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Pharmacy Compliance Promotion Series: Controlled Substances – Inventory Control and Loss or Theft Reporting

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Controlled Substances Program

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Disclaimer

This presentation does not constitute part of the Controlled Drugs and Substances Act (CDSA) or its regulations and in the event of any inconsistency or conflict between the CDSA or regulations and this module, the CDSA or the regulations take precedence.

Information contained in this document is accurate as of the date of the presentation (on the title slide) and is subject to change without notice in the future.



Outline

Associated Regulations and Obligations

Inventory Control

(Physical counts, accountability, reconciliation, discrepancy explanations)

Loss or Theft Reporting

(e-portal, types of losses)

Security

Record Keeping

Additional Resources



Federal Regulations of Controlled Substances

Health Canada authorizes and oversees the legitimate use of controlled substances and precursor chemicals

- Risk-based approach
- Compliance and monitoring activities
- Minimize risk of diversion



Legislative Framework



Pharmacist Obligations NCR 41; FDR G.03.011

A Pharmacist shall:

- Furnish such information respecting the dealings of the pharmacist in any controlled substance in such form and at such times as the Minister may require
 - E.g. sales reports, loss or theft reports, dispensing records, etc.
- Make available and produce to an inspector upon request his special narcotic prescription file together with any books, records or documents which he is required to keep
- Permit an inspector to make copies of or to take extracts from such files, books, records or documents
- Permit an inspector to check all stocks of controlled substances on his premises



Perpetual Inventory

- Captures all controlled substances
 - Viable inventory
 - Unserviceable stock
 - Active Pharmaceutical Ingredients (API) used in compounding
 - » E.g. ketamine, DHEA, testosterone, methadone powder
- Tracked manually (i.e. paper log) or using pharmacy software
 - Neither are fool-proof; both can be manipulated
 - » Set user restrictions as to who can make manual adjustments, and add prompts to require an explanation for each adjustment
- Regular inventory counts help detect and prevent diversion
- Reconciliation validates your perpetual (theoretical) inventory record, and assesses overall inventory control

