Controlled substances guidance for community pharmacists and pharmacy technicians (CS-GD-022)

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Foreword

Guidance documents are meant to provide assistance to industry and health care professionals on how to comply with governing laws and regulations. Guidance documents also assist Health Canada officials, so that the legislation is administered 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 program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

Any questions of interpretation concerning this guidance document should be directed to the National Compliance Section within the Office of Controlled Substances at compliance-conformite@hc-sc.gc.ca.

Preface

The *Controlled Substances Regulations* (CSR), made under the *Controlled Drugs and Substances Act* (the Act), set out authorizations and outline various regulatory requirements for pharmacists and pharmacy technicians handling controlled substances.

The CSR covers the following categories of controlled substances:

- Narcotics
- Controlled drugs
- Targeted substances
- Restricted drugs

For the purpose of this guidance document, the term “controlled substance” refers to narcotics, controlled drugs, and targeted substances set out in schedules 1, 2, and 3 of the CSR. Pharmacists and pharmacy technicians are generally not authorized to conduct activities with restricted drugs, which is the one category of controlled substances that do not have authorized medical uses.

This document provides guidance and recommendations to pharmacists and pharmacy technicians working in community pharmacies on how they can meet regulatory requirements for controlled substances. **Pharmacists and pharmacy technicians working in a hospital or other healthcare settings are outside the scope of this guidance document.**

The words "must" and "should" are used throughout the document. The word "must" represents a regulatory requirement, while the word "should" represents a recommendation on how to meet a regulatory requirement. There may be more than one way to meet a regulatory requirement.

Important: Provincial or territorial regulatory requirements may be stricter than what is outlined in this document. It is the responsibility of pharmacy professionals to consult with the relevant provincial or territorial professional regulatory authority for further guidance.

How to use this document

Each section of this document describes an activity that pharmacists or pharmacy technicians are authorized to conduct under the CSR, and the regulatory requirements associated with that activity.

The document uses text boxes marked ‘**Important**’ to highlight a key piece of information that you should know. Use it as a way for you to best comply with the CSR.

Important: Key or cautionary information to know.

Guidance documents are administrative tools that do not have the force of law. Should any information in this guidance document conflict with the legislation (the Act or the regulations), the legislation prevails.

Ordering and Receiving Controlled Substances

Under the CSR, only pharmacists are authorized to order controlled substances from licensed dealers, hospitals or other pharmacists.

In practice, it is understood that pharmacy technicians assist pharmacists with the preparation of orders for controlled substances, however the order must be placed in the name of a pharmacist, and that pharmacist remains fully accountable for each order's accuracy, appropriateness, and compliance with regulatory requirements.

Pharmacists and pharmacy technicians can receive controlled substances from:

- a licensed dealer
- another pharmacist
- a hospital for emergency purposes
- an individual returning controlled substances for the purposes of destruction

A pharmacist or pharmacy technician must document the receipt of any controlled substance, including low-dose codeine products, when it is received from a licensed dealer, another pharmacist or a hospital.

When a pharmacist or pharmacy technician receives a controlled substance, they must record the following information:

- their name
- the name of the individual or organization from whom the controlled substance is received, their title (if applicable), and their municipal address
- the date the substance was received
- for a controlled substance that is not a finished product (for example, methadone powder), the name, form and quantity of the substance
- for a finished product:
    - name
    - brand name (if applicable)
    - name of the controlled substance it contains
    - form
    - strength
    - number of containers
    - number of units per container (if applicable)
    - drug identification number (if any)

Important: It is critical to record the date that controlled substances are received at the pharmacy to be able to detect loss or theft and conduct effective inventory reconciliation.

Sale or provision of controlled substances

A pharmacist can sell or provide a controlled substance to an individual, pursuant to a prescription.

In addition, a pharmacist can sell or provide a controlled substance, pursuant to an order, to:

- another pharmacist

- a practitioner
- a hospital
- a licensed dealer

Pharmacy technicians are not authorized to sell or provide controlled substances.

Verification of identity for orders and prescriptions

A pharmacist may only sell or provide controlled substances pursuant to an order or a prescription. A pharmacist or pharmacy technician who receives an order or prescription for a controlled substance must verify the identity of the person who issued the order or prescription when it is not already known to them. Elements of identity verification can include:

- the person's name
- their title (if applicable)
- their municipal address (if applicable)
- their signature, if it is not already known to the pharmacist or pharmacy technician (if applicable)

An order from a licensed dealer must be a written order that is signed and dated.

Verification of practitioner identity for prescriptions

In addition to the requirements outlined above, when it comes to prescriptions, pharmacists and pharmacy technicians are responsible for verifying the identity of the practitioner who issued the written or verbal prescription. Pharmacists and pharmacy technicians should have a robust system in place to authenticate the identity of the practitioner who issued the written or verbal prescription, where the system does not solely rely on information readily available to the general public. It is recommended to have a layered approach to authenticate identity, which includes two or more verification methods.

Examples of verification methods include:

- review the prescription transmission information (if sent electronically)
- callback using a known clinic telephone number
- verify that the practitioner is in good standing with their provincial or territorial professional regulatory authority
- verification through previously established practitioner credentials, or
- cross-reference provincial licensing databases with contact information from independent sources

Important: Only pharmacists can sell or provide controlled substances, and it is their responsibility to verify that the substances are being sold or provided for legitimate purposes. Pharmacy professionals may wish to consult with their provincial or territorial professional regulatory authority for further guidance on valid prescriptions and orders.

Electronic orders and prescriptions are acceptable if the digital or electronic signature can be authenticated.

Sale or provision to a licensed dealer

Many pharmacies accept unused or expired medications for safe disposal through take-back programs. A pharmacist can sell or provide a controlled substance, that was returned by an individual for the purposes of destruction, to a licensed dealer specialized in destruction. Refer to the Destruction section for more information about unused stock (also known as unserviceable stock) and post-consumer returns.

Additionally, a pharmacist can sell or provide a controlled substance to a licensed dealer for other reasons, including:

- for the purposes of returning a controlled substance to the licensed dealer from whom the pharmacist purchased the substance in the first place
- for the purposes of testing the controlled substance
- for the purposes of destroying the controlled substance

Sending controlled substances to a licensed dealer for testing purposes can include, but is not limited to:

- sending compounded products for testing to comply with any requirements imposed by the provincial or territorial professional regulatory authority
- sending the product to a licensed dealer for the purposes of testing, for drug products that have been recalled by Health Canada or by the manufacturer

Before sending the controlled substances, the pharmacist must receive a signed and dated written order from the licensed dealer containing the information below, which applies to finished products returned by an individual for the purpose of destruction, controlled substances that are not finished products, as well as finished products:

- name of the licensed dealer
- title of the person signing the order (if applicable)
- municipal address of the licensed dealer
- name of the pharmacist
- name and municipal address of the pharmacy where the pharmacist practices
- date of the order
- if the substance is being sold or provided for the purposes of destruction, a statement to that effect

For finished products returned by an individual for the purpose of destruction:

- the unique identifier marked on the collection container
- the number of collection containers

For controlled substances that are not a finished product:

- the name, form and quantity of the substance

For finished products:

- the name
- brand name (if applicable)
- the name of the controlled substance it contains
- form
- strength
- number of containers
- number of units per container (if applicable)
- the Drug Identification Number (if any)

See the section Documentation requirements for substances sold pursuant to an order for what to record when you have sent controlled substances to a licensed dealer.

Sale or provision to another pharmacist

Sale or provision for the purpose of fulfilling a prescription (central fill)

Prior to October 1, 2026, central fill pharmacies were required to hold a dealer's licence. Under the Controlled Substances Regulations, pharmacists are authorized to sell or provide controlled substances to another pharmacist to fulfill a prescription (e.g., central fill), thus removing this requirement. This sale or provision can only occur pursuant to an existing prescription at the receiving pharmacy. The amount of controlled substance being sold or provided must match the amount on the prescription at the receiving pharmacy.

