



Recommended guidance in the areas of security, inventory reconciliation and record-keeping for community pharmacists

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Health Canada is responsible for helping Canadians maintain and improve their health. It ensures that high-quality health services are accessible, and works to reduce health risks.

Health Canada works to ensure that drugs and controlled substances are not diverted for illegal use. This involves developing legislation, regulations, policies and operations that support the control of illicit drugs and other substances.

Également disponible en français sous le titre :

Lignes directrices recommandées dans les domaines de la sécurité, du rapprochement des stocks et de la tenue de dossiers à l'intention des pharmaciens communautaires

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Foreword

Guidance documents are meant to provide assistance to industry and health care professionals on how to comply with governing statutes and regulations. Guidance documents also provide assistance to staff on how Health Canada mandates and objectives should be implemented in a manner that is fair, consistent, and effective.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document may be acceptable provided they are supported by adequate justification. Alternate approaches should be discussed in advance with the relevant programme area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in this document, in order to allow the Department to adequately assess the safety, efficacy, or quality of a therapeutic product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

Table of Contents

1. Preface	5
2. Security	5
2.1 Physical security measures.....	5
2.2 Reporting prescription forgeries	6
2.3 Reasonable inventory.....	6
3. Destruction procedures	6
3.1 Unserviceable stock	6
3.1.1 Local destruction.....	6
3.1.2 Sending to a Licensed Dealer	7
3.2 Post-consumer returns.....	7
4. Inventory and reconciliation.....	8
4.1 Methadone prescriptions.....	9
5. Records	10
5.1 Purchase/receiving records.....	10
5.2 Dispensing records (sales).....	10
5.3 Special prescription file	11
5.4 Emergency transactions	11
5.5 Destruction records.....	11
5.5.1 Post-consumer returns	11
<i>Local destruction</i>	11
<i>Returns to a licensed dealer</i>	11
5.5.2 Unserviceable stock	12
<i>Local destruction</i>	12
<i>Returns to a Licensed Dealer</i>	12
5.6 Return authorization records.....	12
5.7 Loss or theft reports.....	12
6. Definitions.....	14

1. Preface

The following measures are recommended to community pharmacists in the areas of security, inventory reconciliation and record-keeping, to ensure that federal Regulations under the *Controlled Drugs and Substances Act* (CDSA) are followed, including the *Narcotic Control Regulations* (NCR), the *Benzodiazepines and Other Targeted Substances Regulations* and the *Food and Drug Regulations*. This document intends to highlight specific measures that a pharmacist should take to minimize the potential diversion of controlled substances from their establishments.

It is the responsibility of community pharmacists to consult with the relevant provincial professional licensing authority for further guidance, as provincial requirements may be more stringent than what is outlined below.

2. Security

A pharmacist shall take all reasonable steps that are necessary to protect controlled substances on their premises or under their control against loss or theft. Due to differing provincial requirements in how controlled substances are shelved and stored at the pharmacy level, Health Canada does not require that these products be stored in any specific way (i.e., stored in a safe vs. dispersed on shelves, keeping similar types of drugs together vs. separated out). It is the pharmacist's responsibility to ensure that the methods they use to manage their controlled substance stock allows for a high level of security. The pharmacist must also ensure that an audit can be conducted.

2.1 Physical security measures

The following measures are recommended to ensure compliance with federal regulations:

Alarm system

- If the pharmacy is located in a larger retail space, the dispensary should be on a separate alarm zone.

Physical security measures

- Window protection, locked doors, locked cabinets/drawers, video surveillance and a narcotic safe are recommended.

Restricted access to dispensary

- A pharmacist must always maintain supervision of activities involving controlled substances.
- Only pharmacy personnel are to have access to the dispensary.

- Narcotic ordering codes, PINs and/or keys are not to be shared amongst pharmacy personnel.