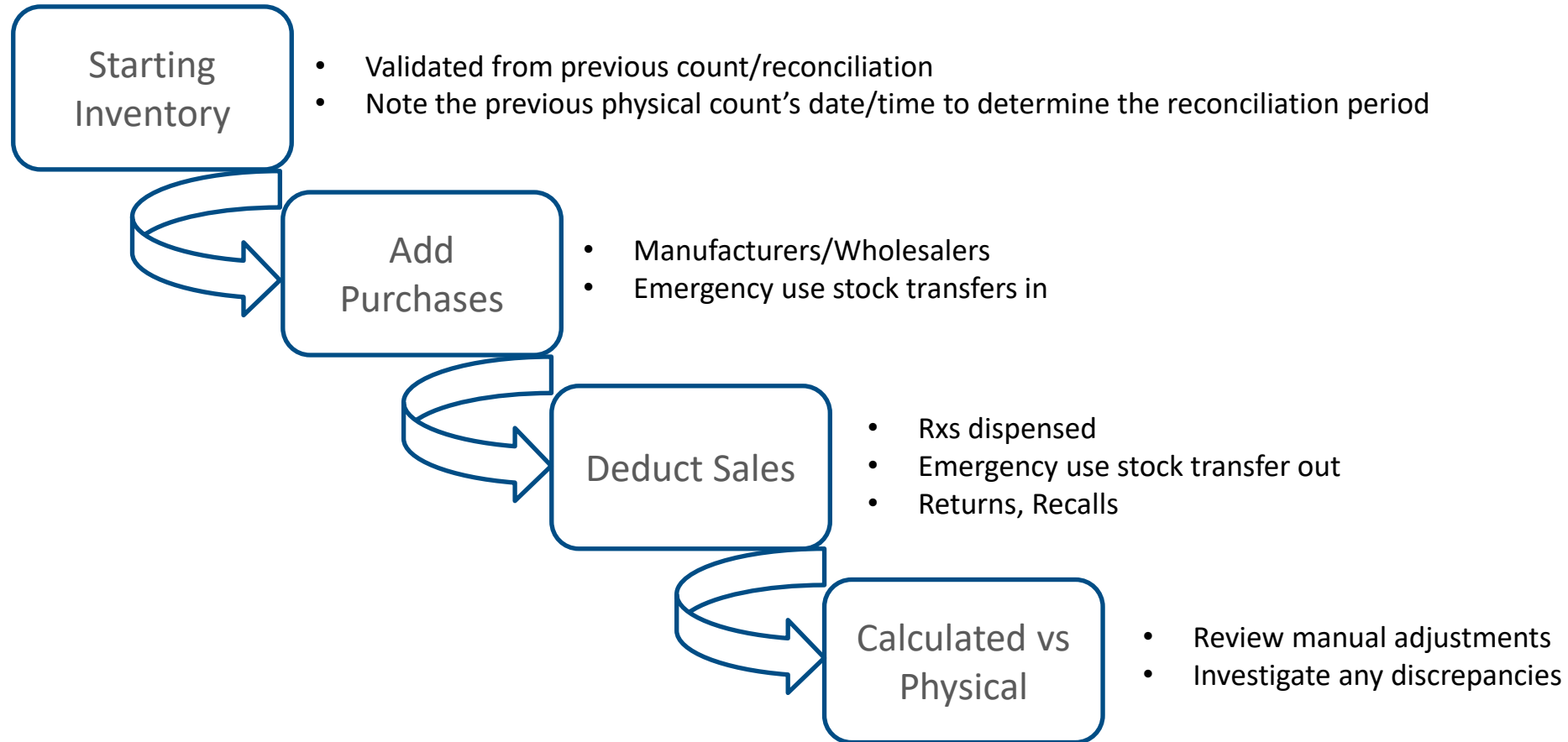


Physical Inventory Counts

- Complete inventory counts and reconciliations for controlled substances (i.e. narcotics, controlled drugs, benzodiazepines and targeted substances) should be conducted (at minimum):
 - every six months (provincial regulations may dictate stricter requirements)
 - after an event where controlled substances security was compromised
 - after a pharmacy move
 - after a change in the pharmacy manager or owner or any unexpected staffing changes
 - after the pharmacy receives a non-compliant inspection rating from Health Canada
- **DO NOT** rely solely on the inventory systems expected on-hand inventory or automated machine/robot counts
 - Periodic manual counts must be done to verify physical quantities
 - Manual counts ≠ reconciliation



Reconciliation



Reconciliation calculation

Part 1:

