

TO PROTECT THE HEALTH AND WELL-BEING OF THE PUBLIC.

From Policy to Practice: A Joint Webinar on Narcotic Accountability

With the College of Pharmacists of Manitoba and Health Canada



**COLLEGE OF
PHARMACISTS
OF MANITOBA**



**Santé
Canada**

**Health
Canada**



YOUR HEALTH AND SAFETY... OUR PRIORITY.

Conflict of Interest / Disclosure

- Presenter: Angela Lina
- I have no conflicts of interest to disclose
- This program has received no financial or in-kind support from any commercial or other organization



Conflict of Interest / Disclosure

- Presenter: Kevin Chaboyer
- I have no conflicts of interest to disclose
- This program has received no financial or in-kind support from any commercial or other organization



Disclaimer

This presentation does not constitute part of the Controlled Drugs and Substances Act (CDSA), the Manitoba Pharmaceutical Act (MPA), their regulations or any CPhM Practice Directions and in the event of any inconsistency or conflict between either Act, regulations, or practice directions and this module, the CDSA, MPA, the regulations, or CPhM practice directions take precedence.

Information contained in this document is accurate as of the date of the presentation June 8, 2023 and is subject to change without notice in the future.



Learning Objectives

- You will gain an understanding of Health Canada and the legislative framework that applies to pharmacists
- You will gain an understanding of Health Canada's Pharmacy Inspection Program and the powers of the inspector
- You will learn ways to comply with the federal laws and regulations
- You will gain an understanding of how the provincial policies align with the federal requirements



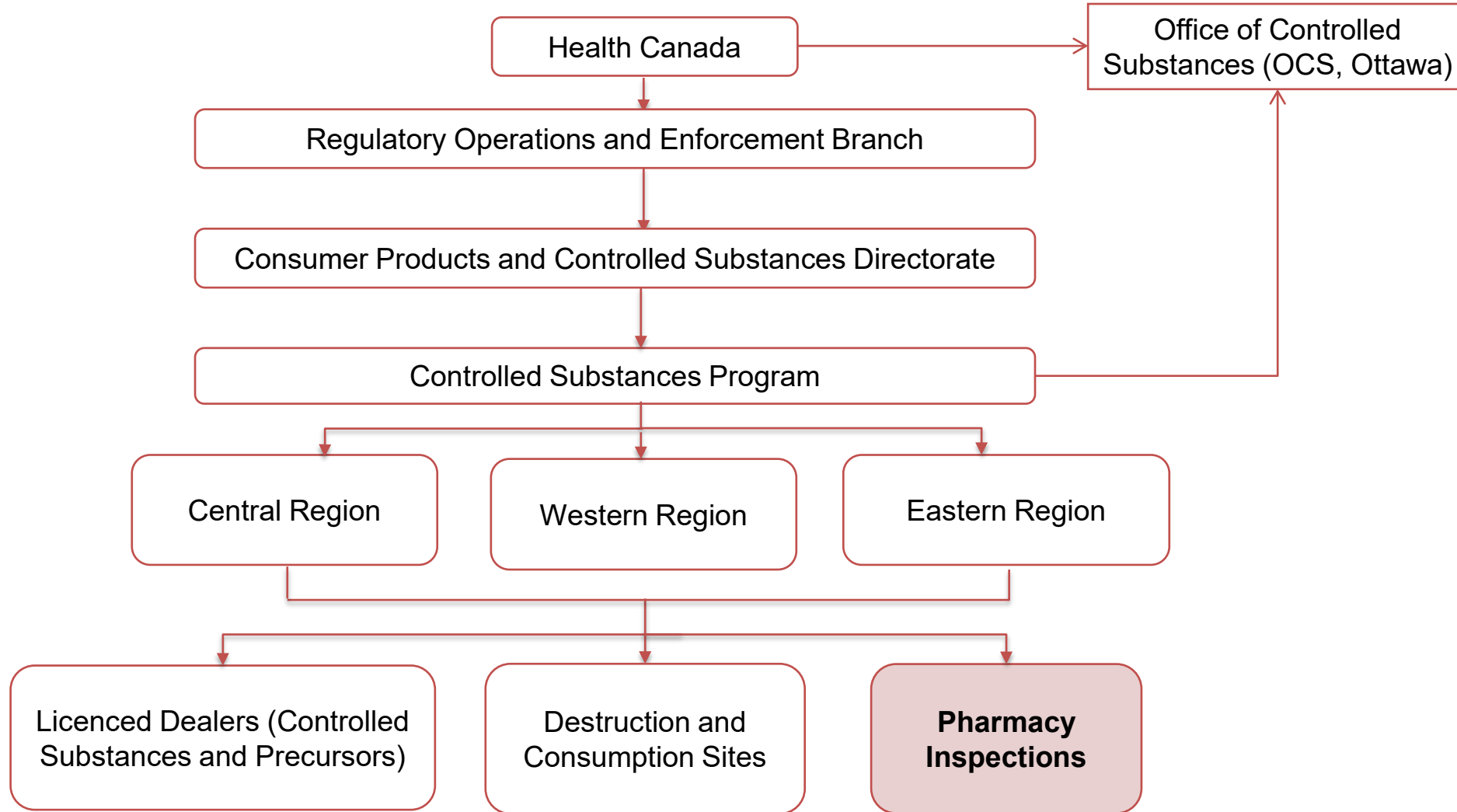
Federal Regulation of Controlled Substances

