



Controlled Substances Reconciliation

DEFINITIONS

“**Controlled Substance**” is a substance listed in Schedules I – V to the [Controlled Drugs and Substances Act](#) (CDSA). Includes narcotics (defined in the [Narcotic Control Regulations](#)), controlled drugs (defined in the [Food and Drug Regulations](#)), and targeted substances (defined in [Benzodiazepines and Other Targeted Substances Regulations](#)). See [Drug Distribution by Prescription](#) for more details of each type of controlled substance.

Pharmacy Manager Responsibilities

As provided for in s. 3 of [Pharmacy Manager – Responsibilities](#) reference document:

The pharmacy manager is ultimately accountable for record keeping, acquisition, storage and distribution of narcotics, controlled drugs, and targeted substances, according to the pertinent laws. As such, the pharmacy manager shall:

- 3.1. *Designate which pharmacists may have signing authority for purchasing narcotics, controlled drugs, and targeted substances in a specific pharmacy.*
- 3.2. *Ensure all requirements for narcotics, controlled drugs, and targeted substances are met and maintained, including record keeping, reconciliation, theft and loss reporting, destruction, forgeries, secure storage (e.g. time-delayed safes) and delivery.*

(See [SCOPE newsletter December 2019 page 6 “Narcotic and Controlled Drug Reconciliation”](#) highlighting of Health Canada “critical” inspection report notices.)

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The record keeping requirements regarding receipt, sales and destruction of controlled substances are outlined in the *Controlled Drugs and Substances Act* (CDSA), *Narcotic Control Regulations*, the *Benzodiazepines and Targeted Substances Regulations* and Part G of the *Food and Drug Regulations*. Along with specific prescription requirements, accurate purchase and sales records, as well as secure storage of products are required within the pharmacy. As well, any [loss or theft](#), including [forgeries](#) that are dispensed, are to be reported to Health Canada within ten (10) calendar days of discovery. (Also see SCPP reference documents: [Reporting Loss or Theft of Controlled Substances](#), and [Forgeries](#).)

An inventory count of all controlled substances should be done on a routine basis but this alone is not reconciliation. It simply provides an inventory. A review of purchases, sales and inventory together using the pharmacy’s records (reconciliation) will identify any losses or discrepancies. (Also see Health Canada’s [Controlled substances guidance for community pharmacists: security, inventory reconciliation and record-keeping](#).)

It is essential to keep your unique personal access wholesale ordering code for controlled substances secure at all times. No one other than the person to whom the order code belongs should be using it to order controlled substances.

Health Canada Guidance: Inventory Reconciliation

Inventory reconciliation activities must be performed by either:

- a pharmacist
- someone under the direct supervision of a pharmacist.

For recommendations on inventory reconciliation see [Health Canada Controlled substances guidance for community pharmacists: security, inventory reconciliation and record-keeping.](#)

Reconciliation

It is important not to rely solely on your computer system's inventory control management system for reconciliation. If there is inadequate security for the ordering, receiving or distribution of controlled substances in the pharmacy, the pharmacy manager may be relying on inaccurate or incomplete information. One method of diversion is to use another person's ordering code and to intercept those orders (and invoices) before they are received into stock and put into the computer. The person whose code is utilized then becomes accountable for the missing products. Most licensed dealers now have online access to your account 'ordering' information and can provide you with a list of all purchases for controlled substances. A quarterly review of purchase records can identify suspected diversion.

When performing reconciliation, it is best to reconcile each specific brand of a particular drug separately. Do not include expired medications or medications which are slated to be returned to the licensed dealer in your first reconciliation. Ensure your sources of information are accurate and up to date, including purchase records (as above) and sales reports. This is a good opportunity to review your sales records to ensure reports contain all the required information. Sales reports must include all controlled substances as required in the regulations.

If your pharmacy software system is capable of generating an inventory report that details perpetual inventory, you can review this report. However, diligence will be required to ensure the accuracy of the data inputted into the computer to ensure no information has been missed. Also take into consideration any prescriptions which have "owed" quantities still outstanding.

Decide upon the date range of your reconciliation. Your first reconciliation should review at least one year of records; subsequent reconciliation time frames will depend upon how often you wish to do inventory counts and reconciliations, but the less data you have to work through, the easier the process will be. If you intend to keep an ongoing reconciliation log, document the last controlled substance prescription filled, count your inventory before filling any more prescriptions, and then proceed to examine your records. If possible, your date range should begin with the date of your last inventory. Any discrepancies should then be investigated for causes and record keeping errors should be corrected. Future reconciliations may also need to consider products returned to the licensed dealer as well as those which have expired.

Reconciliation involves comparing sales and current inventory with purchases. A thorough review of any discrepancies should include a review of the records, your ordering/receiving

systems, your security systems, your storage systems, and your present and previous inventory counts.

Adjustments to Inventory

The pharmacy manager should decide which pharmacy staff members are authorized to adjust inventory and under what specific protocol. Computer permissions and restrictions should be set by 'user group' (i.e. pharmacist, pharmacy technician, pharmacy assistant) for narcotic, controlled and benzodiazepine drug products.

When the on-hand inventory is adjusted either on the computer or manual records such adjustments must be reviewed by the pharmacy manager, or the pharmacist designated to directly supervise the reconciliation process. An on-hand adjustment made to the computer inventory should require a login and password along with a documented reason for the adjustment. Documentation should be retained that supports the reasons for the adjustment and should be reviewed as part of the reconciliation.

Any inventory adjustments must only be made once a thorough review of records (purchase records, sales records, computer records and prescription records, etc.) has been completed.

Also see SCPP's [Reporting Loss or Theft of Controlled Substances](#).

Tips and Suggestions

- Reconcile your inventory four times per year, and more frequently for high volume medications;
- Double count medications at the time of dispensing (ideally by two different pharmacy staff members);
- Keep careful track of medication 'shorts' or 'owes' (if an owe is older than one month call the patient to see if they still require the medication and if they do not, remove the 'owe' from the system);
- Print a monthly sales report of all controlled substances dispensed and review it for unusual patients or quantities of medications;
- Check the PIP failed transaction report for unusual prescriptions and 'out of province' patients (also see SCPP's [Accessing PIP and eHR Viewer](#), and [Relevance of PIP Data Quality to Pharmacy Practice](#));
- Review the drug inventory history report regularly for manual adjustments;
- Compare invoices to the drug receiving history in the computer (and with your online wholesale report) – your accountant/book-keeper may also alert you to unusual purchases for which invoices do not match or exist; and,
- Whenever possible have two people count inventory and rotate the staff who count inventory so that the counts are as random as possible.