College of Veterinarians of British Columbia

Resource: Considerations in Building a Controlled Drug Management Program

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Listed below are questions for a Designated Registrant and their team to pose while developing a management program for the controlled drugs for a facility. The Professional Practice Standard: Management and Disposal of Controlled Drugs details the core requirements of the CVBC that are assessed at inspection. Questions regarding those requirements are bolded below. The additional considerations listed will help you set up a program that should help reduce risk of loss and diversion and aid staff as to next steps when challenges arise, and losses are identified.

The size, scope, and number of staff at the facility may impact how detailed a program you create.

1. **Receiving and Storage**: All steps involved in ordering, acquisition, storage, and documentation of controlled drugs.
    - **Is there an established protocol for the acquisition of controlled drugs that records all orders, purchases and receipts and matches the quantity received with the quantity recorded in the purchase order?**
    - Is that information kept in a Controlled Drug Inventory log *(recommended)*?
    - What is recorded in the Controlled Drug Inventory Log? *(consider: date received, drug name and strength, amount received, invoice #, supplier, assigned bottle # and initials of who entered the inventory)*
    - Where are the physical copies of the invoices stored?
    - **Where are the drugs that are not in use stored securely (overstock)?**
    - Are overstock drugs being counted in the audit as part of inventory?
    - **Controlled drugs requiring refrigeration also need to be secured in a way to protect the public.**
    - **Who has access and authority to handle not in-use controlled drugs and enter them into active use?**

2. **Dispensing**: All Steps from when a bottle is entered into active use from storage.

- **Is there a Controlled Drug Dispensing Log that contains 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 after the controlled substance is dispensed or administered. *(*client address could be substituted with a unique client identifier as per PPS)***
- **Ensure that logs are created for the dispensing of all compounded drugs containing controlled drugs.**
- **How are in-use controlled drugs stored and secured?**
- **Who has access and authority to handle in-use controlled drugs?**
- How are you entering new bottles into the log? *(adding on to existing volume and maintaining a "running total" is not recommended; instead, account for previous bottle and zero it, then add volume of new bottle.)*
- Is there additional information that could be added to the log to aid the process, such as standard amount wasted due to syringe loss, initials of who withdrew drug +/- witness?

3. **Audits**: All steps involved in performing an audit.
   - **Are audits being performed at least every 2 weeks?**
   - **Are audits performed 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*) or when a break-in, robbery, fire, or other physical damage or loss has occurred at the facility?**
   - **Are audits being conducted by two staff who are specifically identified by the designated registrant to manage controlled drugs?**
   - **If you are a single person facility has the CVBC been notified? A single person facility is not exempt from the other PPS requirements.**
   - How are audits performed? Weight method? Empty bottles with known volumes added and marked? *It is not recommended to draw up drugs to count unless an accurate count is required when an irreconcilable loss is identified.*
   - Where and how are audits recorded? *Consider including: date, drug name and strength, initials of both auditors, bottle #, amount measured, amount expected to have (in use active bottles + amount in inventory) discrepancies/adjustments.*
   - Are you keeping a separate audit log, or incorporating into the dispensing log?
   - How are discrepancies investigated and documented?
   - How is hub/vial/bottle loss accounted for?

4. **Disposal**: All steps involved in disposal of controlled drugs.

- **Are controlled drugs disposed of using a process that follows federal regulations and any environmental requirements set out by federal, provincial and/or municipal jurisdictions.**
- If denatured and disposed of in the facility, how is that done?
- Who has the authority to denature?
- Who is the witness of the disposal?
- Where is the destruction of the controlled drug recorded?
- What information is being recorded? *(Consider date, drug name and strength, who destroyed, who witnessed, veterinarian signed).*
- If a biomedical waste handling firm is used for destruction, what is their name and contact information? Is there a receipt and or destruction certificate provided?
- If you transport them to a pharmacy or distributor to dispose of them, is there a protocol for secure transport and will a receipt be issued?

5. **Loss/Theft**: All steps involved in reporting a loss or theft of controlled drugs.
   - **Are irreconcilable loss or theft of drugs reported to police immediately and to Health Canada within 10 days?**
   - Does the Designated Registrant report the loss to the CVBC as required in By-law 3.6?
   - What is the contact information for the police, Health Canada and CVBC?
   - How are losses reported? *(phone, email, Health Canada online portal)*
   - Do the staff involved in controlled drug management and the DR know what amounts are reportable? *(see links below)*
   - What plans are in place to secure controlled drugs and/or account for losses if the facility is compromised *(fire, flood, break in)*?
   - What to do if delivery does not arrive, is left unattended, misdelivered, damaged?

6. **Additional Consideration:**
   - If using computer-based logging/recording, is it set up to prevent unrecorded alterations to allow diversion, or is an audit trail created? Some software has built-in auditing that tracks what user has entered or changed a log.
   - Are there drugs that are not classified as controlled drugs with mandatory logging/reporting, but may be worth incorporating into the processes above, if even to a lesser degree? (*consider: gabapentin, xylazine, others?*)

Additional information on reporting losses to Health Canada, including a form, are linked below:

Control Drug Loss Report Form

Overview of what to do with Loss/Theft Controlled Drugs

Types of Controlled Drug Incidents

Timeframes for Reporting