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

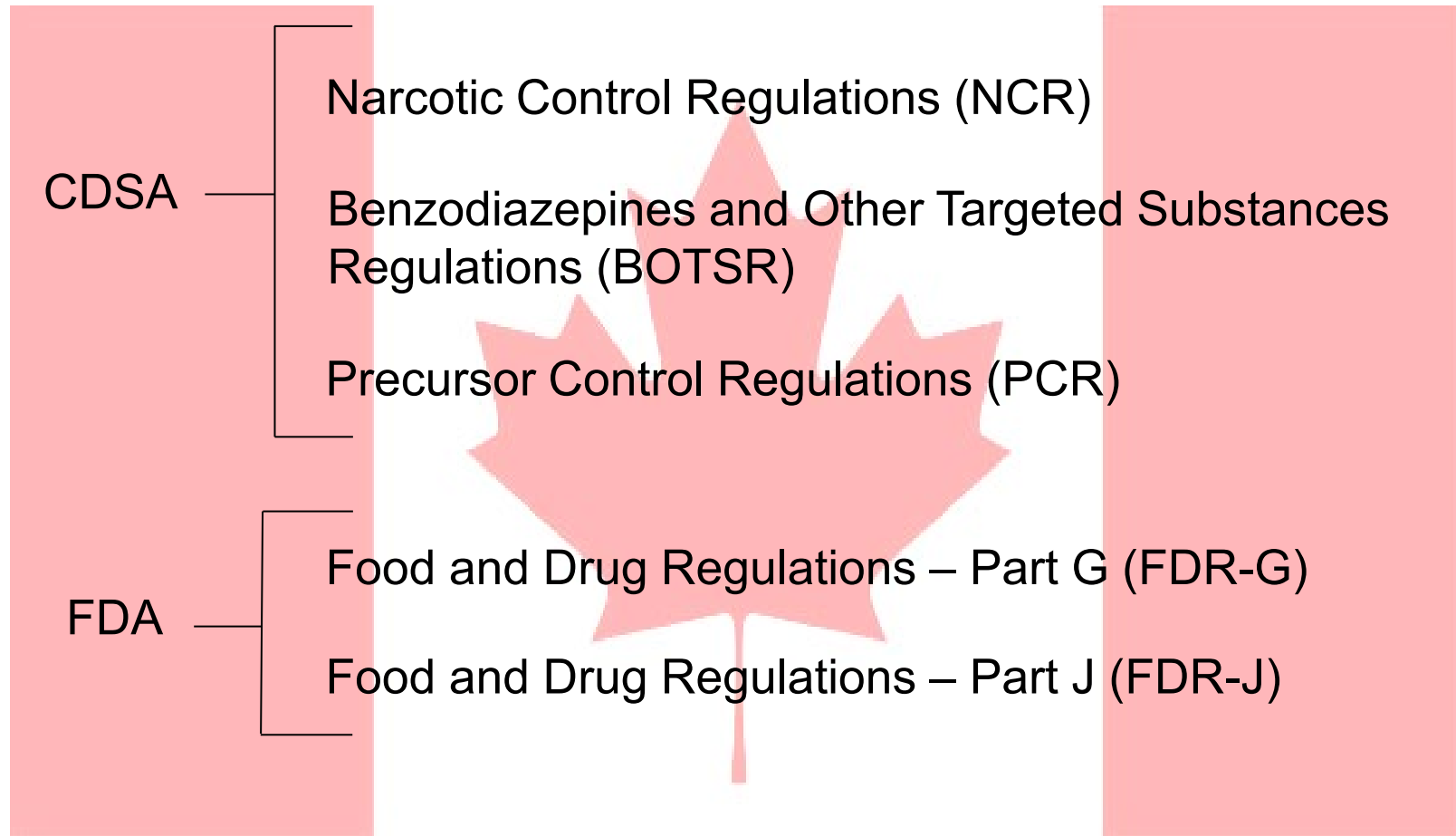
- Risk-based approach
- Compliance and monitoring activities
- Minimize risk of diversion