2.2 Reporting prescription forgeries

- A loss or theft report form must accompany the forgery submission in cases where the prescription was filled since dispensed forgeries must be reported as a loss to the Office of Controlled Substances at Health Canada.
- For more information, refer to the Health Canada guidance document on the [Reporting of loss or theft of controlled substances, precursors and cannabis](#).

2.3 Reasonable inventory

- Unnecessarily large stocks should not be ordered for inventory. This will prevent excessive losses in the event of an armed robbery or break and entry and potentially deter internal thefts or pilferages as small quantities lost would be more quickly noticed and accounted for. Furthermore, unnecessarily large stocks can prove challenging for some pharmacies to store in a secure manner.

3. Destruction procedures

3.1 Unserviceable stock

Pharmacists have various options with respect to the destruction of unserviceable stock of controlled substances. Pharmacists can:

- destroy them locally;
- provide them directly to a licensed dealer authorized to destroy controlled substances; or
- return them to the licensed dealer who sold or provided the controlled substances to them.

3.1.1 Local destruction

Health Canada no longer requires pharmacists, practitioners or persons in charge of the hospital to send destruction requests to Health Canada in order to proceed with local destruction. Destruction must be done in accordance with all applicable federal, provincial and municipal environmental legislation. Controlled drugs, narcotics and targeted substances must be altered or denatured to such an extent that consumption is rendered impossible or improbable. Local destruction can be performed by the pharmacist and a witness. Procedures may vary from substance to substance depending on chemical and physical properties, but a change of state is recommended (e.g. from solid to liquid). Once subjected to local destruction, controlled substances may be placed in an appropriate container and disposed of in a manner that is safe, environmentally responsible, secure and in compliance with legal and professional requirements to protect confidential patient information. Already denatured products do not

need to be sent to licensed dealers for disposal and can be placed in the regular pharmaceutical waste.

An accurate running log of unserviceable stock being held for destruction must be maintained. In addition, a record including a list of drugs destroyed, quantity, strength and method of destruction used must be maintained and signed and dated by the pharmacist who carried out the destruction as well as by a witness. A witness may be a practitioner, pharmacist, a pharmacy intern, or a regulated pharmacy technician in provinces where these are found. Both persons must sign and print their names on a joint statement indicating that they witnessed the destruction. The pharmacist and their witness both need to observe the verification of waste product inventory as well as the actual destruction. For clarity, destruction cannot be performed by only two registered pharmacy technicians.

3.1.2 Sending to a Licensed Dealer

Pharmacists may also send controlled substances to a licensed dealer for destruction, as long as the licensed dealer is authorized to destroy controlled substances. They may also return the controlled substances to the licensed dealer who provided them. Each such transaction must be supported by a written order signed and dated by the licensed dealer specifying the name, quantity and strength of each controlled substance to be provided, the name and address of the licensed dealer and the date on which the substances were provided. Except when returning to the licensed dealer who sold them to the pharmacist, the order must indicate that the sole purpose of the transaction is the destruction of the unserviceable stock.

For more information, refer to the Health Canada guidance document on the [Destruction of Unserviceable Stock](#).

3.2 Post-consumer returns

Effective April 1, 2018, Health Canada no longer requires that pharmacists record the name of drugs, strength and quantity for post-consumer returns. Consequently, there is no requirement to separate post-consumer returned controlled substances from other post-consumer returns. Instead, pharmacists should treat all post-consumer returns as controlled substances.

Post-consumer returns must be received by a pharmacist, pharmacy intern or registered pharmacy technician and deposited in a one-way entry container with a unique identifier number. It is recommended that collection containers are also opaque, inconspicuous and tamper-evident. Collection containers must be kept in the dispensary when in use. They should only be accessible to pharmacy staff. If space is limited, they may be placed outside of the dispensary in plain sight of the pharmacy staff and secured to the floor.

Pharmacists have various options with respect to the destruction of controlled substances returned to a pharmacy by an individual customer. Pharmacists can:

- destroy them locally;

- use a post-consumer returns container with an integrated system to destroy products that are placed within it; or
- provide them directly to a dealer licensed to destroy controlled substances.