Licensing requirements still apply. Should pharmacists wish to sell or provide controlled substances to other pharmacists on a regular basis outside of a prescription, they would be required to first obtain a controlled substances dealer's licence. For more information on how to apply for and receive a controlled substances dealer's licence, please refer to the Management of Applications for Controlled Drugs and Substances Dealer's Licences.

Where a business operates both as a pharmacy and as a licensed dealer, pharmacy activities, inventory, and records must be kept separate from the licensed dealer operations and inventory. Controlled substances and other health products obtained and intended for pharmacy sale or provision must not be stored, processed, or co-mingled in the licensed dealer's secure environ, including safes or automated dispensing equipment.

Table 1 Comparison of authorizations and requirements for pharmacists and licensed dealers

Pharmacist	Licensed dealer
Provides controlled substances directly to patients or to another pharmacist pursuant to a prescription	Provides controlled substances to pharmacies pursuant to a written order, but without the need for a prescription (e.g., bulk sales in anticipation of a prescription)
Must ensure controlled substances are stored in secure location and limit access	Must adhere to the security requirements outlined in the Directive on Physical Security Requirements for Controlled Substances and Drugs Containing Cannabis

Can order controlled substances from a licensed dealer, as needed	Can only conduct activities with the controlled substances listed on the licence
Must report a loss or theft to Health Canada within 10 days after the day on which they become aware	Must report a loss or theft to Health Canada within 72 hours after becoming aware; Must report thefts to police within 24 hours after becoming aware
No requirement for suspicious transaction reporting	Must report suspicious transactions to Health Canada within 72 hours after becoming aware
No requirement for Monthly Activity Reports	Must submit Monthly Activity Reports to Health Canada
Pharmacists have overall responsibility for the activities at a pharmacy	Activities with controlled substances must be supervised by a Qualified Person in Charge or their alternate
Can destroy controlled substances with a witness without prior approval from Health Canada	Must obtain prior approval from Health Canada prior to destruction of controlled substances
No requirement to notify Health Canada when a pharmacy is closing	Must notify Health Canada 30 days before ceasing activities. Must notify Health Canada within 10 days when they cease to produce or package a mixture or finished product. If changing locations, the new location must be approved by Health Canada before moving controlled substances there.

Sale or provision when a pharmacy ceases operations

In the event of a pharmacy ceasing its operations, the pharmacist may sell or provide their controlled substances inventory to another pharmacist. Ceasing operations can include:

- a pharmacy closing its physical location, or
- a transfer of ownership, where the physical location remains unchanged

At the time of the transfer, both pharmacists should:

- sign a record of transfer
- complete an inventory of the substances, and
- keep a record of the inventory for a minimum of 2 years to allow for an audit to be made

In addition to selling or providing their controlled substances to another pharmacist in the event of a pharmacy ceasing its operations, pharmacists also have the option to sell or provide their controlled substance inventory to a licensed dealer pursuant to a written order. If sale or provision is for the purposes of destruction, it must be to a licensed dealer specialized in destruction. All pharmacists must:

- report any loss or theft of a controlled substance to Health Canada, including if it occurred while in their possession or while in transit to another pharmacy or a licensed dealer

- take all reasonable steps necessary to ensure the security of the controlled substances in their possession, including when the substances are in transit between the two pharmacies or to a licensed dealer

Important: Pharmacists are not required to notify Health Canada when they transfer controlled substances to another pharmacy due to a pharmacy closure and they are not required to notify Health Canada of the pharmacy closure. Pharmacists should check for any additional closing requirements specific to their province or territory.

Emergency purposes

A pharmacist can sell or provide a controlled substance to another pharmacist for emergency purposes pursuant to a written or verbal order from the other pharmacist. The order must be captured by both pharmacists in their respective receiving and dispensing records.

Emergency purposes can include, but are not limited to:

- a critical shortage of stock
- an urgent public health need
- an order that could not be processed and needed immediate action

Example of a situation where emergency purposes would apply: Pharmacy A receives a prescription for a controlled substance and they do not have that substance in stock. Therefore, pharmacy A orders the substance from another pharmacy.

Emergency sale or provision should not be used as a routine inventory management practice.

Documentation requirements for sale or provision to another pharmacist

When a pharmacist sells or provides a controlled substance to another pharmacist, they must first receive a signed and dated written order from the other pharmacist. Verbal orders are only acceptable if the controlled substances are being ordered for emergency purposes.

The written order must contain the information outlined below:

- the name of the pharmacist placing the order and the name and municipal address where they practise
- the name of the pharmacist selling or providing the controlled substance and the name and municipal address where they practise
- the date of the order
- if the substance is not a finished product: the name, form and quantity
- if the substance is a finished product:
    - the name
    - brand name (if applicable)
    - name of the controlled substance it contains
    - form
    - strength
    - number of containers (if known)
    - number of units per container (if applicable), and

    - the Drug Identification Number (if any)
- for emergency sale or provision, a declaration that the controlled substance is required for emergency purposes whether this is by a written or verbal order
- for prescription-based sale or provision, the number assigned to the prescription by the pharmacist placing the order

The number of containers and number of units per container may not be applicable or relevant in all cases. In these cases, Health Canada will accept "total quantity" as an alternative. Examples of the total quantity could include the number of tablets, grams of powder, or millilitres of liquid. The units of the total quantity will depend on the dosage form.

A drug identification number only needs to be included on an order when it is known, as it may not be available to the pharmacist placing an order.

Important: If the controlled substance inventory of the closing pharmacy is sold to another pharmacist, records must be kept on behalf of both the selling and receiving pharmacies for at least 2 years.

Sale or provision when a pharmacy is impacted by an emergency evacuation

The Subsection 56(1) class exemption for community pharmacists impacted by an emergency evacuation in Canada allows pharmacists who need to evacuate their pharmacy due to an emergency caused by a natural phenomenon, such as a wild fire or a flood, to transfer their controlled substances inventory to another pharmacist, subject to any applicable provincial or territorial requirements. The exemption has been posted online and you can consult it at the following Health Canada web page Subsection 56(1) class exemption for community pharmacists impacted by an emergency evacuation in Canada.

Evacuating pharmacists must:

- protect the controlled substances against loss or theft until they are received at the other pharmacy
- if possible, conduct a physical inventory of the controlled substances being transferred
- if a physical inventory is not possible, take alternate measures to document the inventory, such as printing the theoretical inventory list
- conduct an inventory count once the substances arrive at the receiving pharmacy
- report any losses or thefts to Health Canada
- keep a record of the transfer of the controlled substances, which includes:
    - the brand name (if applicable), substance name and DIN (if any) of each controlled substance
    - the strength, dosage form and total amount of each controlled substance
    - the date the controlled substances are received at the other pharmacy
    - the name and municipal address of the evacuating pharmacist
    - the name and municipal address of the receiving pharmacist
- in instances where the substances are provided to a pharmacist located in another province, notify the provincial or territorial professional regulatory authority of that province

Receiving pharmacists must record:

- the name and quantity of the controlled substances received

- the date of receipt
- the name and address of the evacuating pharmacist

Once the evacuating pharmacist can return to their pharmacy, the receiving pharmacist can transfer the controlled substances back to the evacuating pharmacist. In this instance, the receiving pharmacist must:

- conduct a physical inventory of the substances prior to transfer
- ensure the security of the substances in transit
- report any losses or thefts to Health Canada
- keep a record of:
    - the brand name (if applicable), substance name and DIN (if applicable) of each controlled substance
    - the strength, dosage form and total amount of each controlled substance
    - the date the controlled substances are returned to the evacuating pharmacist
    - the name and municipal address of the receiving pharmacist
    - the name and municipal address of the evacuating pharmacist

Upon return of the controlled substances to the evacuating pharmacist, the evacuating pharmacist must record:

- the name and quantity of the controlled substances received
- the date of receipt
- the name and address of the pharmacist who sent the substances back

All records made under this exemption must be kept for a period of two years.