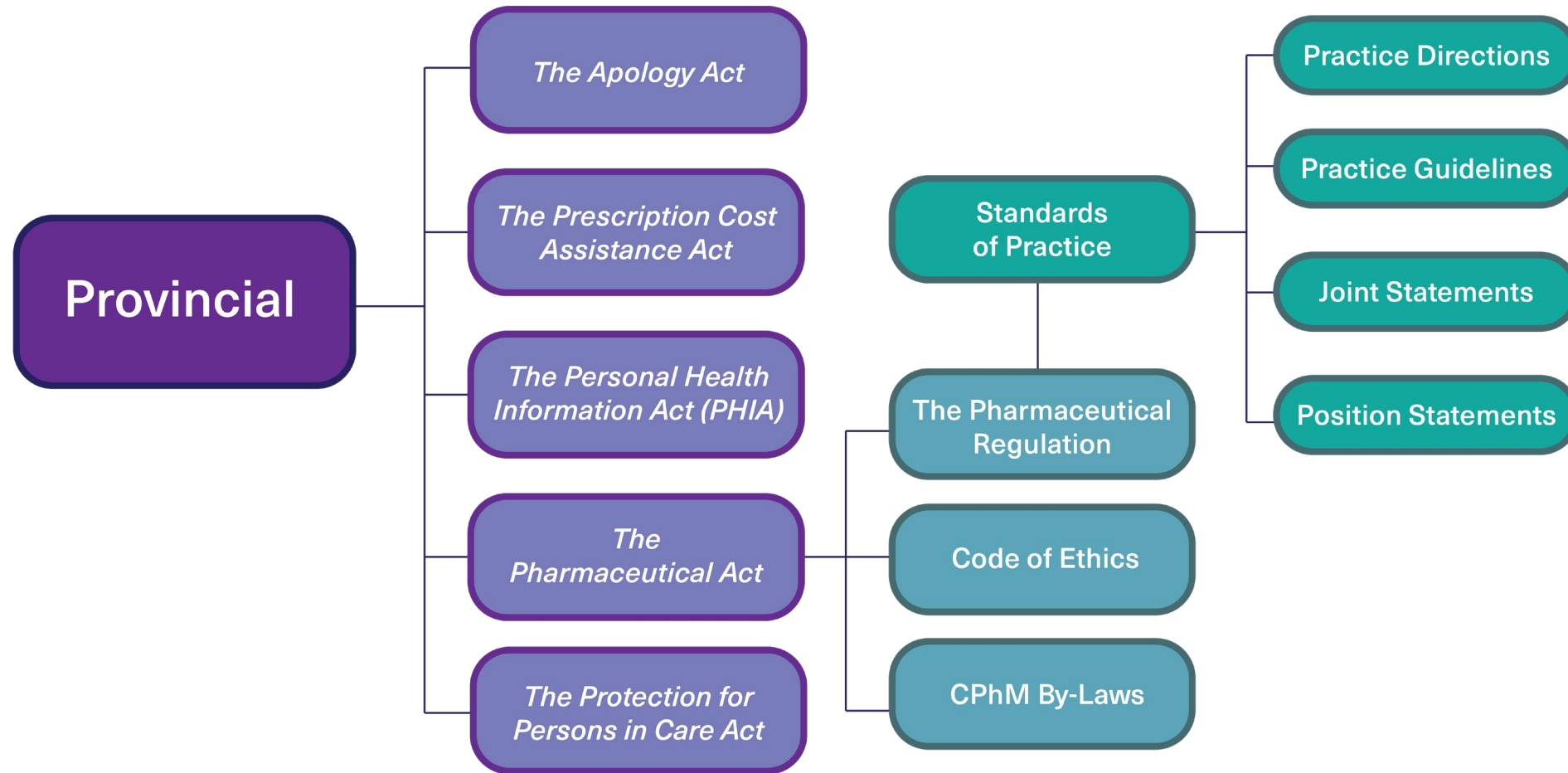
Organizational Structure



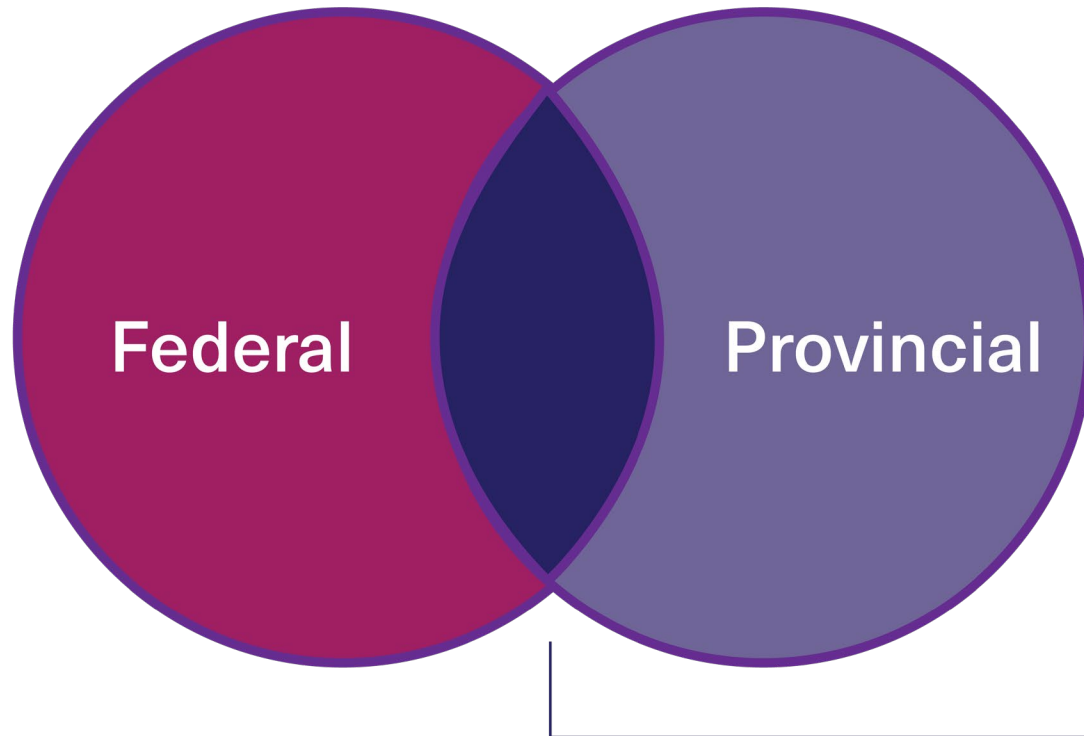
Legislative Framework



Provincial Legislative Framework



Federal and Provincial Legislative Overlap



Provincial legislation may strengthen the requirements of federal legislation.



Regulated Activities – Pharmacist

Provide, Sale, Return

Records

Security

General Obligations

Advertising



Exemptions CDSA s.56(1)

The Minister may, on any terms and conditions that the Minister considers necessary, exempt from the application of all or any of the provisions of this Act or the regulations any person or class of persons or any controlled substance or precursor or any class of either of them if, in the opinion of the Minister, the exemption is necessary for a medical or scientific purpose or is otherwise in the public interest.

For example:

- Class Exemption for Pharmacists, Practitioners, Persons in Charge of a Hospital and Licensed Dealers for the Provision and Destruction of Unserviceable Stock and Post-consumer Returns
- Class Exemption for the Person in Charge of a Hospital and/or a Pharmacist who Supplies Controlled Substances to a Community Health Facility
- Subsection 56(1) class exemption for patients, practitioners and pharmacists prescribing and providing controlled substances in Canada



Exemptions CDSA s.56(1) in Manitoba

- The Federal Subsection 56(1) class exemption of the Controlled Drugs and Substances Act (CDSA) for patients, practitioners and pharmacists prescribing and providing controlled substances in Canada during the coronavirus pandemic is NOT in effect in Manitoba.
- Currently in Manitoba
 - narcotic and controlled drug prescriptions cannot be transferred between pharmacies
 - Pharmacies cannot receive verbal orders for narcotic and controlled drugs with the exception of
 - Narcotic and controlled drugs for residents of a personal care home
 - Verbal prescription narcotics not covered under the M3P program
- CPhM is working on implementation, more news to come.