For local destruction, pharmacists should follow the same procedures as for unserviceable stock, with the exception of record keeping. For local destruction of post-consumer returns, including destruction using a container with an integrated system, the pharmacist must record the date the destruction took place, the unique identifier of the container and the number of containers destroyed. This record must be signed and dated by the pharmacist and a witness. In the case of containers with an integrated system, the date and unique identifier are recorded once the container is full.

For returns to a licensed dealer, a pharmacist must record the number of containers collected, date the containers are collected, unique identifier assigned to each container and name and address of the licensed dealer. The record requesting the destruction of post-consumer returns must be signed and dated by the pharmacist.

Finally, pharmacists should denature or send post-consumer returns for destruction to a licensed dealer on a regular basis as an accumulation may increase diversion risk.

For more information, refer to the Health Canada Guidance Document on the [Destruction of Post-consumer Returns](#).

4. Inventory and reconciliation

A perpetual inventory for unserviceable stock (including expired controlled substances) must be maintained. For clarity, records for active inventory should be kept separate from the records for unserviceable stock.

Complete inventory counts and reconciliations for controlled substances, i.e., narcotics, controlled drugs and targeted substances, should be completed (at minimum):

- every six months;
- after an event where controlled substances security was compromised, such as:
 - armed robbery or break and entry;
 - suspected or detected internal theft or drug diversion;
 - discovery of faulty security measures (i.e., unlocked or unsecured door and/or window);
- after a pharmacy move;
- after a change in the pharmacy manager or owner or any unexpected staffing changes; and/or
- after the pharmacy receives a non-compliant inspection rating from Health Canada.

Controlled substances inventory reconciliations (the inventory count as well as a review of purchases, sales and inventory adjustments together for comparison) must be performed on a regular basis to ensure that all controlled substances are accounted for. A starting or baseline inventory should be determined, with selected controlled substances that have higher diversion potential (e.g., oxycodone, hydromorphone, codeine, morphine, hydrocodone, methadone, fentanyl) indicated. Please note that this is the recommended starting point; however, all controlled substances must undergo this process every six months at a minimum. The pharmacist should verify that the prescriptions for these products are all present and the sales reports are accurate. If shortages between the theoretical perpetual inventory and the actual physical inventory are discovered, they must be investigated and if they cannot be explained or justified, they must be reported to the Office of Controlled Substances as a loss or theft within 10 days of discovery, as required by the *Narcotic Control Regulations*, the *Benzodiazepines and Other Targeted Substances Regulations* and the *Food and Drug Regulations*. Manual adjustments cannot be made to the inventory without documented justification. It is recommended that there should be a process in place to review all manual adjustments and that the ability to make manual adjustments should be a restricted privilege.

Any brand substitutions must be adequately reconciled in the inventory for all involved molecules. This will ensure proper inventory control.

Accountability reconciliations represent the best means by which a pharmacy's inventory control can be assessed. Pharmacists should not expressly rely on the inventory system's expected on hand inventory or automated machine/robot counts alone. Periodic manual counts must be done to verify physical quantities within the dispensary (stock bottles, blister packs, etc.). A manual count does not constitute a reconciliation since a comparison of a manual count to a theoretical on-hand inventory will not necessarily reveal discrepancies.

The pharmacist must always be able to generate the necessary inventory and sales reports using their logistical software to allow an audit to be conducted.

4.1 Methadone prescriptions

The Government of Canada introduced regulatory amendments to change the way methadone is regulated under the CDSA and the NCR. Effective May 19, 2018, these amendments allow practitioners to prescribe, administer, sell or provide methadone without an exemption under subsection 56(1) (section 56) of the CDSA. As such, pharmacists no longer need to contact Health Canada to verify if a practitioner holds a valid section 56 exemption to prescribe methadone. Rather, methadone will be prescribed in the same manner as any other narcotic under the NCR. Pharmacists will be able to sell or provide methadone to a person if they have first received a written order or prescription, signed and dated by a practitioner. In addition, pharmacists will still be required to meet all other applicable provisions of the CDSA and associated regulations (including the NCR), as well as any requirements established by their relevant licensing authorities.