Sale or provision to a practitioner or hospital

Pharmacist to practitioner sales are intended to be for in office use, low volume and infrequent, or where no other reasonable supply options are available, and not for the purposes of resale or activity of wholesaling.

A pharmacist can sell or provide a controlled substance to a practitioner or to a hospital, if they first receive a signed and dated written order containing the information outlined below. In the case of an emergency, a verbal order would also be acceptable.

- for sale to a practitioner, the name of the practitioner and the name and municipal address of the place where they practise
- for sale to a hospital, the name of the hospital and its municipal address as well as the name and the title of the person placing the order
- the name of the pharmacist and the name and municipal address where they practise
- the date of the order
- for a controlled substance, other than a finished product, the name of the controlled substance, its form and quantity
- for a finished product:
    - name
    - brand name (if applicable)

    - name of the controlled substance it contains
    - form
    - strength
    - number of containers (if known)
    - number of units per container (if applicable)
    - Drug Identification Number (if any)

The number of containers and number of units per container may not be applicable or relevant in all cases. In these cases, Health Canada will accept "total quantity" as an alternative. Examples of the total quantity could include the number of tablets, grams of powder, or millilitres of liquid. The units of the total quantity will depend on the dosage form.

Important: Before selling or providing controlled substances to another pharmacist or to a practitioner, the pharmacist must verify that the receiving pharmacist or practitioner is in good standing with their provincial or territorial professional regulatory authority and that there are no restrictions on their licence that would prevent them from conducting activities with controlled substances. This information is usually available through the website of the provincial or territorial professional regulatory authority.

Documentation requirements for substances sold pursuant to an order

Pharmacists must record the following information:

- their name
- the name of the person to whom the substance was sold or provided, their title (if applicable), and their municipal address
- the date of the sale or provision
- for controlled substances, other than finished products, the name, form and quantity of the substance
- for finished products:
    - the name
    - its brand name (if applicable)
    - the name of the controlled substance it contains
    - form
    - strength
    - number of containers
    - the number of units per container (if applicable)
    - the Drug Identification Number (if applicable)
- If the sale or provision is for substances returned by an individual for the purpose of destruction, the unique identifier on the collection container and the number of containers.
- if the sale or provision is for emergency purposes, a statement to that effect explaining the reason for the emergency

Sale to an individual

A pharmacist can only sell or provide a controlled substance to an individual pursuant to a prescription. The prescription can be for:

- the individual’s own use

- the use of another individual
- an animal

A pharmacist or pharmacy technician can receive a written prescription from:

- an individual (including their delegate)
- another pharmacist or pharmacy technician transferring a copy of the original prescription
- a practitioner

The CSR allow another individual (e.g., spouse, partner, parent) to pick up medication on behalf of a patient or an animal.

A pharmacist or pharmacy technician may also receive a verbal prescription from a practitioner.

Documentation requirements for sales to individuals

The dispensing records should be in chronological order to allow an audit to be made. The records must contain:

- the pharmacist's name
- the name of the individual named in the prescription (or who is responsible for the animal identified in the prescription and, if known, the name of the animal)
- the name of the practitioner who issued the prescription and the name and municipal address of the place where they practise
- the number assigned to the prescription
- the date of the sale or provision
- the name
- the brand name (if applicable)
- the name of the controlled substance it contains
- the form
- the strength
- the number of containers
- number of units per container (if applicable)
- the Drug Identification Number (if any)
- if applicable, the number of times that the prescription may be refilled and, if specified, the intervals between refills

Administration to a patient

Provided the pharmacist is duly registered and authorized to administer a given controlled substance under the laws of the province or territory where the administration takes place, this activity is authorized by the Subsection 56(1) class exemption for pharmacists administering controlled substances in Canada.

The exemption is only applicable if the following conditions are met:

- Administration of a controlled substance must be conducted by the pharmacist themselves and cannot be delegated

- Pharmacists must only administer a controlled substance to a patient who has a prescription for that substance
- Pharmacists must destroy any remaining controlled substance that cannot be administered in accordance with the Destruction section of this guidance document

Documentation requirements for administration of a controlled substance to a patient

When administering a controlled substance to a patient, a pharmacist must also document the following:

- the name and quantity of the controlled substance administered
- the date of administration

Pharmacists must also comply with any other policies, guidelines, restrictions and requirements, including record-keeping requirements established by the relevant provincial or territorial government and by any relevant provincial or territorial professional regulatory authority.

It is also recommended to record:

- the name of the pharmacist who administered the substance
- the route of administration
- the lot number of the drug product administered

Required records must be retained for two (2) years from the date each record was created.

Advertising

Pharmacists and pharmacy technicians must not advertise or promote the sale or provision of controlled substances to the general public. This includes content accessible through websites, social media platforms, digital or printed materials.

One way to limit the audience, is to restrict written advertisements to documents distributed to, or in a trade publication intended for:

- licensed dealers
- pharmacists
- pharmacy technicians
- practitioners
- hospitals

In addition, written advertisements must include a statement that clearly and visibly says that the substance is a controlled substance. Pharmacists and pharmacy technicians cannot advertise a restricted drug.

For more information about what is considered advertising, refer to Health Canada's Guidance on distinction between advertising and other activities for health products.

Compounding of finished products

Pharmacists or pharmacy technicians can compound finished products containing controlled substances.

Pharmacists or pharmacy technicians are not authorized to compound finished products with restricted drugs.

A pharmacist or a pharmacy technician can compound a finished product containing a controlled substance for an individual if they first receive a written prescription from:

- the individual
- a practitioner
- another pharmacist or pharmacy technician transferring the prescription

They may also receive a verbal prescription from:

- another pharmacist or pharmacy technician sending the prescription, in the form of a copy of the document on which the information for the verbal prescription was recorded
- a practitioner

A pharmacist or pharmacy technician can also compound a finished product containing a controlled substance pursuant to a signed and dated written order from:

- another pharmacist
- a practitioner
- a hospital

In the case of an emergency, a pharmacist may also compound a finished product containing a controlled substance, pursuant to a verbal order for another pharmacist, a practitioner or a hospital.

The written order must contain the following information:

- the name of the pharmacist, practitioner, or hospital placing the order (and the name of the person permitted to place the order on the hospital's behalf)
- the name and municipal address where the pharmacist or practitioner practices, or the name and municipal address of the hospital
- the name of the pharmacist or pharmacy technician compounding the product and the name and municipal address where they practise
- the date of the order
- the name, form and strength of the finished product
- number of containers (if known)
- number of units per container (if applicable)
- if applicable, a declaration from the other pharmacist that they require the finished product for emergency purposes

Health Canada will accept "total quantity", when the number of containers is not known. Examples of the total quantity could include the number of tablets, grams of powder, or millilitres of liquid. The units of the total quantity will depend on what the dosage form is.

Refer to the Policy on Manufacturing and Compounding Drug Products in Canada (POL-0051) for information on making the distinction between compounding and manufacturing.

Important: Since compounded products do not have a brand name, the name of the finished product is the name of the controlled substance(s) it contains.

Documentation requirements for compounded finished products

Pharmacists and pharmacy technicians who compound a finished product containing a controlled substance must record the following information:

- their name
- the name of the individual named in the prescription or responsible for the animal identified in the prescription (and, if known, the name of the animal)
- the name of the practitioner who issued the prescription, and the name and municipal address of the place where they practise
- the number assigned to the prescription
- the date of compounding
- the name of the finished product, as well as its form, strength, the number of containers, and the number of units per container (if applicable)

Important: Since compounded products do not have a brand name, the name of the finished product is the name(s) of the controlled substance(s) it contains.

