GUIDE TO THE PROFESSIONAL PRACTICE STANDARD



Management and Disposal of Controlled Drugs

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Introduction

The College's Professional Practice Standard: Management and Disposal of Controlled Drugs describes the expectations a veterinarian must meet when controlled drugs are 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.

Definition¹

The term controlled drug means controlled substances.

¹ Definitions used in the Guide are from the associated *Professional Practice Standard*.



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Frequently Asked Questions - Inventory Management and Audits

1. 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 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.

2. 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. Veterinarians should provide a written protocol to guide staff who are responsible for doing audits. Each audit should be documented and include signatures of the auditor(s), date of the audit and any explanatory notes. Refer to the resources listed at the end of this Guide to the Professional Practice Standard.

3. Who should conduct audits?

Monthly controlled drug audits (performed every 21 to 31 days) should be conducted by two staff who are specifically identified by a veterinarian to manage controlled drugs. If possible, staff should alternate in the auditor role.

4. When should controlled drugs be audited?

Mechanisms should be in place for both regular and random audits. Audits of controlled drugs are required on a monthly basis (performed every 21 to 31 days). Additional audits may be necessary in the following situations:



- 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.
- 5. If a companion animal facility uses an electronic order processing system and an electronic controlled drug log, is an audit required?

Audits of controlled drug inventory in companion animal facilities must be completed regardless of whether the records are paper-based or electronic.

Frequently Asked Questions - Security of Controlled Drugs

6. 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.
- 7. 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

8. What information is required in a controlled drug log?

A controlled drug log contains information about what drugs 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, the name, strength, and quantity of the controlled substance dispensed or administered, and the quantity of the controlled substance remaining in the member's inventory after the controlled substance is dispensed or administered. It is also recommended that the veterinarian or staff member entering the information in the log should identify the patient for which the controlled drug has been dispensed and sign their name or initials to that entry in the drug log. In addition to recording information on all controlled drugs, the log should document inventory of any compounded products that include controlled drugs. A sample log that incorporates the requirements described in Regulation 1093 and required by the Professional Practice Standard can be found on the College's website.

9. 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

10. 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.

11. 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 that any loss or theft of these drugs must be reported to Health Canada, using the required form, within ten days of the practitioner's discovery of the shortage, loss or theft.

12. Which incidents of loss or theft of controlled drugs should be reported to Health Canada?

Veterinarians are required to report all thefts involving a controlled substance, regardless of the amount. Reporting is also required for losses, regardless of the amount, when:

- There is no reasonable explanation on the basis of normally accepted business activities for the loss at the time of discovery, or;
- It is suspected that the missing controlled substance has been diverted to the illegal market

Losses or thefts of unserviceable stock (such as expired controlled drugs) or post-consumer returns must also be reported.

Please review Health Canada's <u>Guidance on reporting loss or theft of controlled substances</u> and precursors for full details.

13. Are there incidents of loss of controlled drugs that do not require reporting?

Veterinarians should not report any discrepancies in their controlled drug logs that can be reconciled, such as when it can be explained through other records, normal business practices, or a physical inventory count.

If a discrepancy is due to a prescription to the wrong patient or for an incorrect quantity dispensed to a patient, this should be retrieved by the veterinarian and documented in the controlled drug log. If it can



be retrieved, then it should not be reported as a loss.

Please review Health Canada's <u>Guidance on reporting loss or theft of controlled substances</u> and precursors for full details.

14. Who should report incidents to Health Canada?

The veterinarian is responsible for reporting incidents to Health Canada. If someone other than the veterinarian discovers a loss or theft, they should inform the veterinarian as soon as possible.

Frequently Asked Questions - Disposal of Controlled Drugs

15. 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.

16. 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.

17. 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.

18. What methods can a veterinarian use to destroy a controlled drug?

Health Canada provides two guidance documents related to the destruction of controlled drugs:

- Guidance Document for Pharmacists and Dealers Licensed to Destroy Narcotics, Controlled Drugs or Targeted Substances: Handling and Destruction of Post-Consumer Narcotics, Controlled Drugs or Targeted Substances; and
- Guidance Document for Pharmacists, Practitioners and Persons in Charge of Hospitals:
 Handling and Destruction of Unserviceable Stock Containing Narcotics, Controlled Drugs and Targeted Substances.

Licensed veterinarians have a variety of options related to the destruction of controlled drugs. These options may be used as a single solution, or may be combined in a manner suitable to individual practice. Options include:

- 1. Sending controlled drugs off-site for destruction and disposal purposes. This may be done by:
 - a. Using the services of a third-party collection service who is a licensed dealer;
 - b. Providing controlled drugs returned by a client to a licensed pharmacy operating under the Ontario Medications Returns Program; or
 - c. Returning the controlled drugs to the licensed dealer who sold or provided them as per their return policies.
- 2. Local Destruction If a licensed veterinarian chooses to destroy controlled drugs by means of local destruction, they must do so in a manner that will alter or denature the drugs to such an extent as to make them non-recoverable and their consumption rendered impossible or improbable. While the College does not evaluate, review, or approve specific methods that may be used, a change in state is recommended. (i.e. from solid to liquid) Veterinarians are encouraged to consult WHMIS sheets to determine methodology. Bleach is not recommended as it may produce an exothermic reaction. Once the controlled drug is denatured, it is the responsibility of the veterinarian to ensure that it is placed in a suitable waste container for disposal in an appropriate manner. (i.e. in a manner compliant with all applicable federal, provincial, and municipal environmental waste legislation).



Legislative Authority

R.R.O. 1990, Reg. 1093: General, s. 28 (Veterinarians Act)

SRO/2000-217, s. 1(1), 2, 6, 7, 58-62 (<u>Benzodiazepine and Other Targeted Substances</u>, Controlled Drugs and Substances Act, Canada)

C.R.C., c 870, Part G.01.001-002, G.04.001-002, G.05.001 (<u>Food and Drug Regulations</u>, Food and Drugs Act, Canada)

C.R.C., c 1041, s. 54, 63, 65(1-2) (<u>Narcotic Control Regulations</u>, Controlled Drugs and Substances Act, Canada)

Resources

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

- 1. Professional Practice Standard: Management and Disposal of Controlled Drugs
- 2. Professional Practice Standard: Medical Records
- 3. Guide to the Professional Practice Standard: Medical Records
- 4. Sample Controlled Drug Audit Tracking Sheet
- 5. Sample Controlled Drug Log with Audit

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.