Filled prescriptions for methadone, when spilled, can be re-filled; however, the replenishment amount must be accounted for from the original authorization. This can be represented by an incident report that is kept on-site at the pharmacy for two years and does not require a loss or theft report as long as the spillage was witnessed, can be explained and is documented in the perpetual inventory log.

5. Records

This section outlines the types of records that should be kept in the pharmacist's possession for a period of at least two years (or longer when required by provincial/territorial regulations) in a manner that permits an audit to be made.

More pharmacists are moving to a paperless environment and filing records electronically. Health Canada has no objection to this transition provided that the electronic system chosen meets the requirements of the relevant regulations and that the electronic files are saved in a secure, high resolution format to ensure the information is easily readable. Lastly, pharmacists must have an appropriate backup system to avoid any loss of relevant information. Any record, whether paper or electronic, must be retrievable in a timely manner in order to permit an efficient audit to be made.

5.1 Purchase/receiving records

If the pharmacist receives a controlled substance, including exempted codeine products, from a licensed dealer, the following information must be entered in a book, register or other record:

- name and quantity of the substance received;
- date the substance was received; and
- name and address of the person from whom the substance was received.

Receiving records must also be maintained for any controlled substance received for emergency purposes.

5.2 Dispensing records (sales)

These records should be in chronological order by date and sequence dispensed to permit an audit to be made. They should contain the following:

- name and address of the person named in the order or prescription;
- name, quantity and form of the substance;
- name, initials and address of the practitioner who issued the order or prescription;
- name or initials of the pharmacist who sold or provided the controlled substance;
- date on which the substance was sold or provided; and
- number assigned to the order or prescription.

5.3 Special prescription file

The special prescription file must include:

- all written orders or prescriptions for all controlled drugs and narcotics dispensed (including part-fills and/or refills with respect to controlled drugs); and
- a written record of all controlled drugs and/or verbal prescription narcotics dispensed pursuant to a verbal order or prescription.

A report generated from electronic software can be provided to present this information in lieu of paper records. If hard copies are scanned and no physical copies are kept, they should be stored/organised in a manner that allows for easy extraction of the special prescription file. A number must be assigned to the order or prescription so that it can be easily extracted for audit.

5.4 Emergency transactions

Any emergency transfer must be captured within both the pharmacy's receiving records and dispensing records.

5.5 Destruction records

Although post-consumer returns and unserviceable stock can be shipped to a licensed dealer together for the purpose of destruction, the record keeping requirements for the two types of products are different and, as such, the records should be kept separate.

5.5.1 Post-consumer returns

Local destruction

For local destruction of post-consumer returns, the pharmacist must record:

- the date the destruction took place;
- the unique identifier of the container; and
- the number of containers destroyed; and this record must be signed and dated by the pharmacist and a witness.

Returns to a licensed dealer

If a shipment provided to a licensed dealer authorized to destroy contains post-consumer returns, a pharmacist must record the following:

- the number of containers collected;
- the unique identifier assigned to each container;
- the date the containers are being provided to the licensed dealer for destruction; and
- the name and address of the licensed dealer to whom the shipment was sold or provided.

The record requesting the destruction of post-consumer returns must also be signed and dated by the pharmacist.

5.5.2 Unserviceable stock

Local destruction

The pharmacist must keep a record of the unserviceable stock they are destroying locally for the purposes of stock reconciliation. The record must include the following:

- brand name or common name of each narcotic, controlled drug or targeted substance that is being destroyed;
- quantity and strength per unit of the narcotic, controlled drug or targeted substance;
- method of destruction used; and
- date the destruction took place.