Modification of Prescriptions by Pharmacists

While Health Canada recognizes that provincial or territorial professional regulatory authorities may define prescriptions differently, under the CSR, prescriptions have a specific legal meaning. Under the CSR, prescriptions are documents, that are initiated by a practitioner, and authorize a set amount of a controlled substance to be sold or provided to a named person or an identified animal.

Where a prescription for a controlled substance initiated by a practitioner exists and the activity is permitted at the provincial/territorial level, pharmacists can:

- conduct a therapeutic substitution
- adjust a prescription as long as the quantity dispensed does not exceed the amount originally authorized by the practitioner, such as adjusting the formulation, dose and regimen, de-prescribing, or part-filling, or
- extend a prescription for up to two years after the date of receipt of that prescription. Note, pharmacists also have the option to use the date the prescription was issued to calculate the two-year period for extensions

Therapeutic Substitution

Provided this activity is permitted at the provincial or territorial level, a pharmacist may, before selling, providing or compounding a finished product, substitute a controlled substance identified in a prescription for another controlled substance.

The ability to substitute a controlled substance is limited to prescription-based activities and does not apply to order-based activities.

A pharmacist is not authorized to substitute a non-controlled substance specified in a prescription with a controlled substance.

It is expected that the substitution would be therapeutically equivalent and not exceed the duration of treatment prescribed by the practitioner. The determination of therapeutic equivalency, and the calculation of the amount of substituted medication that is equivalent to the duration of therapy indicated on the original prescription, are left to pharmacists as part of their scope of practice.

Example: A pharmacist receives a prescription for a controlled substance with three refills on it. The pharmacist dispenses one of the refills. When the patient comes in for their second refill, there is a drug shortage, and the pharmacist chooses to perform a substitution. The substitution can only be done for the remaining two refills.

Important: When pharmacists substitute a controlled substance in a prescription for another controlled substance, they must document this substitution as described below.

Documentation requirements for therapeutic substitutions

When a pharmacist substitutes a controlled substance in a prescription for another controlled substance, they must record the following information:

- their name
- the number assigned to the original prescription
- the date of the substitution
- the name of the controlled substance on the original prescription
- the name of the substituted controlled substance

Adjusting prescriptions

Under the CSR, pharmacists can also conduct the following activities, as long as the quantity dispensed does not exceed the amount originally authorized by the practitioner:

- **Adjusting the formulation**: adjusting the dosage form in which the drug is prescribed
    - e.g., change from pill to liquid formulation
- **Adjusting the dose and regimen**: a structured plan that specifies the frequency in which a dose of medication should be ingested
    - e.g., change from 20 mg per day for 5 weeks to 10 mg per day for 10 weeks
    - e.g., change from 10 mg per day for 10 weeks to 20 mg per day for 5 weeks
- **De-prescribing**: the planned and supervised process of reducing or stopping a medication
- **Part-filling:** dispensing a quantity of a medication which is less than the total amount of the drug specified by a practitioner

- For greater clarity, this includes when a pharmacy is dealing with an inventory shortage, situations where the nature of the part-fill is a matter of discussion between the pharmacist and patient, or as requested by the patient.

Extending Prescriptions

A pharmacist may extend a prescription for a period that is no later than two years from the date on which a pharmacist received the initial prescription, if known. Health Canada will accept using the date the prescription was issued by a practitioner to calculate the two-year period.

Pharmacists must be authorized to conduct this activity by their provincial or territorial legislation and scope of practice. When extending a prescription for any drug, including a controlled substance, pharmacists are expected to use their professional judgment and to adhere to any requirements or guidelines that exist at the provincial or territorial level.

Pharmacists cannot verbally extend a prescription and they must keep written records.

The same prescription can be both extended and therapeutically substituted. These two actions can occur independently, consecutively, or concurrently, within the two-year period that is always calculated from the date the original prescription was received at a pharmacy (or the date the prescription was issued as described above).

Important: The two-year extension period applies to transferred prescriptions as well and is calculated from the date the original prescription was received at the first pharmacy. Therefore, the pharmacist who receives a transferred prescription should document the date the original prescription was received at the first pharmacy to determine the two-year extension period. Health Canada will accept using the date the prescription was issued by a practitioner.

Important: Prior to October 1, 2026, prescription extensions were authorized under a Subsection 56(1) class exemption for patients, practitioners and pharmacists prescribing and providing controlled substances in Canada. To facilitate the transition to the regulatory requirements under the Controlled Substances Regulations and ensure continuity of care for patients, Health Canada will allow prescriptions received prior to October 1, 2026 to be extended or transferred until October 1, 2028, regardless of the date on which they were received at the pharmacy, subject to any applicable provincial or territorial requirements.

Example 1: Extension followed by substitution

A pharmacist receives a prescription for a controlled substance on November, 2026. The pharmacist fully dispenses the prescription.

The patient cannot get to their practitioner in time for a new prescription; the pharmacist can extend the prescription up to a maximum of two years from November, 2026. The pharmacist can extend the prescription multiple times if needed, as long the two-year maximum is not exceeded.

When the patient comes to pick up their medication, after the pharmacist has extended the prescription, the pharmacist notes there is a drug shortage for the prescribed medication. The pharmacist substitutes the controlled substance from the original prescription for another controlled substance and dispenses it to the patient.

Example 2: Substitution followed by extension followed by another substitution

Conversely, there may be a drug shortage on November 1, 2026, when the pharmacist first receives the prescription, so the pharmacist can substitute the controlled substance from the original prescription for another controlled substance and dispense it to the patient. Should the patient need their prescription extended, the pharmacist can extend for up to two years based on the date the original prescription was received by the pharmacy.

When pharmacists extend a prescription, they must document this extension as described below.

Documentation requirements for prescription extension and refills

One of the aims of the documentation requirements is to have a clear audit trail that links the original prescription to the substituted, extended, or transferred prescription.

A pharmacist who extends or refills a prescription must record:

- their name
- the number assigned to the original prescription
- the date of the prescription extension or refill; and
- if applicable, the new expiration date of the extended prescription

Important: Prescriptions can be extended for up to two years from the date the original prescription was first received by the first pharmacist. Health Canada will also accept using the date the prescription was issued by a practitioner to calculate the two-year period.

Prescription transfer

A pharmacist or pharmacy technician can transfer a prescription for a controlled substance to another pharmacist or pharmacy technician. The regulations do not limit the number of times a prescription can be transferred, but rather the time period during which a prescription can be transferred. The time period is limited to two years from the date on which the prescription is first received by the first pharmacist. Health Canada will accept using the date the prescription was issued by a practitioner to calculate the two-year period.

It is understood that the original prescription would typically be kept at the first pharmacy that received it. A copy of the original prescription, or detailed information from the original prescription (e.g., prescription number, name and quantity of the controlled substance from the original prescription, date issued) must be sent to the receiving pharmacy. The aim is to have a clear audit trail that links the original prescription to the transferred prescription.

Once the transfer has been sent, the pharmacist or pharmacy technician who initiated the transfer should ensure the prescription cannot accidentally be filled or transferred again, for example, by inactivating the original prescription or the most recently modified prescription on file.

In addition, if any extensions or substitutions have been made prior to the transfer, this information should also be provided to the receiving pharmacy.

Example: Pharmacist A receives a prescription for a controlled substance with four refills on it. They dispense two of the refills and then they transfer the prescription to Pharmacist B. Pharmacist B can only

dispense the remaining two refills. Furthermore, should Pharmacist B choose to substitute the prescription, they can only do so for the two remaining refills on the prescription.