1. **Starting Inventory** = count done October 3rd, 2023

250

+

2. **Purchases** = number purchased

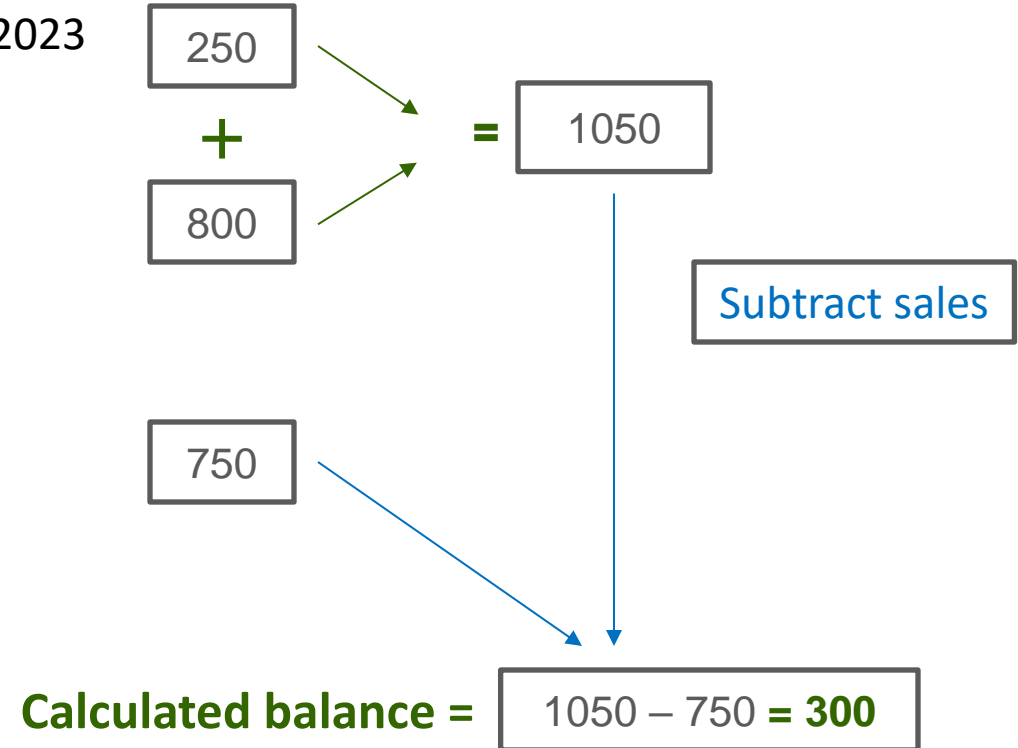
800

Oct 3 – present date

3. **Total sales** = number dispensed

750


Oct 3 – present date



Reconciliation calculation... cont'd

Part 2:

4.	Today's inventory = count done present day		200
		-	
5.	Calculated balance from above		300
6.	Difference = present day count – calculated balance	=	-100



Investigate the difference – do you have records to account for this?