The record must be signed and dated by the pharmacist performing the destruction and a witness. Both persons must sign and print their names on a joint statement indicating that they witnessed the destruction and that the substance was altered or denatured to such an extent that its consumption was rendered impossible or improbable.

Returns to a Licensed Dealer

Transactions relating to unserviceable stock between a pharmacist and a licensed dealer must be supported by a written order signed by the licensed dealer, and retained by the pharmacist, specifying the following:

- name, quantity and strength per unit of each substance in the stock being sold or provided for destruction;
- name and address of the licensed dealer to whom it was sold or provided; and
- date on which it was sold or provided.

Except when returning to the licensed dealer who sold them to the pharmacist, the order must indicate that the sole purpose of the transaction is the destruction of the unserviceable stock.

5.6 Return authorization records

A pharmacist may, on receiving a written order for a controlled substance, return the substance to the licensed dealer who sold or provided it to the pharmacist, if the order is signed and dated by the licensed dealer. The pharmacist must keep the details of this transaction in a book, register or other record and the copy of the return authorization should be kept on site. The date on which the substance left the pharmacy should also be recorded. This includes substances that are returned to licensed dealers for destruction.

5.7 Loss or theft reports

Losses and thefts must be reported to Health Canada's Office of Controlled Substances within 10 days of the discovery of the loss or theft via the [Loss or Theft Report Form for Controlled Substances, Precursors and Cannabis](#).

- Additional clarifying information should be included, such as steps taken for an internal investigation, findings, an explanation of the overall situation and any corrective action measures taken that will prevent or eliminate the potential for a reoccurrence.
- The form must be submitted within the 10 day timeline. Amendments, however, may be made post-submission (provide the original report alongside the amended version).

A reportable loss is an incident in which the possibility that the lost substance will be diverted to an illegal market is high or where no explanation exists at the time of reporting as to how the substance has gone missing (unexplainable negative variance). Any discrepancies (regardless of diversion risk) should be recorded in an incident report and filed on site for 2 years to be made available during inspections.

Note that the lost substance may come from unserviceable stock, filled prescriptions awaiting pickup, delivery, transportation or inventory. This should be indicated on the loss or theft report submitted.

Physical inventory counts that fall short of the theoretical on-hand inventory require investigation and reconciliation. Any apparent shortage that cannot be reconciled or explained must be reported.

For more information, refer to the Health Canada guidance document on the [Reporting of loss or theft of controlled substances, precursors and cannabis](#).

6. Definitions

Controlled drug:	a drug set out in the Schedule to Part G of the FDR, including a preparation
Controlled substance:	refers to a narcotic, controlled drug or targeted substance, as laid out in Schedules I, II, III, IV or V of the <i>Controlled Drugs and Substances Act</i>
Destruction:	to alter or denature a controlled substance to such an extent that its consumption is rendered impossible or improbable
Emergency transfer:	To be done on a prescription-basis per provisions of NCR 45(1), FDR G.03.014(b), 55(1)(b)(ii) and 55(2).
Licensed dealer:	the holder of a dealer's licence issued under the NCR, the FDR – Part G or the BOTSR
Local destruction:	on-site destruction
Narcotic:	any substance set out in the Schedule to the NCR or anything that contains any substance set out in that Schedule
Pharmacy technician:	a person who works in a pharmacy or dispensary and meets any applicable provincial or professional requirements in order to work as a pharmacy technician or equivalent designation
Post-consumer returns:	means unused or expired substance that is, or contains, a narcotic, targeted substance or a controlled drug, that has been returned by an individual to a pharmacy for the purpose of destruction, but does not include any substance that has been returned to a hospital pharmacy from a patient ward.
Targeted substance:	a controlled substance that is included in Schedule 1 to the BOTSR or a product or compound that contains a controlled substance that is included in Schedule 1 to the BOTSR
Unserviceable stock:	drug product containing a narcotic, controlled drug or targeted substance that is unused, expired and/or that cannot be dispensed for some reason.