FACT SHEET

Controlled Substances: Security and Reconciliation

A fact sheet is a plain-language explanation of the legislation that forms the foundation of certain pharmacy practices. It provides useful information and references to help pharmacy professionals understand a particular topic. A fact sheet is an informational resource and is not considered legal advice. Always refer to the legislation for full context

Legislative References

- *Controlled Drugs and Substances Act, 1996* (CDSA)
    - *Controlled Substances Regulations*

Additional References

- Article – Safety and Security for Pharmacies: Preventing Robberies (Pharmacy Connection Winter 2018)
- e-Learning Module – Reconciliation of Controlled Substances
- Fact Sheet – Controlled Substances: Purchase & Sales Record Requirements (Federal)
- Fact Sheet – Controlled Substances: Reporting Loss or Theft
- Designated Manager – Medication Procurement and Inventory Management Policy
- Time-Delayed Safes Policy
- Video – Narcotic Reconciliation

Definitions

Controlled drug: A substance set out in Schedule 2 of the *Controlled Substances Regulations*.

Controlled substance: A substance set out in Schedules I, II, III, IV, or Part 1 of V of the federal *Controlled Drug and Substances Act*. This resource applies to the substances named in Schedule 1 (narcotics), Schedule 2 (controlled drugs) and Schedule 3 (targeted substances) under the *Controlled Substances Regulations*.

Diversion: The transfer of a controlled substance from the licit to illicit market (i.e., a lawful to an unlawful use), such as through theft. (HC)

Loss: The physical disappearance of controlled substances that is unexplained at the time of discovery but is not the result of a theft. (CS-GD-005)

Narcotic: A substance set out in Schedule 1 of the *Controlled Substances Regulations*.

Targeted substance: A substance set out in Schedule 3 of the *Controlled Substances Regulations*.

Theft: The removal of any quantity of controlled substances or precursors under the custody of a regulated party without its legitimate consent. (CS-GD-005)

Background

Controlled substances are regulated federally by Health Canada (HC) and the Office of Controlled Substances (OCS). The *Controlled Drugs and Substances Act* (CDSA) provides a legislative framework aimed at controlling access to substances that can alter mental processes and produce harm to the health of an individual and/or society when diverted or misused.

Pharmacists, pharmacy technicians, and hospitals are required to comply with the *Controlled Substances Regulations* (CSR) made under the CDSA and must take all reasonable measures to ensure the security of all controlled substances in their possession. The Standards of Operation expect that controlled substances are stored and managed according to national and provincial requirements.

Security

The regulations do not define what is considered reasonable or necessary to ensure the security of controlled substances, nor do they establish specific storage requirements. To safeguard drugs from diversion, a combination of methods should be employed, such as (but not limited to) physical security measures, limiting personnel who have access, operational processes (i.e., organized storage, routine inventory counts, accurate record-keeping), audits, and reconciliations.

Examine the inventory management processes in detail for potential opportunities for security lapses or diversion to occur, including ordering, receiving, dispensing, removing unserviceable stock, handling post-consumer returns, etc. There is also the potential for loss through damages and miscounts.

- In community pharmacies, the Time-Delayed Safes Policy requires all narcotics to be securely locked in a time-delayed safe within the dispensary.
    - Controlled drugs and targeted substances may also be stored in a time-delayed safe, in a safe without a time-delay mechanism, or, at a minimum, must be stored in the dispensary area where only authorized pharmacy personnel have access.
    - For further details on security and reconciliation processes, please consult Health Canada's Controlled substances guidance for community pharmacists: security, inventory reconciliation and record-keeping (January 2023)
- Persons in charge of hospitals must have policies and procedures in place to safeguard the controlled substances under their control. For further details on security and reconciliation processes, please consult:
    - Controlled Drugs and Substances in Hospitals and Health Care Facilities: Guidelines on Secure Management and Diversion Prevention (Canadian Society of Hospital Pharmacists (CSHP) February 2019)
    - Framework for Improving the Safety and Security of Controlled Substances in Hospital High Risk Areas (December 2019)

Reconciliation

Inventory reconciliation is an important process to fulfill the legislated requirement to protect controlled substances from loss or theft and provides evidence of taking reasonable or necessary steps to keep controlled substances secure. The purpose of performing routine reconciliations is to detect, investigate, resolve and document any differences between the *actual amount* of physical inventory counted ("on-hand") with the *expected amount* of inventory that should be on-hand (derived from purchase and sale records).