Internal Investigation

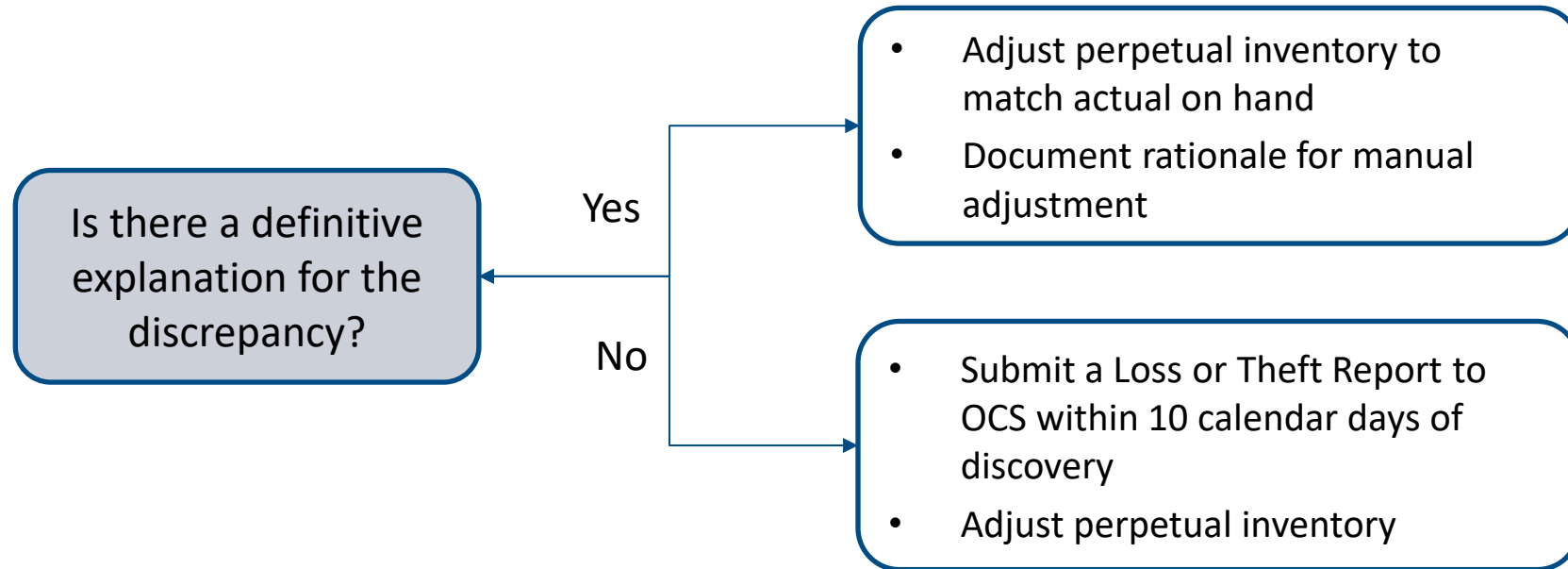


Note: retain documentation of completed investigation

- ⇒ Double check reconciliation numbers
i.e. wholesaler's sales report vs pharmacy software's receiving/purchasing report
- ⇒ Balance Owing
- ⇒ Pre-packed blisters
- ⇒ Brand-generic / pack size substitutions
- ⇒ Cancelled prescriptions not returned to stock
 - Conversely, returning to stock prescriptions not picked up without cancelling in the computer system
- ⇒ Unserviceable stock
 - Local destruction log: credit notes/authorizations for returns to wholesaler
- ⇒ Borrowing/lending of controlled substances between pharmacies (the regulations do not permit these practices)



Result of discrepancy investigation



Note: When overages in the inventory are identified, do investigate and document your findings in your record keeping. **You do not have to report overages to HC.**



When to report a Loss of Theft

Appendix A: Types of incidents (Guide CS-GD-005)

Incident type	Incident sub-type	Definition	Report?
Loss	Loss unexplained	A loss that cannot be attributed to any particular cause or action on the basis of normally accepted business activities	Yes
	Manufacturer's shortage	The content of a sealed bottle is less than expected after counting	No, if the quantity is smaller than or equal to permitted value listed in FDR C.01.061 . Yes, if it is greater than permitted value.
	Wrong dispensing	Documented dispensing the wrong quantity or to the wrong patient	No, if the substance is returned by patient. Yes, if it is not returned by patient
	Breakage and liquid spillage	Change in the dosage form, or other known incident preventing dispensing (for example crushed tablet)	No, if the substance is retrieved or destroyed on clean up. Yes, if it is not fully or partially retrieved and not destroyed.

[Guidance on reporting loss or theft of controlled substances and precursors \(CS-GD-005\): Overview - Canada.ca](#)



When to report a Loss of Theft

Appendix A: Types of incidents (Guide CS-GD-005) Continued...

Solid spillage	Incidents preventing dispensing such as dropped tablets	No, if the substance is retrieved or destroyed during spillage. Yes, if it is not retrieved or destroyed during spillage.
Unusual waste	Waste or destruction of inventory beyond what is expected on the basis of normally accepted business practices. This could arise from unusual yield loss due to problems in the manufacturing process or broken equipment.	Yes
Miscounts	Error made in counting during inventory reconciliation or during dispensing	No, if it is documented and part of normal business practices. Yes, if the error is only assumed, then it is reportable as Loss Unexplained.
Overages	Quantity found to be in excess of inventory	No
Destruction	Denaturation of a controlled substance to an extent that its consumption is rendered impossible or improbable	No
Other	Any other type of loss not described above	Yes

[Guidance on reporting loss or theft of controlled substances and precursors \(CS-GD-005\): Overview - Canada.ca](#)



When to report a Loss of Theft

Appendix A: Types of incidents (Guide CS-GD-005) Continued...

Theft	Filled forged prescription	Dispensing of a prescription that was found to be fraudulent	Yes
	Unfilled forged prescription	Forged prescription that was not dispensed	No
	Armed robbery	Theft accomplished through threats of violence toward personnel at a site	Yes
	Pilferage (internal theft)	Theft from a site by authorized personnel	Yes
	Grab theft	Theft from a site during working hours without warning. The person conducting the theft 'grabs' the product and escapes.	Yes
	Break and entry	Theft from a site by forced entry	Yes
	Impersonation	An individual impersonating the individual for which the prescription has been dispensed	Yes
	Other	Any other type of theft not described above	Yes

[Guidance on reporting loss or theft of controlled substances and precursors \(CS-GD-005\): Overview - Canada.ca](#)



Health Canada E-Services Portal

- Submit, access and view your loss or theft reports online anytime
- Access searchable controlled substance and precursor chemicals and drug product databases
- Notifications when your report has been received
- Receive secure messages from Health Canada
- **Amend, download and save reports as PDFs / print copies for pharmacy records**