Documentation requirements for prescription transfers – transferring pharmacy

A pharmacist or pharmacy technician who transfers a prescription to another pharmacist or pharmacy technician must record:

- their name
- the name of the pharmacist or pharmacy technician to whom the prescription is being transferred, as well as the name and municipal address of the place where they practise
- the number they assigned to the prescription
- the date of the prescription transfer
- the date of the last refill of the prescription
- if applicable, the number of authorized refills remaining and, if specified, the interval between refills
- if applicable, the date of the prescription extension and the new expiration date of the extended prescription

Documentation requirements for prescription transfers – receiving pharmacy

A pharmacist or pharmacy technician who receives a transferred prescription must record:

- their name
- the name of the pharmacist or pharmacy technician from whom they received the prescription, as well as the name and municipal address of the place where they practise
- the number assigned to the prescription by the transferring pharmacist
- the new number assigned to the prescription by the receiving pharmacist
- the date the prescription was received
- the date of the last refill of the prescription
- if applicable, the number of authorized refills remaining and, if specified, the interval between refills
- if applicable, the date of the prescription extension and the new expiration date of the extended prescription

Important: The date a prescription is first received is used to calculate the two-year period for prescription transfers or extensions. Therefore, the pharmacist who receives a transferred prescription should document the date the original prescription was received at the first pharmacy to determine the two-year extension period. Health Canada will accept using the date the prescription was issued by a practitioner to calculate the two-year period.

Documentation requirements for orders and prescriptions

Written orders and prescriptions

Pharmacists or pharmacy technicians who receive a written order or written prescription must record:

- their name
- the date of the order or prescription

In practice, it is understood that another pharmacy professional might receive the written order or prescription. In those instances, the name of the person who created the record should be recorded.

Verbal orders and prescriptions

Pharmacists or pharmacy technicians who receive a verbal order or prescription must record:

- their name
- with regard to the person placing the order or issuing the prescription:
    - if another pharmacist, their name, the name and municipal address of where they practise and a declaration that they require the substance for emergency purposes
    - if a practitioner, their name, the name and municipal address of the place where they practise, and (for orders) a declaration that they require the substance for emergency purposes
    - if a hospital, its name and municipal address, the name of the person authorized to place the order, and a declaration that the hospital requires the substance for emergency purposes
- the date of receipt of the order or prescription
- for a controlled substance, other than a finished product, the name of the controlled substance, its form and quantity
- for a finished product:
    - name
    - brand name (if applicable)
    - name of the controlled substance it contains
    - form
    - strength
    - number of containers (if known)
    - number of units per container (if applicable)
    - Drug Identification Number (if any)
- if applicable the number of refills authorized in the prescription and, if specified, the interval between refills

The number of containers and number of units per container may not be applicable or relevant in all cases. In these cases, Health Canada will accept "total quantity" as an alternative. Examples of the total quantity could include the number of tablets, grams of powder, or millilitres of liquid. The units of the total quantity will depend on the dosage form.

Low-dose codeine products

There is an exception in the regulations that allows “low-dose” codeine products to be sold or provided without a prescription. Therefore, the record-keeping requirements for the sales to individuals do not apply, however pharmacists should still have a system in place to track inventory for these products. A low-dose codeine product is a finished product containing:

- no more than 8 mg (or its equivalent) of codeine phosphate per solid dosage form unit; or
- no more than 20 mg (or its equivalent) of codeine phosphate per 30 mL of liquid
- and either:

- two additional medicinal ingredients, other than a narcotic, whose amount is no less than the regular minimum single dose for one such ingredient or one-half of the regular minimum single dose for each such ingredient; or
- three additional medicinal ingredients, other than a narcotic, where the amount of each of the additional medicinal ingredients is no less than:
  - the regular minimum single dose; or
  - one third the regular minimum single dose

The Controlled Substances Regulations specify that pharmacists who sell or provide low-dose codeine products must:

- have reasonable grounds to believe that the product will only be used for recognized medical purposes; and
- ensure that the following caution (or equivalent) is conspicuously and legibly printed, to the inner and outer label of the product: "This product contains codeine and should not be administered to children except on the advice of a physician, dentist or nurse practitioner"

In determining whether there are reasonable grounds to believe that the low-dose codeine product will only be used for recognized medical purposes, the pharmacist is expected to use their professional judgment to determine the appropriateness of the patient's request to self-medicate for a recognized medical or dental reason.

Note that there may be additional rules that apply to low-dose codeine products in some provinces.

Ephedrine and pseudoephedrine products

Under the *Precursor Control Regulations*, pharmacists are required to keep non-combination natural health products containing ephedrine and/or pseudoephedrine behind the counter. These products should not be accessible to the public for self-selection.

The terms ephedrine and pseudoephedrine include any of their salts.

The *Precursor Control Regulations* state the minimum federal standards that apply to the sale of natural health products and non-prescription drugs containing ephedrine and/or pseudoephedrine. It is possible that these products are also subject to additional provincial or territorial requirements and/or regulations or contain other ingredients that are subject to the National Association of Pharmacy Regulatory Authorities' (NAPRA) National Drug Schedules.

Security

Pharmacists must ensure:

- all controlled substances are stored in a secure location at the place where they practise
- only persons they have authorized have access to this secure location

Important: All pharmacists working in a pharmacy are responsible for the overall secure storage of controlled substances at the place where they practise. It is the pharmacist's responsibility to ensure only authorized persons are accessing the secure location. This responsibility cannot be delegated to a pharmacy technician.

Important: Pharmacy technicians may perform their scope of practice with controlled substances independently without a pharmacist's direct supervision, as authorized in the province or territory in which they practise. For example, under the Controlled Substances Regulations, pharmacy technicians are authorized to independently conduct several regulated activities, such as receiving controlled substances, compounding finished products containing controlled substances, transferring a prescription, or accepting post-consumer returns for destruction. For clarity, a pharmacy technician can receive shipments of controlled substances and accept post-consumer returns. However, a pharmacist must be present on site while activities with controlled substances are taking place. For example, a pharmacy technician must not have access to controlled substances in the absence of the pharmacist. Activities with controlled substances cannot occur in the absence of a pharmacist.

Furthermore, in the course of conducting activities with controlled substances, pharmacists and pharmacy technicians working at the pharmacy must take all reasonable measures to ensure the security of any controlled substance in their possession, including substances returned by individuals for the purpose of destruction.

While pharmacists are required to store controlled substances in a secure location and ensure that only authorized persons have access, Health Canada does not require that these products be stored in any specific way. There are differing provincial or territorial requirements related to how controlled substances are shelved and stored at the pharmacy level. For example, pharmacists may:

- store controlled substances in a safe or
- dispersed on shelves

It is the pharmacist's responsibility to ensure that the method they use to manage their controlled substances stock:

- protects these substances against loss or theft
- respects any provincial or territorial guidelines established by the professional regulatory authority

The CSR do not prescribe to whom the pharmacist can grant access to the secure location where controlled substances are stored. While access can be granted to any person based on operational needs, the pharmacist assumes overall responsibility for activities at the pharmacy involving controlled substances and must ensure compliance with the regulations.

The following are examples of practices that may be used to achieve compliance with the CSR. The list of recommendations is not exhaustive. Other methods may be deemed acceptable if the regulatory requirement of ensuring the security of the controlled substances is met.

Alarm system

If the pharmacy is part of a retail space, the dispensary should be on a separate alarm zone.

Physical security measures

To protect controlled substances against loss or theft, pharmacists can use one or more of the following:

- window protection

- locked doors
- locked cabinets and drawers
- video surveillance
- a controlled substances safe
- a time-delayed safe

Restricted access to dispensary

Activities with controlled substances cannot occur in the absence of a pharmacist. Pharmacists must supervise cleaning or maintenance staff if they are accessing an area where controlled substances are stored. This responsibility cannot be delegated to a pharmacy technician.

