Nova Scotia College of Pharmacists

PRACTICE POLICY

Inventory Management of CDSA and Z-Drugs

Introduction

The public expects that pharmacy practitioners take reasonable steps to protect drugs in the pharmacy from loss, theft, and diversion (LT & D). The requirements set out in this policy are in addition to those in federal and provincial legislation including the:

- Nova Scotia College of Pharmacists: Pharmacy Practice Regulations
- Controlled Drugs and Substances Act (CDSA)
- Narcotic Control Regulations (NCR)
- Food and Drugs Regulations (Part G)
- Benzodiazepines and Other Targeted Substances Regulations (BOTSR)

Fulfilling these expectations requires diligence in guarding against both external and internal LT & D. While the use of appropriate locks, safes, and alarms, and the identification of fraudulent prescriptions can help guard against external LT & D, additional strategies including robust drug reconciliation procedures are necessary to protect against internal LT & D.

Definitions

CDSA Drugs:

For the purposes of this policy, CDSA Drugs include those listed in Schedules I-IV of the CDSA (including narcotics, controlled drugs, and benzodiazepines), with the exception of low dose codeine preparations as described in section 36 (1) of the NCR.

Z-Drugs:

For the purposes of this policy, Z-Drugs include zopiclone and its enantiomers (i.e., eszopiclone).

Note: Zolpidem is a controlled drug and listed in Schedule IV of the CDSA.

Purpose

This policy sets out the responsibilities related to the prevention of internal LT&D of CDSA and Z-Drugs. It represents the minimum requirements expected of pharmacies in achieving this purpose. Pharmacy managers and owners are expected to ensure compliance with this policy and pharmacy practitioners are expected to adhere to this policy.

Policy

Pharmacy managers are responsible for the implementation of this policy, however, compliance with the Pharmacy Act and its Regulations is a shared responsibility among pharmacy owners, pharmacy managers and other licensed pharmacy professionals. There must be no policies, procedures, or directives in place that impede a pharmacy manager's ability to ensure the requirements in this policy are met.

Ordering and Receiving

Pharmacy managers are responsible for:

- implementing a process that ensures **ALL** orders, and in particular, manual orders and those for emergency use, are accounted for and received accurately. This process may differ depending upon the order management and pharmacy software system used and should include (where possible), but is not limited to:
  - a random audit of a selection of dispensed prescriptions to ensure there is a corresponding valid prescription.
  - a random audit of a selection of purchase invoices to ensure they were received accurately.
  - a random audit of emergency use prescriptions to ensure that the inventory was received accurately.
  - being satisfied that the pharmacy software system is kept up to date so that technology safeguards remain current.
- ensuring that no manual orders can be placed undetected.
- ensuring they have oversight of ordering and receiving, including being able to place and receive an order.

NOTE: Where possible, the various activities involved in this process should be assigned to different people.

Inventory Reconciliation

Pharmacy managers are responsible for ensuring that the requirements described below are completed and documented **monthly**, and that the documentation:

- includes explanations of any discrepancies,
- is stored in a readily retrievable format in the pharmacy, in a location separate from the storage of the CDSA Drugs, and
- is retained for two years.

Pharmacy managers must be able to demonstrate that they have reviewed this documentation **monthly**.

Reconciliation of On-hand Inventory

Reconciliation is a careful and systematic process of comparing the quantity on-hand (verified by a physical count) against the amount expected to be on-hand. The expected on-hand quantity is calculated by taking the total inventory on-hand at the last physical count plus amounts received since that date, and subtracting the amounts dispensed since that date. For most drugs, this calculation is done automatically in the pharmacy software, but for some drugs, such as active pharmaceutical ingredients (APIs) used for compounding, it must be completed manually.

A physical count of the inventory must be completed, documented, and reconciled with the expected inventory.

- The documentation must include:
  - the expected and actual quantity of each drug;
  - the identity of the individual who completed the count (where possible, different individuals should perform the monthly count);
  - the date of the count (where possible, the date should not be predictable); and
  - an explanation of any discrepancies.
- Pharmacy stock[1] (e.g., expired medication) awaiting local destruction must be included as part of this reconciliation including being reconciled with any manual adjustments.
- A reconciliation must also take place **immediately upon a change in pharmacy manager**, after any break and enter or theft from the pharmacy, after any unexpected change in pharmacy staff, or any other event that creates concern that security of the drugs may have been compromised.

Discrepancies

Discrepancies must be investigated without delay and the reason documented and included as part of the reconciliation.

- Any unexplained loss or theft of CDSA Drugs must be reported to the Office of Controlled Substances (OCS) at Health Canada within 10 days of discovery. (See resource 1.2 below) **(DO NOT include Z-Drug losses.)**
- A copy of this must be forwarded to the NSCP by email: reports@nspharmacists.ca or fax: 902-444-7071. **(INCLUDE Z-Drug losses with loss or theft reports to the NSCP.)**

Reconciliation and Audit of Manual Adjustments

Any manual adjustment made to the inventory, including when drugs are removed from inventory and are awaiting return for credit or destruction, must be identified, and accounted for by documenting the:

- date;
- reason; and
- individual who made the adjustment.

Resources

1. Health Canada (Pharmacists): Regulatory Information for Controlled Substances and Precursors
   - 1.1. Guidance Document: Handling and destruction of post-consumer returns containing controlled substances
   - 1.2. Controlled substances guidance for community pharmacists: security, inventory reconciliation and record keeping

[1] Pharmacy stock does not include post-consumer returns. These must be managed in accordance with Health Canada requirements. See resource 1.1.

1.3. Loss or Theft Report Form for Controlled Substances and Precursors
1.4. Guidance on reporting loss or theft of controlled substances and precursors
1.5. Guidance on reporting loss or theft of controlled substances and precursors: Types of Incidents

2. Professional Practice Policy: Destruction of Unusable and Expired Controlled Drugs and Substances