Submitted Reports			
Filter Items	<input type="text"/>	Showing 1 to 10 of 25 entries Show <input type="text" value="10"/> entries	
Report ID	Site Information	Date Submitted	Status
SUB-2021-2725	place 745-1470 Rue Peel MONTRÉAL Quebec H3A 1T1	2021-10-13	Accepted
SUB-2021-2726	la place 190 Simcoe Ave KESWICK Ontario L4P 2H7	2021-10-13	Accepted




Loss or Theft Report Form

For Controlled Substances and Precursors



Keep a copy for **2 years** and make it available for inspection



Office of Controlled Substances
Controlled Substances and Cannabis Branch
Protected A When completed
August 2022

2 | Loss or Theft Report Form for Controlled Substances and Precursors (CS-FRM-011) **Protected A** When completed

Loss or Theft Report Form for Controlled Substances and Precursors
Instead of this form, try using the [Health Canada E-Services Portal](#) to easily and conveniently complete a report
Consult the [Guidance Document \(CS-GD-005\)](#) for more information on reporting loss or theft

All required fields are marked with an asterisk *

Report Summary			
Date of Submission of This Report yyyy/mm/dd	Type of Report * Click to see options	Date of Submission of Initial Report (if amendment) yyyy/mm/dd	
1. Submitter Information			
First Name *	Last Name *	Email Address *	Telephone Number
Professional Title * Click to see option	If Other, please specify:		Licence / Registration Number
2. Site Information			
Legal Entity Name *		Site Name	
Type of location * Click to see options	If Other, please specify:		
Canada Revenue Agency Business Number	Site Licence Number	Telephone Number *	Extension
Municipal Address *			
City *	Province/Territory * Click to see option	Postal Code *	Email Address
3. Incident Details			
Date of Discovery * yyyy/mm/dd	Incident Sub-Type * Click to see options	If Other, please specify:	
Has this incident been reported to police? * <input type="radio"/> Yes <input type="radio"/> No (If Yes, please complete row A below)	Did the incident occur in transit? * <input type="radio"/> Yes <input type="radio"/> No (If Yes, please complete row B below)	Are you reporting this incident as a result of a Health Canada inspection? * <input type="radio"/> Yes <input type="radio"/> No	
A. Date reported to Police yyyy/mm/dd	Name of Police Service	Incident Number	
B. For in transit incidents, you were Click to see option	Name of the Transit Company and/or other party	Shipping or Tracking Number	

Details of Discovery
Please provide details of how the loss or theft occurred and/or was discovered, as available. It is preferred that the explanation be as detailed and accurate as possible.

4. List of Controlled Substances and/or Precursors Lost or Stolen

DIN/NPN	Name of Raw Material or Product (Brand or Generic) and Strength*	Quantity *	Dosage Form *
			Click to see options
			Click to see options
			Click to see options
			Click to see options
			Click to see options
			Click to see options
			Click to see options
			Click to see options
			Click to see options
			Click to see options

5. Preventative Measure
Please provide a description of any security measures you will be putting in place to prevent future loss or theft incidents at your site.



6. Review
By submitting a report, you agree to the following declarations: I hereby declare that I am familiar with the provisions of the [Controlled Drugs and Substances Act \(CDSA\)](#) and its regulations that apply to my report; I hereby declare that all the information I am submitting is, to the best of my knowledge, true, accurate, current, and complete; I understand that it is considered fraud to knowingly submit false or misleading information.

Save and attach this report in an email to ocs.reporting-rapporteur.bsc@hc-sc.gc.ca.

Privacy Notice
The collection of your personal information is authorized under the [Controlled Drugs and Substances Act \(CDSA\)](#). The information you provide to Health Canada is governed in accordance with the [Privacy Act](#). This information will be used to process your report under the CDSA and its regulations and may be used for research, planning, reporting, audit or evaluation purposes. In limited and specific situations, your personal information may be disclosed without your consent to law enforcement or in accordance with subsection 8(2) of the [Privacy Act](#).