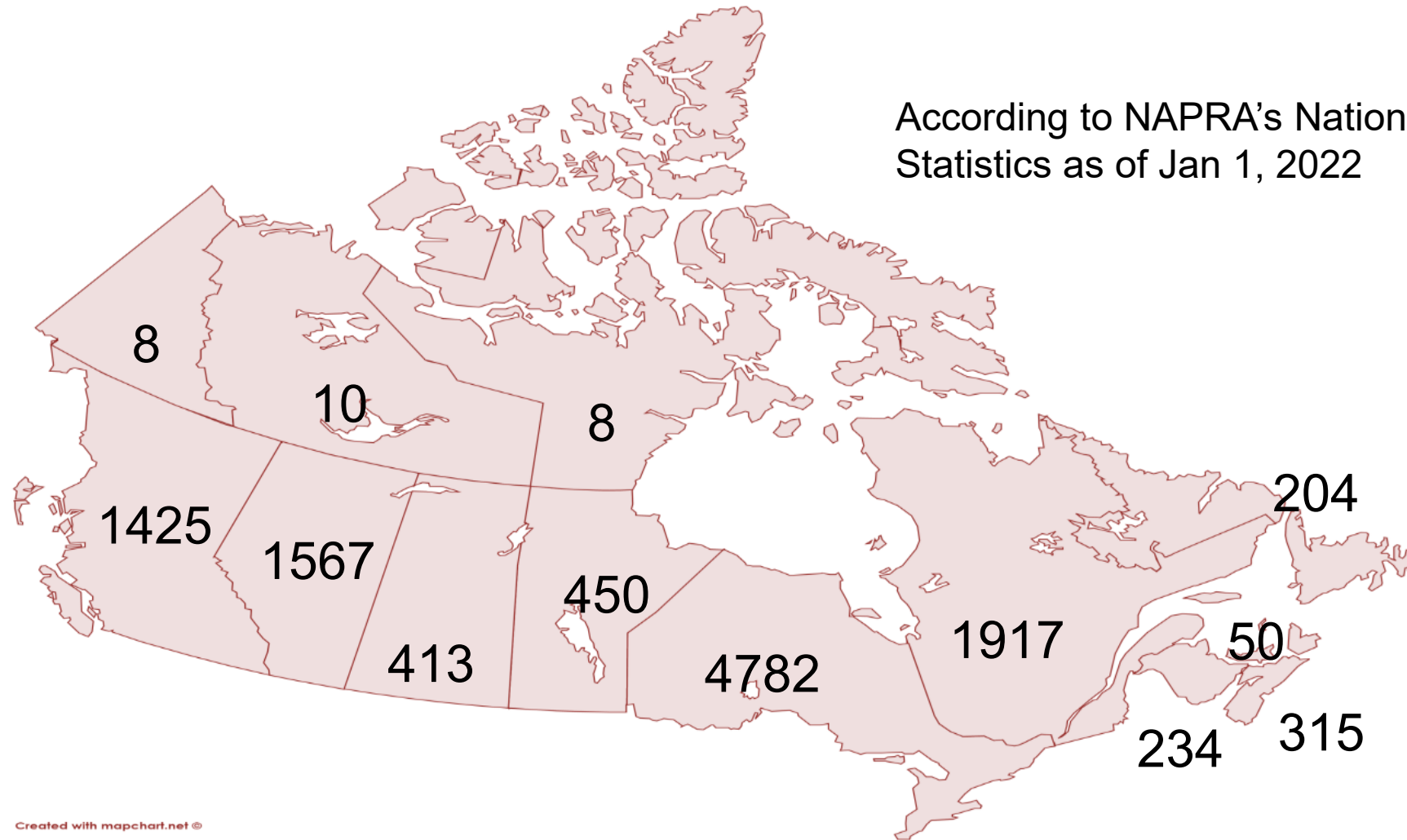
Problematic Prescription Drug Use

Diverting to the illicit market



Community Pharmacies in Canada (Total 11,356)

According to NAPRA's National Statistics as of Jan 1, 2022



Created with mapchart.net ©



Pharmacy Inspection Program

Objectives:

- Compliance among pharmacists
- Cooperation and communication between regulatory authorities, regulated parties and other stakeholders
- Address problematic prescription drug use by preventing opportunities for diversion



Powers of Inspector CDSA 31(1)

At any place the inspector believes on reasonable grounds is used for conducting the business or professional practice of any person authorized under the regulations:

- open and examine any receptacle or package
- examine anything found on site
- examine any labels or advertising material or records, books, electronic data
- use or cause to be used any computer system
- reproduce any document from any electronic data
- take labels or advertising material or records, books or other documents
- use or cause to be used any copying equipment
- take photographs and make recordings/sketches
- examine substances and for purposes of analysis obtain samples
- seize & detain any controlled substance, precursor, conveyance or device
- order any person on site to establish their identity
- order any person on site to refrain from, or engage in, a CDSA regulated activity



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



Compliance and Enforcement Tools

- Inspection Reports and Monitoring Letters
- Risk-based Inspections
- Inspection Blitzes based on signals of risk
- Import Alerts
- Seizures, Retention, Voluntary Forfeiture
- Warning Letters / Prosecution
- Referral (i.e. Law Enforcement, Provincial Regulatory Authority, other Federal Regulatory Body)
- Licence Suspension (Licensed Dealers)
- Notice of Restriction