Pharmacists should not share or post ordering codes for controlled substances, PINs, or keys.

Reasonable inventory

Pharmacists should order quantities of controlled substances that align with prescription volumes. This will prevent excessive quantities of controlled substances from being lost or stolen.

Inventory counts and reconciliation

Inventory counts and reconciliation activities should be performed by either:

- a pharmacist
- someone under the direct supervision of a pharmacist, such as a pharmacy technician

The following recommendations regarding inventory counts and reconciliation will assist pharmacists and pharmacy technicians with the detection and prevention of loss or theft. The list of recommendations is not exhaustive.

1. Regularly perform a manual inventory count of all controlled substances, verifying the count against your perpetual inventory. Investigate all discrepancies identified.
2. At minimum, perform a complete manual inventory count:
    - twice a year
    - before and after a pharmacy move
    - after the pharmacy receives a non-compliant inspection rating from Health Canada
    - after a change in the pharmacy manager or owner or any unexpected staffing changes
    - 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 (for example, an unlocked window)
3. Maintain an active perpetual inventory to flag any discrepancies in real-time.

4. Separate the records for active inventory from the records for inactive inventory (unserviceable stock, expired stock, post-consumer returns).
5. Record any substitutions relating to brand changes, package size or strength to ensure accuracy. Note: Pharmacists are required to comply with record-keeping requirements for therapeutic substitutions completed as described in the Substitution section of this document.
6. Ensure the necessary inventory and sales reports can be generated by your logistical software to allow an audit to be conducted at any time.
7. Conduct regular inventory reconciliations and investigate all discrepancies – this is not the same as a manual inventory count verification. Inventory reconciliations should be conducted when manual counts are off or when there are concerns with manual adjustments. See details below.

Conducting a manual inventory count

The recommended steps to conduct a verified inventory count are as follows:

1. Complete a manual count of the current inventory in stock.
2. Compare the manual count to the perpetual inventory in your system – this is the calculated theoretical number to be verified.
3. Investigate and record reasons for any discrepancies (shortages or overages) between the manual count and the perpetual inventory:
    - review all manual inventory changes since the last inventory count
        - justify manual adjustments of the perpetual inventory using supporting documentation (destruction records, spill logs, returns, etc.)
        - regularly review all manual adjustments and restrict the ability to make manual adjustments in the inventory system
4. Report any unexplained shortages to the Office of Controlled Substances as a **loss or theft** within 10 days after the day on which they become aware, as required by the CSR.
5. Develop and implement measures to maintain an accurate inventory.

Conducting an inventory reconciliation

The recommended steps to conduct an effective inventory reconciliation are as follows:

1. Retrieve the verified inventory count numbers from the last inventory conducted.
2. Determine the **starting inventory** of each controlled substance:
    - start with the previous verified inventory count
    - add all the controlled substances received since the last verified inventory count according to the receiving records
        - include any substances transferred from another pharmacy (emergency supply, central fill, etc.)

3. Determine the quantity of controlled substances **sold or provided** since the last verified inventory count:
    - verify that all corresponding prescriptions and orders for controlled substances sold or provided are present
4. Complete a **manual count of the current inventory** in stock.
5. Calculate the theoretical inventory:
    - **Starting inventory** (step 2) – **number sold or provided** (step 3) = **theoretical inventory**
6. Compare **calculated theoretical inventory** to the **manual count of the current inventory:**
    - **Manual count of current inventory** – **calculated theoretical inventory** = **possible discrepancy**
    - If the possible discrepancy is a negative number then you have a possible shortage
    - If the possible discrepancy is a positive number then you have a possible overage
7. Investigate and record reasons for any discrepancies (shortages or overages) between:
    - the **calculated theoretical inventory** and the **manual count of the current inventory**
    - review all manual inventory changes since the last reconciled inventory count
        - justify manual adjustments of the perpetual inventory using supporting documentation (destruction records, spill logs, returns, etc.)
        - regularly review all manual adjustments and restrict the ability to make manual adjustments in the inventory system
        - any outstanding discrepancy is considered unexplained
8. Report any unexplained shortages to the Office of Controlled Substances as a **loss or theft** within 10 days after the day on which they become aware, as required by the CSR.
9. Develop and implement measures to maintain an accurate inventory.

Delivery, sending and transportation

A pharmacist or pharmacy technician can deliver, send or transport a controlled substance and must take all reasonable measures to ensure the security of the substance during this time. Furthermore, a pharmacist or pharmacy technician can hire an individual or a transport company to deliver and transport a prescribed controlled substance to a patient named in a prescription. The pharmacist or pharmacy technician must use a method of delivery that ensures the tracking of the controlled substance until the consignee receives it.

Recommendations for ensuring security in transit:

- choose a transportation company that is able to ensure security in transit

- implement a chain of signatures including the name or employee identifier of everyone handling the controlled substances, including employees of involved transportation companies, up to the final recipient

Furthermore, for controlled substances delivered, sent or transported to a licensed dealer, the pharmacist or pharmacy technician must ensure that the substances are placed in a container that is:

- sealed
- tamper evident – meaning you will know if someone tried to open the container
- marked in a manner sufficient to identify the container (unique identifier)

Important: Controlled substances must be delivered to the patient or to a person designated to accept the delivery on behalf of that individual. Proof of delivery, such as a signature, should be obtained. For example, if the final recipient is not home, controlled substances should not be left in an unsecured location.

Documentation requirements for transportation

A pharmacist or pharmacy technician who delivers, sends or transports a controlled substance must record:

- their name
- the name and municipal address where they practise
- if applicable, the name of the agent or mandatary of the pharmacist who delivered, sent or transported the controlled substance
- the name and title (if applicable) of the person to whom the substance is delivered, sent or transported (and, in the case of an animal, the name of the person responsible for the animal and the name of the animal, if known)
- the municipal address of the place where the controlled substance is delivered, sent or transported
- the date on which the substances were sent to their destination (this is the date on which the substances leave the pharmacy)
- the date on which the substances are received at their destination
- means of transportation (e.g., ground transit)
- for a controlled substance, other than a finished product, the name of the controlled substance, its form and quantity
- for a finished product:
    - name
    - brand name (if applicable)
    - name of the controlled substance it contains
    - form
    - strength
    - number of containers
    - number of units per container (if applicable)
    - Drug Identification Number (if any)

- for a finished product returned by an individual for the purposes of destruction, only the unique identifier marked on each collection container as well as the number of collection containers need to be recorded

Loss or theft reporting

Pharmacists are required to report all losses or thefts of controlled substances, regardless of the amount lost or stolen, to the Office of Controlled Substances within 10 days after the day on which they become aware. For example, even if one pill is lost, it must be reported.

Manual inventory counts that fall short of the active perpetual inventory require investigation and reconciliation. Any identified shortage of inventory that cannot be reconciled or definitively explained must be reported as a loss or theft.

Furthermore, if an agent or mandatary of a pharmacist becomes aware of a loss or theft of a controlled substance, they must notify the pharmacist immediately, and the pharmacist must report the loss or theft to the Office of Controlled Substances.

An agent or mandatary of a pharmacist usually means an employee of the pharmacist, or a contractor. For more information, refer to the Agents and Mandataries section.

The preferred method of reporting losses or thefts is on the Health Canada E-Services Portal (by filling in the information online and submitting it from there). Alternatively, pharmacists can also fill out a loss or theft report form and send it by email to ocs.reporting-rapporter.bsc@hc-sc.gc.ca.

Regardless of how it is submitted, the report should include:

- a description of the loss or theft
- the details and findings of an internal investigation
- any corrective action measures taken to prevent reoccurrence

Do not include patient information in the loss or theft report.

The pharmacist must keep a copy of the loss or theft report on site for 2 years and make it available upon request (such as during a Health Canada inspection).