- In community pharmacies, the Designated Manager – Medication Procurement and Inventory Management Policy requires a physical count and reconciliation of all controlled substances to be conducted regularly, **at least once every six months**, and that the records are retained by the pharmacy for a two-year period in a readily retrievable format.

Accurate record-keeping and frequent physical counts facilitate regular reconciliations, which can help identify underlying issues and inform continuous quality improvement, including whether further security measures are needed.

It is important that a physical count AND reconciliation occur. Simply counting the controlled substances provides the amount of the inventory that is present "on hand" at that moment in time. Accurate on-hand amounts are important for managing inventory levels, however, for the count to be useful as a security measure, it must be used as a starting point to conduct a reconciliation. Note that "on hand" amounts from a perpetual inventory management system cannot be used in place of an actual physical count for the purposes of reconciliation, as the potential for human and/or data entry errors still exists.

Routine reconciliations should be used in conjunction with random audits on drugs that have a high risk of diversion, and as described in the CSHP Guidelines. Sales/dispensing records or similar reports should be reviewed frequently and regularly, cross-referencing against actual prescriptions and orders to determine, for example:

- All prescriptions/orders are accounted for, e.g., no prescriptions or prescription numbers are missing
- Prescriptions are valid and meet the requirements of the relevant legislation
- Any unusual names, drugs, quantities or patterns are identified and investigated

The frequency of review should be appropriate for the pharmacy environment. For instance, recent or frequent staff turnover; temporary, relief or casual staff; high volume of controlled substances dispensed; history of past discrepancies identified; etc.

Reconciliation Process

The process of reconciliation validates that the controlled substance inventory amount "on-hand" agrees with what is expected based on the purchases (inventory IN) and sales (inventory OUT) over a specific time period. In cases where these amounts are not in agreement, discrepancies need to be investigated to pinpoint and resolve the underlying issue(s).

Problem Solving Discrepancies (Shortages or Overages)

Apparent shortages or overages can often be accounted for, such as when they are the result of human error in prescription processing or software errors in record-keeping.

- Ensure all purchase orders received are accounted for and up-to date in perpetual systems, including orders received from other pharmacies or hospitals
- Ensure any software interfaces have been functioning properly (e.g., check for missing or duplicated records)
- Determine whether the shortage is a result of a "balance owing" or prescriptions processed through the pharmacy and inventory software systems but waiting for stock to arrive
- Determine whether there is an error in record keeping when dispensing, i.e., interchangeable brand dispensed, without a corresponding change in the dispensing record
- Check that completed prescriptions which were not picked up and returned to stock have been properly reflected by an adjustment to the dispensing record
- Ensure that all inventory credits, returns, or drugs awaiting destruction are accounted for
- Account for all inventory, including:
    - drugs used in compounds;
    - inventory in compliance packaging or automated dispensing machines that has not been processed through the software system
    - prescriptions where more than one pack size (UPC or SKU) of a drug was dispensed

When differences can be explained, and ideally corrected, they may not need to be reported to Health Canada, however internal documentation must still be retained.

Shortages that cannot be explained indicate potential internal theft or diversion. In these situations, depending on the level of access an employee has to physical records and to edit electronic records, it is important to be aware these can be manipulated or falsified to conceal unauthorized activity. From a loss prevention perspective, regularly reviewing all systems and procedures related to managing controlled substance is advised.

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Revision History

Version #	Date	Action
1	August 2012	Published as "Narcotic Reconciliation and Security"
2	October 2021	Title changed to Controlled Substances: Security, Reconciliation and Reporting Loss or Theft to include all controlled substances and hospitals; minor updates to content and references
2.1	September 2022	Revised Additional References; minor reformatting

Version #	Date	Action
3.0	March 2023	Updated to include time-delayed safes and link to revised Health Canada guidance
4.0	October 2026	Revised to reflect Controlled Substances Regulations coming into effect; minor copy edits