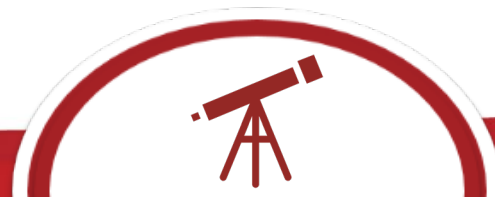


Inspection Scope

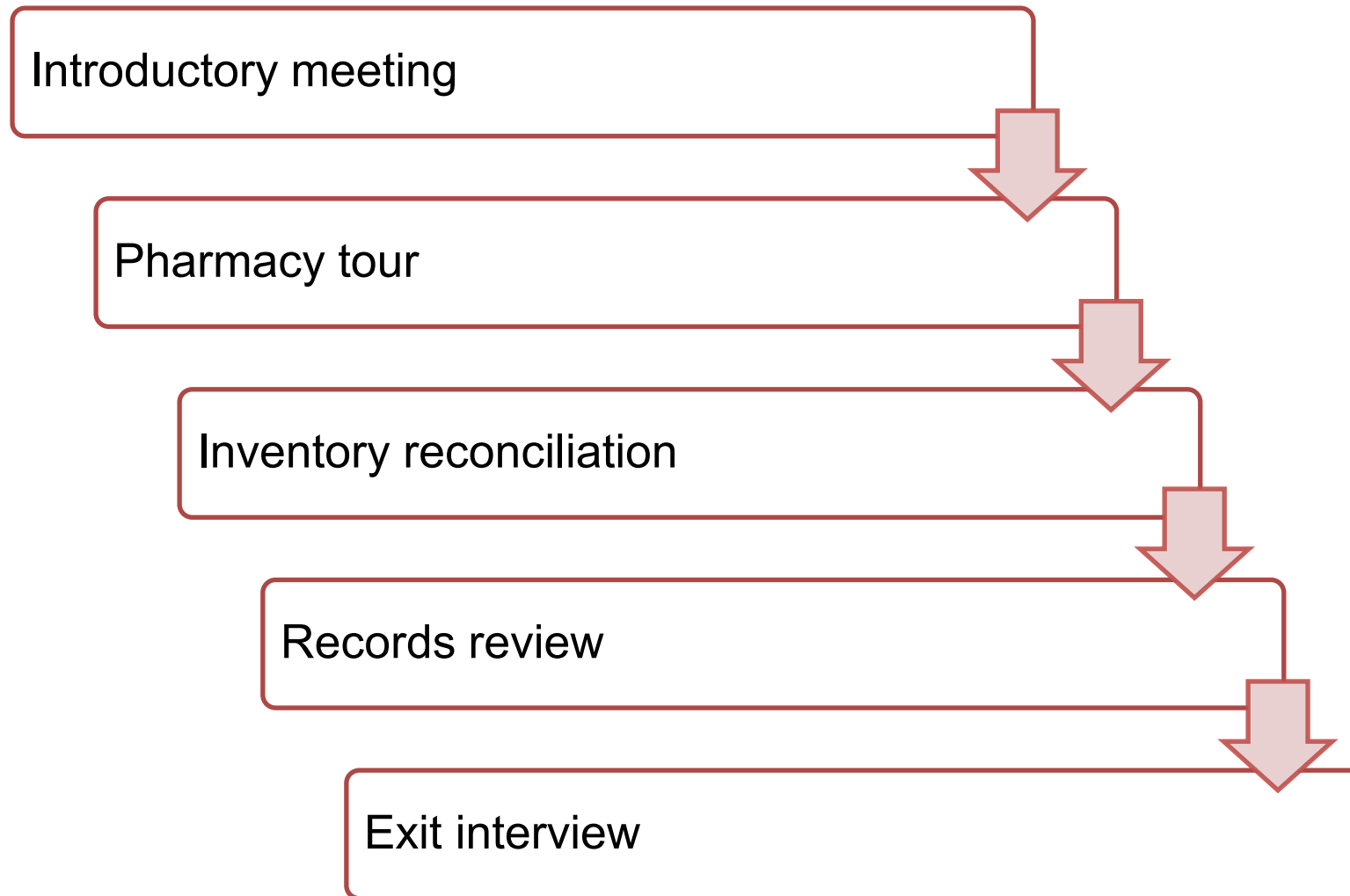
Assess all applicable requirements of the Controlled Drugs and Substances Act and its Regulations

Areas of Review:

- Security measures
- Inventory control
- Purchase/receiving and dispensing records
- Prescription files
- Loss or Theft reports
- Destruction procedures and records



Pharmacy Inspection Process



Introductory Meeting

- Introduction with designated manager or pharmacist on duty
- Inspector designation card and business card
- Purpose of inspection and CDSA 31 lawful authority
- Compliance information package (provided during or after inspection)

Note: Inspectors can sign a visitor log if required by store policy, but at no time will an inspector sign a confidentiality agreement or similar document and will not authorize the handling or photocopy of their designation card or badge



Security 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.

- Measures that ensure a high level of security
- Physical security recommendations
 - Alarm and surveillance system
 - Physical barriers and deterrents
 - Restricted access to dispensary
- Reasonable inventory levels
 - Excessive loss and storage considerations
 - Ability to count regularly and accurately



Provincial Security Requirements

Drug Distribution and Storage 2.1.1, 2.3 Pharmacy Facilities
2.2.8, 2.2.15, Guideline on Minimum Pharmacy Policy and Procedures Manual

- There must be adequate policies and procedures to identify
 - theft
 - loss
 - diversion
- Inventory orders should be received by the dispensary as soon as possible
- All drugs must be secured
- Narcotic and controlled drugs must be stored in the pharmacy safe
- Benzodiazepines and other targeted drugs do not have to be in the safe
 - However, you remain responsible for their security



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 adjustments, and 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 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 system's expected on-hand inventory or automated machine/robot counts
 - Periodic manual counts must be done to verify physical quantities
 - Manual counts \neq reconciliation



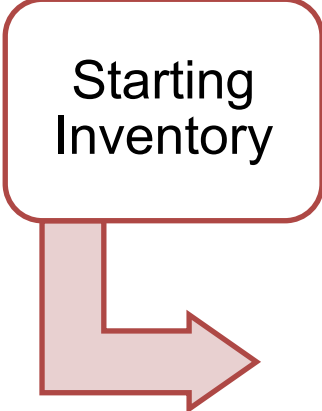
Provincial Physical Counts Requirements

Drug Distribution and Storage 2.3,
Narcotic & Controlled Drug Accountability Guidelines

- Counts must be
 - completed at a minimum of every three months
 - documented
- When there is a pharmacy manager change the outgoing and incoming managers should
 - complete the count together, and
 - both sign the documentation
- Any discrepancy identified during the count must be investigated with documentation



Reconciliation



Reconciliation calculated on June 8, 2023

Part 1:

1. **Starting Inventory** = count done Jan 2, 2023

250

+

2. **Purchases** = number purchased
Jan 2 – June 8, 2023

800

1050

Subtract sales

3. **Total sales** = number dispensed
Jan 2 – June 8, 2023

750

Calculated balance =

1050 - 750 = 300



Reconciliation continued

Part 2:

4. **Today's inventory** = count done June 8th, 2023 200

-

5. **Calculated balance** from above 300

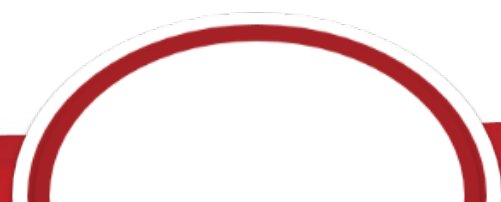
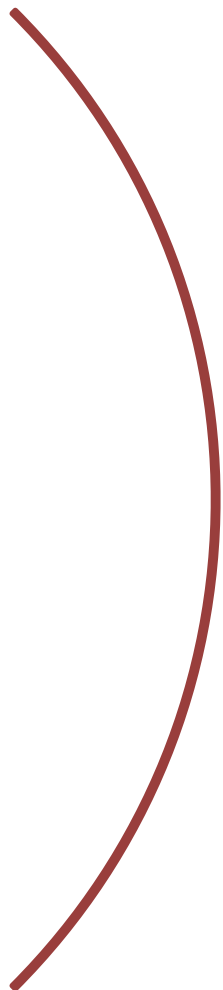
6. **Difference** = today's count – calculated balance = -100