Types of losses

Inventory may be lost:

- from the pharmacy's active inventory
- from stock awaiting destruction
- from prescriptions awaiting pickup
- during delivery or transport

Indicate the type of loss on the loss or theft report.

Information about reporting losses and thefts has also been published in Health Canada's Guidance on reporting loss or theft of controlled substances and precursors.

Important: If the loss is due to a short-fill or under-fill, it does not need to be reported to Health Canada as a loss or theft. Short-fill or under-fill occurs when a sealed bottle contains less dosage units than indicated on the label. Pharmacists should document this shortage and adjust the inventory accordingly.

Loss or theft in transit

When a loss or theft occurs in transit, en route to a pharmacy, it is the responsibility of the sender (e.g., licensed dealer, other pharmacy) to report and investigate the loss or theft. The sender is ultimately responsible for the security of the substances in transit until they reach their final destination.

When pharmacists or pharmacy technicians receive controlled substances from a licensed dealer, hospital or from another pharmacist, they should:

- Immediately inspect the package for any damage or evidence of tampering.
- Open packages received as soon as possible and verify that all the contents are there.
- If contents are missing, investigate if the loss could have occurred at the pharmacy.
- If the loss did not occur at the pharmacy, contact the sender as soon as possible, who is then responsible for investigating and reporting the loss to Health Canada.
- If applicable, make a record of the discussion with the sender, including details such as the date, the name of the person contacted, and a description of the loss in transit.

Losses or thefts in transit can happen during a delivery from:

- a licensed dealer to a pharmacy
- the pharmacy directly to a patient
- the pharmacy to a licensed dealer specialized in destruction
- the pharmacy to a licensed dealer
- the pharmacy to a practitioner or hospital
- one pharmacy to another pharmacy

Forgeries

Pharmacists must submit a loss or theft report form when a forged prescription is dispensed. Attempted forgeries where no controlled substances were dispensed do not need to be reported to Health Canada, however the provincial or territorial regulatory authority may have their own requirements.

More information can be found in Health Canada's Guidance on reporting loss or theft of controlled substances and precursors.

Destruction

Pharmacists or pharmacy technicians can accept controlled substances from individuals for the purpose of destruction; these substances are also known as post-consumer returns. Pharmacists and pharmacy technicians must place these substances in a collection container located in a secure location. Only individuals who have been authorized by a pharmacist or pharmacy technician, such as pharmacy personnel, can have access to the secure location.

Collection containers must be marked in a manner that is sufficient to identify them, for example by using a numbering system with a unique identifier or a combination of numbers such as an ID number

and a date. It is also recommended that the container is opaque, inconspicuous and tamper evident once sealed.

Important: Pharmacists and pharmacy technicians are authorized to destroy controlled substances locally at their pharmacy, including substances returned by individuals for the purpose of destruction (post-consumer returns), or substances that have expired or have been damaged and cannot be dispensed (unserviceable stock).

Destruction procedures

Local Destruction

Pharmacists and pharmacy technicians can collect substances that need to be destroyed in a collection container and subsequently destroy the substances locally at the pharmacy, periodically, or when the container is full.

The destruction must be witnessed by one of the following:

- another pharmacist, pharmacy technician or intern
- a practitioner
- any other health professional

The destruction must be carried out in accordance with a method that complies with all federal, provincial and municipal environmental protection legislation applicable to the place of destruction.

The pharmacist or pharmacy technician carrying out the destruction and the witness must include the following information on a joint declaration attesting that the controlled substance was destroyed:

- each of their names in printed legible letters
- each of their signatures
- the date of the destruction

A controlled substance is considered destroyed when it is altered or denatured to such an extent that its consumption is rendered impossible or improbable.

Pharmacists and pharmacy technicians may choose to use a container with a built-in denaturing agent. When pharmacists and pharmacy technicians receive substances from an individual for the purpose of destruction, they may place these in the container. No witnessing is required each time a substance is placed in the container. Once the container is full, the pharmacist or pharmacy technician should seal the container in the presence of a witness, and complete the joint declaration as described above.

Pharmacists should be aware that the destruction process may vary from substance to substance depending on the chemical or physical properties of the substance in question, however a change of state is recommended (e.g., from solid to liquid).

The use of chlorine bleach to destroy narcotics, controlled drugs, or targeted substances has been reported to result in exothermic reactions, and should only be used as a method of destruction by licensed dealers who have the appropriate equipment for this procedure.

Pharmacists are encouraged to consult Workplace Hazardous Materials Information System (WHMIS) sheets or their respective provincial or territorial professional regulatory authority for instructions on the appropriate method of destruction for controlled substances.

Once subjected to local destruction, post-consumer returns may be placed in an appropriate container and disposed of in a manner that is safe, environmentally responsible, secure and compliant with legal and professional requirements to protect confidential patient information.

Documentation requirements for local destruction

A pharmacist or pharmacy technician who destroys a controlled substance must record:

- their name
- the name of the witness for the destruction
- signature of the person conducting the destruction
- signature of the witness
- an attestation statement
- the municipal address of the place of destruction
- the date of the destruction
- the method of destruction
- for a controlled substance, other than a finished product, the name of the controlled substance and its quantity
- for a finished product:
    - name
    - brand name (if applicable)
    - name of the controlled substance it contains
    - form
    - strength
    - number of containers (if known)
    - number of units per container (if applicable)
    - drug identification number (if any)
- Note that for a substance returned by an individual for the purpose of destruction, only the unique identifier on the collection container and the number of collection containers need to be recorded

The number of containers and number of units per container may not be applicable or relevant in all cases. In these cases, Health Canada will accept "total quantity" as an alternative. Examples of the total quantity could include the number of tablets, grams of powder, or millilitres of liquid. The units of the total quantity will depend on the dosage form.

Sending controlled substances to a licensed dealer specializing in destruction

Pharmacists also have the option to sell or provide controlled substances, including substances returned by an individual for the purpose of destruction, to a licensed dealer specializing in destruction. Pharmacists should ask the company to whom they intend to send the substances for destruction for proof that they hold a dealer’s licence authorizing them to receive controlled substances for the purpose of destruction.

For substances returned by an individual for the purposes of destruction, pharmacists may also choose a third-party service provider to collect the substances and send them to a licensed dealer specializing in destruction. Pharmacists are still responsible for maintaining records pertaining to the destruction of these substances and should not rely solely on the third-party service provider for maintaining these records.

For more information, see the section on Documentation requirements for substances sold pursuant to an order.

Record-keeping requirements

This section outlines the types of documents that a pharmacist must keep in their possession for a period of at least 2 years (or longer when required by provincial or territorial regulations) in a manner that permits an audit to be made. These documents must be kept at the pharmacy where the information was recorded.

This requirement also applies in instances where a pharmacy closes. In those instances, all records required by the CSR must be kept on behalf of the pharmacy for at least 2 years at a place in Canada. For more information, see the section about Sale or provision when a pharmacy ceases operations.

While both pharmacists and pharmacy technicians are authorized to conduct various activities with controlled substances, it is the pharmacist who is ultimately responsible for ensuring that this requirement is met. Both pharmacists and pharmacy technicians are required to ensure that information is recorded in an auditable manner.

Health Canada recognizes that not all pharmacies have a pharmacist who manages the operations of the pharmacy. The regulatory requirements of the CSR apply to pharmacists and to pharmacy technicians. Regardless of how a pharmacy is managed, all pharmacists and pharmacy technicians working at a pharmacy remain responsible for complying with the record-keeping requirements set out in the CSR.

Important: The word “documents” includes both paper and electronic documents.