This personal information collection is described in Info Source, available online at www.cic-ci.gc.ca/en/info-source. In addition to protecting your personal information, the [Privacy Act](#) gives you the right to request access to and correction of your personal information. For more information about these rights, or about our privacy practices, please contact Health Canada's Access to Information and Privacy Coordinator at atip-aiprp@hc-sc.gc.ca. You also have the right to file a complaint with the Office of the Privacy Commissioner of Canada if you think your personal information has been handled improperly.

CS-FRM-011



Security

Regulations: NCR 43; FDR G.03.012; BOTSR 72(1)

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.



Security

Measures that ensure a high level of security

- Physical security recommendations
 - Alarm and surveillance system
 - Physical barriers and deterrents
 - Restricted access to dispensary
 - No sharing of narcotic ordering codes, PINS and/or keys



Security

- Time-delay safes (*may depend on province)
- Reasonable inventory levels
 - Excessive loss and storage considerations
 - Ability to count regularly and accurately



Records

Retention requirements:

- 2 years (or longer per provincial regulations)
- Auditable manner (i.e. records onsite or promptly retrievable)

Requirements for paperless/electronic records:

- System meets requirements of the relevant regulations
- Files saved in secure, high-resolution format
- Backup system in place



Note: Do not rely solely on electronic storage at a 3rd party platform



Types of Records

Type	Content	Notes
Purchase/ receiving	<ul style="list-style-type: none"> - Name, quantity of substance - Date received - Name, address or source 	<ul style="list-style-type: none"> - Emergency use stock transfers inbound
Dispensing	<ul style="list-style-type: none"> - Patient's name, address - Name, quantity, form - Prescriber's name, address - Pharmacist's name/initials - Dispense date - Prescription/transaction # 	<ul style="list-style-type: none"> - Filed in order by date and number sequence - Including sales reports for exempted codeine products
Loss/theft	<ul style="list-style-type: none"> - Incident details + clarifying info (internal investigation, findings, corrective action) 	<ul style="list-style-type: none"> - Submit within 10 days of discovery - Can amend thereafter as needed
Return authorizations	<ul style="list-style-type: none"> - Order from LD signed & dated - Transaction details in pharmacy's record 	<ul style="list-style-type: none"> - 2-year retention



[Health Canada Pharmacy Splash Page](#)



Scan to access

Includes links to:

- Federal regulatory record keeping requirements
- Guidance Documents for pharmacists
- Reporting Loss or Theft of Controlled Substances and Precursors
- Community Pharmacy Inspection Program Annual Report
- Section 56 exemption
- Q&A for opioid sticker and handout



Resources (continued)

Other useful links:

- [Policy documents/CDSA section 56 exemptions](#)
- [Drug Product Database](#) (DIN products)
- [Stakeholder Registry](#) (Consultations)
- [Adverse reaction reporting](#)
- [Adverse reaction database](#)
- [Recalls and safety alerts](#)
- [Health Product InfoWatch publications](#)
- [Natural Health Product Database](#) (NPN, DIN-HM)
- [Policy on Manufacturing and Compounding Drug Products in Canada \(POL-0051\)](#)



Contact Information

Region	Contact info
Central (ON, NU)	Controlled Substances Program, Central Region Regulatory Operations and Enforcement Branch, Health Canada 200 Town Centre Court, 3 rd floor Scarborough, Ontario M1P 4X8 Email: ontario.pharmacy.inspections-de.pharmacie@hc-sc.gc.ca
Eastern (QC, NL, NB, NS, PEI)	Controlled Substances Program, Eastern Region Regulatory Operations and Enforcement Branch, Health Canada Complexe Guy-Favreau 602 - 200 René-Lévesque Blvd Ouest Montréal, Quebec H2Z 1X4 Email: csp.east-psc.est@hc-sc.gc.ca
Western (BC, AB, SK, MB, YT, NWT)	Controlled Substances Program, Western Region Regulatory Operations and Enforcement Branch, Health Canada 400 – 4595 Canada Way Burnaby, British Columbia V5G 1J9 Email: cspwestern@hc-sc.gc.ca



Questions



Compliance Promotion Survey



https://healthcanada.qualtrics.com/jfe/form/SV_25ku4X7U15h7LNA?Q_Language=EN