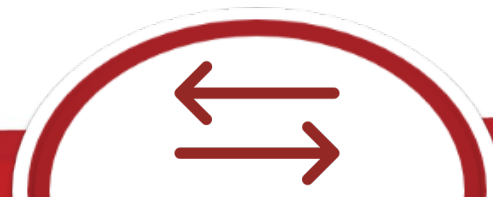
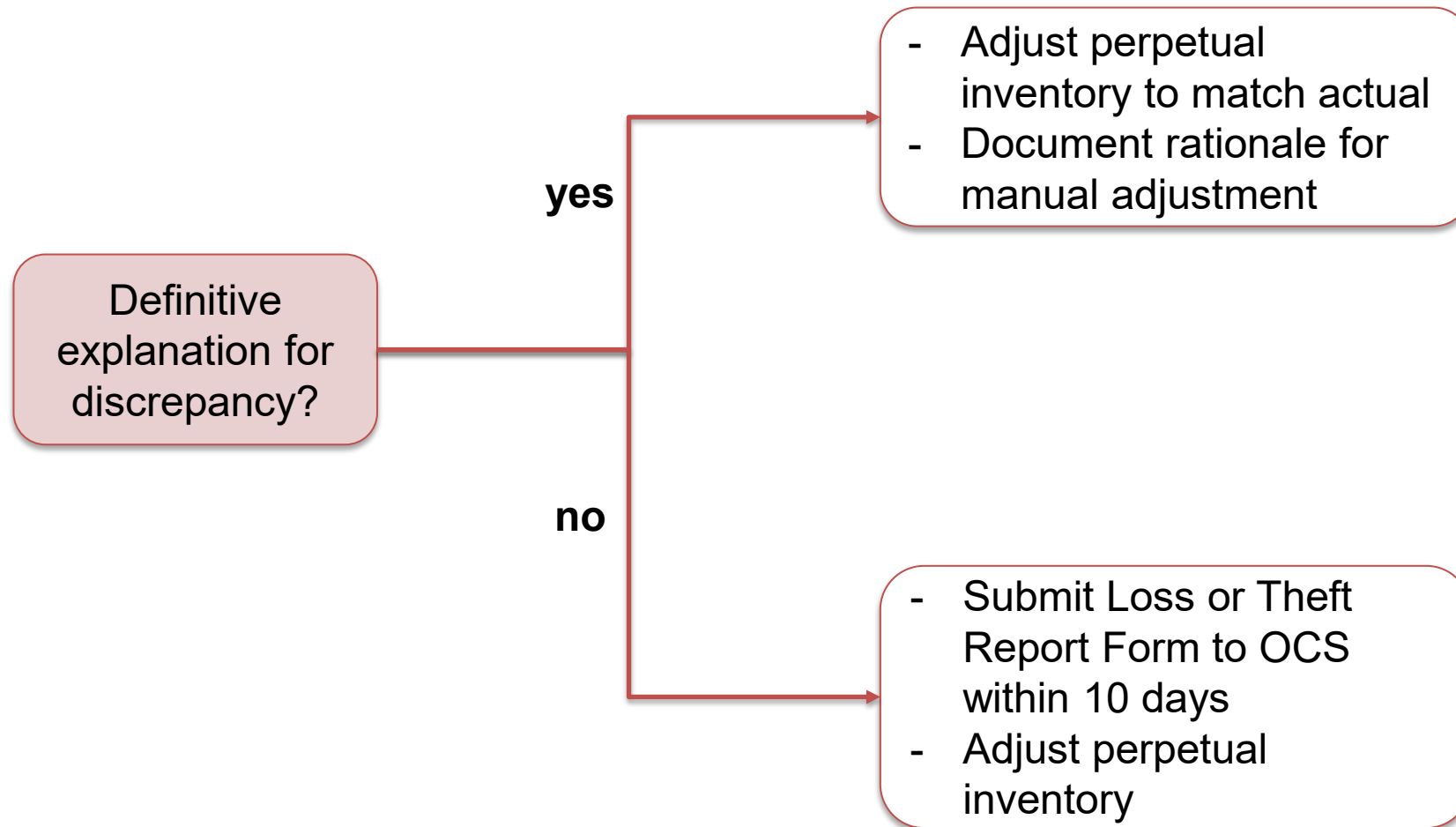
Investigate the difference – do you have records to account for this?



Internal Investigation



Result of Investigation



Sample manual adjustment record

14-Jun-2022	Rx# 9007874	Fill	6	
14-Jun-2022	adjustment	(Manual)		116
	Reason: 2 - Inventory adjustment			
15-Jun-2022	Rx# 9007877	Fill	6	
15-Jun-2022	Rx# 9007879	Fill	100	
16-Jun-2022	Rx# 9007880	Fill	6	

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



Health Canada / Santé Canada

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


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

CS-FRM-011



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

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 *
			<small>Click to see options</small>
			<small>Click to see options</small>
			<small>Click to see options</small>
			<small>Click to see options</small>
			<small>Click to see options</small>
			<small>Click to see options</small>
			<small>Click to see options</small>
			<small>Click to see options</small>
			<small>Click to see options</small>
			<small>Click to see options</small>


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.





Provincial Loss/Theft Reporting Requirements Drug Distribution and Storage

2.3

- **Any** loss or theft of a narcotic, targeted or controlled drug must be reported to CPhM within 10 days of discovery.
- Must manually submit reports to CPhM regardless of the submission method to Health Canada
 - Fax: 204-237-3468
 - Email: losstheft@cphm.ca
- Reporting ensures transparency and accountability.
- The pharmacy manager **must** evaluate whether procedural changes or preventative measures are required to prevent future discrepancies.