The table below outlines the types of records and their corresponding retention time:

Record type	**Retention period**
Documents containing information that must be recorded under the CSR	Two years after the day on which the last record is recorded in the document
Written orders and prescriptions kept in sequence by date and number	Two years after the day on which they are received at the pharmacy
Declarations and reports	Two years after the day on which they are provided or received

Important: The regulations require that all documents regarding the sale or provision of a controlled substance be kept separately, in sequence as to date and number. Health Canada recognizes that there are multiple ways to comply with this requirement. For example, these documents may not necessarily be kept physically separate from all other documents, but rather they may be part of the overall electronic record-keeping system of the pharmacy. This is permitted as long as the system allows for

quick and easy retrieval of all documents in an auditable format without having to access individual patient files.

More pharmacies are moving to a paperless environment and filing records electronically. Health Canada has no objection to this, provided:

- the electronic files are saved in a secure and legible format
- the electronic system meets the requirements of the CSR
- pharmacists 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 to permit an efficient audit.

Important: Pharmacists must provide any record they are required to keep under the CSR to Health Canada upon request in a timely manner.

Agents and mandataries

A person may act as an agent or mandatary for a pharmacist and may be able to conduct certain activities with controlled substances for the pharmacist if certain conditions are met. An agent/mandatary can include an employee of the pharmacist, or a person acting under a contract with the pharmacist.

It is recommended that you document who is conducting activities as your agent or mandatary and what activities you are delegating to them.

Important: As the pharmacist, you have overall responsibility for the management and supervision of all activities involving controlled substances and for ensuring that those activities comply with the Act and its regulations.

Under the CSR, in order for an agent/mandatary to act on behalf of a pharmacist:

- the pharmacist must be authorized to perform the activity themselves under the CSR; and
- the provincial or territorial professional regulatory authority of the province or territory where the pharmacist practices must not prohibit the delegation of the activity to the agent/mandatary, as applicable

In addition, the agent/mandatary must:

- be authorized by the provincial or territorial professional regulatory authority where they are practising to conduct the activity, if applicable
- conduct the activity either as part of their role as agent/mandatary, as part of their employment duties and functions, or in performance of their contract; and
- comply with the requirements that apply to the pharmacist on whose behalf they are conducting the activity

Important: A pharmacist cannot delegate the activity of ordering controlled substances to a pharmacy technician or to an agent/mandatary. While pharmacy technicians play a key role in inventory

management within pharmacies, orders for controlled substances must be placed by the pharmacist. A pharmacy technician, or a pharmacy assistant in the capacity of an agent/mandatary, can assist a pharmacist with the preparation of an order for controlled substances, but the regulations only authorize a pharmacist to place the order.

Important: A practitioner cannot delegate their prescribing authority to a pharmacist.

Loss or theft

If an agent/mandatary of a pharmacist becomes aware of a loss or theft of a controlled substance, they must notify the pharmacist right away and the pharmacist must then report the loss or theft to Health Canada.

Appendix A: Summary of authorized activities and requirements for pharmacists and pharmacy technicians

Activity	Authorized person
Sell/provide	Pharmacist
Sell/provide low-dose codeine products	Pharmacist
Substitute a controlled substance	Pharmacist
Refill or extend a prescription	Pharmacist
Store controlled substances in a secure location	Pharmacist
Restrict access to controlled substances	Pharmacist
Supervise activities with controlled substances in the pharmacy	Pharmacist
Report a loss or theft to Health Canada	Pharmacist
Ensure records are retained	Pharmacist responsible for the operations of a pharmacy (or, if a pharmacy ceases its operations, the person who was responsible for those operations on the date those operations ceased)
Order controlled substances	Pharmacist
Verify identity	Pharmacist Pharmacy technician
Compound finished products containing controlled substances	Pharmacist Pharmacy technician
Transfer a prescription	Pharmacist Pharmacy technician
Accept and destroy substances returned by an individual for the purpose of destruction	Pharmacist Pharmacy technician
Take protective measures to ensure security of the controlled substances in their possession	Pharmacist Pharmacy technician
Possess controlled substances for the purposes of their work, including restricted drugs	Pharmacist Pharmacy technician
Send, Deliver, Transport	Pharmacist Pharmacy technician
Destroy controlled substances locally	Pharmacist Pharmacy technician
Witness destruction	Pharmacist Pharmacy technician intern, practitioner, or other health professional
Receive controlled substances	Pharmacist Pharmacy technician

Activity	Authorized person
Receive and record verbal orders and prescriptions	Pharmacist Pharmacy technician
Receive written orders and prescriptions	Pharmacist Pharmacy technician
Ensure information is recorded using a method that permits an audit to be made	Pharmacist Pharmacy technician

Appendix B: Glossary

Acronyms

CDSA	Controlled Drugs and Substances Act
CSR	Controlled Substances Regulations
DIN	Drug identification number

Terms

Important: If there is any conflict in this document with a definition in the Controlled Drugs and Substances Act or the Controlled Substances Regulations, the definition in the act/regulation prevails.

Controlled drug	A substance included in Schedule 2 of the Controlled Substances Regulations
Controlled substance (for the purposes of this document only)	A substance included in Schedules 1, 2, or 3 of the Controlled Substances Regulations
Destroy	To alter or denature a controlled substance to such an extent that its consumption is rendered impossible or improbable
Drug identification number	The identification number assigned to a drug under paragraph C.01.014.2(1)(a) of the Food and Drug Regulations
Finished product	A finished product that contains a controlled substance set out in Schedules 1 to 4 of the Controlled Substances Regulations, that is in a form that is intended to be administered to an individual or animal and, in the case of a finished product that does not contain a restricted drug, that has a drug identification number; or is compounded by a pharmacist or pharmacy technician in accordance with the Controlled Substances Regulations
Health professional	Also known as regulated health professional, an individual who is entitled under the laws of a province to practise a profession in a health care field and who is practising in that province.
Intern	An individual who is entitled under the laws of a province to work as an intern in a health care field, or to work under a designation that the Minister considers equivalent, and who is working as such in that province

Licensed dealer	The holder of a licence issued under subsection 12(1) of the Controlled Substances Regulations.
Narcotic	A substance set out in Schedule 1 of the Controlled Substances Regulations.
Non-combination product containing ephedrine or pseudoephedrine	A natural health product that contains — as its only medicinal ingredients — ephedrine or any of its salts or pseudoephedrine or any of its salts, or any combination of those ingredients.
Order	Any requisition for a controlled substance is considered an order. An order does not include a prescription, which is always patient-specific.
Pharmacist	An individual who is entitled under the laws of a province to practise pharmacy and who is practising pharmacy in that province
Pharmacy technician	An individual who is entitled under the laws of a province to practise as a pharmacy technician or to practise under a designation that the Minister considers equivalent and who is practising as such in that province
Practitioner	A person who is registered and entitled under the laws of a province to practise in that province the profession of medicine, dentistry or veterinary medicine, and includes any other person or class of persons prescribed as a practitioner (midwife, nurse practitioner, podiatrist)
Prescription	An authorization given by a practitioner that a stated amount of a controlled substance, other than a restricted drug, be sold or provided for the individual named or the animal identified in it
Restricted drug	A substance set out in Schedule 4 of the Controlled Substances Regulations
Send	Does not include sending by mail
Specialized in destruction	A licensed dealer whose licence specifies that it only deals in the destruction of controlled substances
Targeted substance	A substance set out in Schedule 3 of the Controlled Substances Regulations

Appendix C: References

Laws and regulations

- Controlled Drugs and Substances Act
- Controlled Substances Regulations
- Precursor Control Regulations
- Food and Drug Regulations

Related documents

- Guidance on reporting loss or theft of controlled substances and precursors (CS-GD-005)
- Policy on Manufacturing and Compounding Drug Products in Canada (POL-0051)

Web pages

- Controlled substances
- Access to Information and Privacy
- Compliance and enforcement policy framework
- Regulating Controlled Substances and Precursors
- List of class exemptions and related guidance