage of prescription pads.

Resources

The following can be found on the College's website (www.cvbc.ca) under 'For Registrants':

- Sample Templates of:
  - Controlled Drugs Dispensing Log
  - Controlled Drug Inventory Log
  - Controlled Drug Audit Tracking Log
- Examples of each of these templates, showing how they should be implemented
- Health Canada, CVO Update December 2013, *Correspondence to Veterinarians on Steps to Minimize the Loss and Theft of Controlled Substances within their Practices*

Other Website Resources

- Health Canada, Office of Controlled Substances Contact Information: http://www.hc-sc.gc.ca/contact/dhp-mps/hecs-dgsesc/ocs-bsc-eng.php
- Health Canada, Reporting of Loss or Theft of Controlled Substances, Precursors and Cannabis (with link to Report Form): https://www.canada.ca/en/health-canada/services/publications/healthy-living/loss-theft-controlled-substances-precursors.html#a8
- Provincial Drug Schedules Regulations and Controlled Prescription Program. http://www.bcpharmacists.org/drug-distribution

Legislative Authority

- *BC Veterinarians Act*, SBC 2010 c. 15
- CVBC Bylaws, Schedule D – Accreditation Standards, Section 09 – Pharmacy Area, s. 78
- SOR/2000-217, s. 1(1), 2, 6, 7, 58-62 (Benzodiazepine and Other Targeted Substances, *Controlled Drugs and Substances Act*, Canada)
- C.R.C., c 870, Part G.01.001-002, G.04.001-002, G.05.001 (Food and Drug Regulations, *Food and Drugs Act*, Canada)
- C.R.C., c 1041, s. 54, 63, 65(1-2) (Narcotic Control Regulations, *Controlled Drugs and Substances Act*, Canada)

Acknowledgement

Adapted with permission from the College of Veterinarians of Ontario's "Guide to the Professional Practice Standard: Management and Disposal of Controlled Drugs".