Destructions



Unserviceable stock

- System in place to track items perpetually



Post-consumer returns

- No longer required to record drug name, strength and quantity for post-consumer returns
- Since no requirement to separate controlled substances from non-controlled, treat all post-consumer returns as controlled substances
- One-way entry container (opaque, inconspicuous, tamper-evident) with a unique identifier number

Note:

- **Potential risk of pilfering/diversion from destruction-bound substances**
- **Do not comingle the two streams**



Destruction Options

Unserviceable stock

1. Destroy locally
 - Method has to denature
 - Performed by pharmacist + witness
 - Record drug name, strength, quantity; pharmacist + witness to sign and date; method of destruction

Post-consumer returns

1. Destroy locally
 - Same procedures as for unserviceable stock, with the exception of record keeping
 - Record destruction date, number of containers destroyed and unique identifier of each container and must be signed and dated by pharmacist + witness
 - For containers with integrated system, the date and unique identifier are recorded once the container is full

Note: Use denaturing method that achieves a change of state (i.e. into a slurry)



Destruction Options

Unserviceable stock

2. Send to licensed dealer (LD)
 - Provide to LD authorized to destroy controlled substances
 - Return to LD who sold or provided the controlled substances
 - Written order signed & dated by LD, specifies name, quantity, strength of each controlled substance to be provided; LD's name & address; date on which substances provided

Post-consumer returns

2. Provide to licensed dealer authorized to destroy controlled substances
 - Record number of containers collected, date, unique identifier and LD's name and address
 - Pharmacist must sign and date the destruction request

Note: Documentation mentioned above (i.e. written order from LD, record of transaction, etc.) must be retained for 2 years in an auditable manner



Provincial Destruction Requirements Drug Distribution and Storage 2.4

- Until unserviceable stock and post-consumer return of controlled drugs and substances are destroyed, they must be secured
 - counted quarterly
- Sequester from active pharmacy inventory to prevent accidental use
- Destruction records must be maintained for 5 years

Note: Controlled substances remain the pharmacist's responsibility from the time they are received until they are destroyed with documentation.



Provincial Destruction Requirements (Continued)



College of Pharmacists of Manitoba

**Destruction of Drugs Covered by the
Controlled Drugs and Substances Act**

Pharmacy: _____ Pharmacy manager: _____

Address: _____ City: _____ Province: _____

Names of two healthcare professional witnessing the destruction:

- 1) _____
- 2) _____

Date of destruction: _____

This form can be used to track the destruction of narcotic, controlled and targeted drugs.

Drug name	Strength	Dosage form	Quantity	Expired or returned from patient (please check one)	
				Expired	Returned
				<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>	<input type="checkbox"/>

These records must be kept for a minimum of 5 years after the last date of destruction. These records are not required to be submitted to the College of Pharmacists of Manitoba or Health Canada, but must be available for inspection on demand and may be requested at any time by the College.



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 of 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
Special Rx file	<ul style="list-style-type: none"> - Original written orders/scripts for narcs and controlled drugs (incl. part-fills & refills) - Assoc. dispensing records 	<ul style="list-style-type: none"> - Electronic report can suffice provided it is auditable (i.e. chronological; timely extraction of special Rx file)
Emergency transactions	<ul style="list-style-type: none"> - Captured in both receiving and dispensing records 	



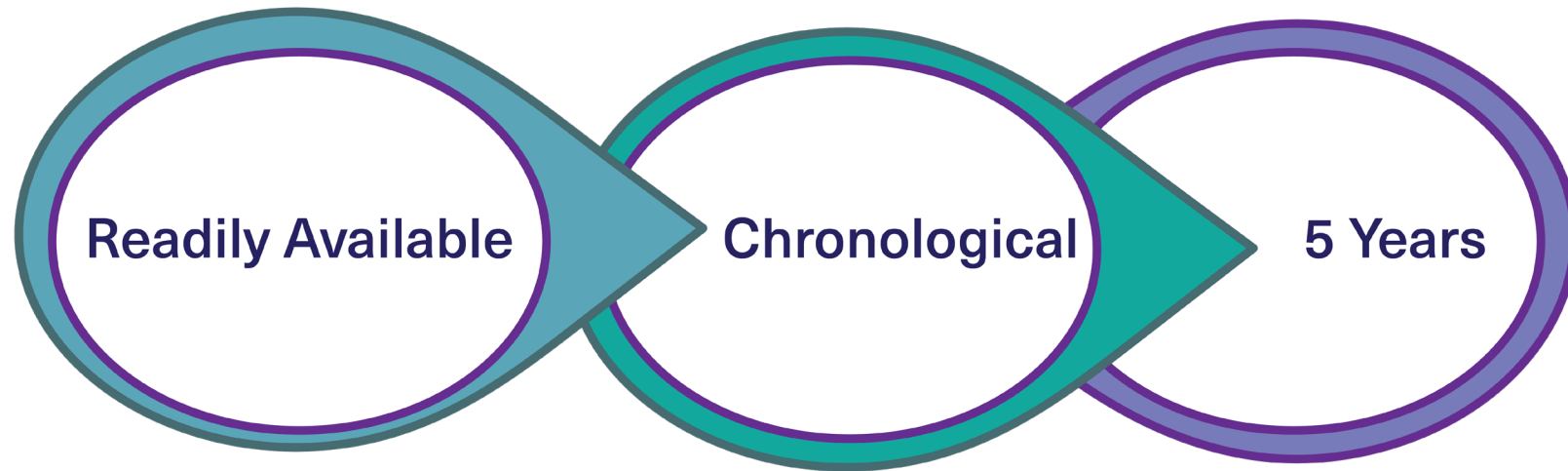
Types of Records (continued)

Type	Content	Notes
Destruction	Post-consumer returns <ul style="list-style-type: none"> - local: date, bin ID, #bins, signatures (x2) - LD: date, # of bins, bin ID's, LD name + address, pharmacist signature 	<ul style="list-style-type: none"> - 2nd signature must be from an eligible witness (i.e. practitioner, pharmacist, pharmacy intern, or regulated pharmacy technician)
	Unserviceable stock <ul style="list-style-type: none"> - local: date, name, quantity, strength, method, signatures (x2) - LD: date, name, quantity, strength, LD name + address, pharmacist signature 	
Return authorization	<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
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



Provincial Records Requirements


Pharmaceutical Regulation 79, Records and Information
Practice Direction



Opioid Labelling

- Opioid sticker and handout requirement came into effect Oct 23, 2018
- Warning sticker (aux label) must be applied to the container each time an opioid is dispensed to a patient
(except for dependence treatment)
- Info handout provided to the patient at the same time
- key messaging on safe use of opioids, and on associated risks



Opioid Medicines  Information for Patients and Families

You have been prescribed an opioid medicine for the treatment of pain or for another condition.
Talk to your doctor or pharmacist if you:

- Have questions about your opioid medicine.
- Do not understand the instructions for using the opioid medicine given to you.
- Develop side effects or your condition worsens.

SERIOUS WARNINGS	SIGNS OF OVERDOSE
<ul style="list-style-type: none">• Opioid overdose can lead to death. Overdose is more likely to happen at higher doses, or if you take opioids with alcohol or with other sedating drugs (such as sleeping pills, anxiety medication, anti-depressants, muscle relaxants).• Addiction may occur, even when opioids are used as prescribed.• Physical dependence can occur when opioids are used every day. This can make it hard to stop using them.• Life-threatening breathing problems or reduced blood pressure may occur with opioid use. Talk to your doctor about whether any health conditions you have may increase your risk.• Your pain may worsen with long-term opioid use or at higher doses. You may not feel pain relief with further increases in your dose. Talk to your doctor if this happens to you, as a lower dose or a change in treatment may be required.• Withdrawal symptoms, such as widespread pain, irritability, agitation, flu-like symptoms and trouble sleeping, are common when you stop or reduce the use of opioids.• Babies born to mothers taking opioids may develop life-threatening withdrawal symptoms.• Use only as directed. Crushing, cutting, breaking, chewing or dissolving opioids before consuming them can cause serious harm, including death.	<ul style="list-style-type: none">• Hallucinations• Confusion• Difficulty walking• Extreme drowsiness/dizziness• Slow or unusual breathing• Unable to be woken up• Cold and clammy skin <p>Call 911 right away if you suspect an opioid overdose or think you may have taken too much. *</p> <p><small>* Naloxone has been approved by Health Canada to temporarily reverse known or suspected opioid overdoses.</small></p>

POSSIBLE SIDE EFFECTS

<ul style="list-style-type: none">• Reduced physical and/or mental abilities, depression• Drowsiness, dizziness, risks of falls/fractures• Heart palpitations, irregular heartbeat• Problems sleeping, may cause or worsen sleep apnea	<ul style="list-style-type: none">• Vision problems, headache• Low sex drive, erectile dysfunction, infertility• Severe constipation, nausea, vomiting
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YOUR OPIOIDS MAY BE FATAL TO OTHERS

- **Never give your opioid medicine to anyone.**
- Store opioids (including used patches) in a secure place to prevent theft, problematic use or accidental exposure.
- Keep opioids out of sight and reach of children and pets. Taking even one dose by accident can be fatal.
- Never throw opioids (including used patches) into household trash where children and pets may find them.
- Return expired, unused or used opioids (including patches) to a pharmacy for proper disposal.

This handout is a summary and will not tell you everything about opioid medicines.
More information about the opioid you have been prescribed (or naloxone) can be found online in the Product Monograph: <https://health-products.canada.ca/dod-bdoo/index-eng.jsp> Date: 2018/05/02



Exit Interview and Report

- Cover off any remaining areas of review
- Re-cap of Observations
- Discuss reporting and response timelines



Compliance Promotion


Information Package

PHARMACY INSPECTIONS


Pharmacy inspections aim to **promote and improve compliance** with the *Controlled Drugs and Substances Act (CDSA)* and its relevant regulations. The pharmacy inspection program strengthens communication between Health Canada, provincial professional licensing authorities, professional associations and pharmacists.

This document highlights **best practices** that a pharmacist should take to minimize the risk of diversion of controlled substances in their establishments. **It contains information on:**


Security




Inventory and Reconciliation



Destruction



Records



Pharmacists are reminded that it is their responsibility to consult with the relevant provincial professional licensing authorities for further guidance. Provincial requirements may be more stringent than what is outlined here.

Pharmacy inspections also aim to **verify a pharmacist's compliance** with applicable regulations.

Health Canada inspectors within the Controlled Substances Program are designated under the *CDSA* and *Food and Drugs Act (FDA)*. Inspectors have specific authorities regarding compliance verification and enforcement of the *CDSA*, *FDA* and their associated regulations as they apply to controlled substances.

A typical inspection involves:

Introduction: The Health Canada inspector will introduce themselves with the appropriate documentation, then request to meet with the pharmacist on duty.


Inspection process: Inspections will focus on the verification of purchase/receiving records, prescription records, electronic transaction records, loss or theft reports, destruction protocols and records, inventory reconciliation, security measures and any other information relevant to the act of dispensing controlled substances.

The inspector will inform the pharmacist on duty and/or the designated pharmacy manager of any observations made throughout the inspection and discuss any potential deficiencies that may be observed (to ensure understanding of the regulations).

Exit interview: The inspector will inform the pharmacist on duty that a copy of the Inspection Report will be issued to the pharmacy within Health Canada's operational service standards.

Compliance promotion: The inspector will also provide the pharmacist with documents such as compliance promotion materials and a loss or theft report form.

As per the standard processes currently being practiced within the Controlled Substances Program, **follow-up inspections** can occur and would be subject to the same authorities, privacy and processes as the initial inspection. Similarly, the standards currently in practice when reporting misconduct under the *CDSA* will continue to be followed.


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Observations

- Characterizes and describes observations (deficiencies/deviations from regulation) as critical, major or minor based on the risk of diversion
 - National uniformity
 - Compliant or Non-Compliant inspection ratings
- Takes into account:
 - Scope
 - Severity
 - Compliance history
 - Implemented corrective actions
 - Willingness to comply



Observation ratings

Critical

Inspection Ratings

Non-Compliant Inspection Rating

- One or more critical observations are identified
- Pharmacist failed to take all reasonable steps to protect all controlled substances on their premises or under their control
 - Demonstrated by several major observations
- Compliance/enforcement actions can include:
 - Referral to provincial or territorial professional licensing authority
 - Referral to law enforcement (active diversion situation)
 - Referral to other federal regulatory body
 - Restrict pharmacist's privileges to order narcotics
 - Follow-up inspection



Forward Planning

- National guidance to address diversion risk issues
- Stakeholder engagement
- Adapt risk-based approach as regulatory landscape evolves
- Utilizing intelligence and other data to focus inspections based on risk
- Develop and implement compliance promotion material and tools



Health Canada Resources

- [Reporting loss or theft of controlled substances or precursors](#)
- [Controlled substances guidance for community pharmacists](#)
- [Community Pharmacy Inspection Program Annual Report](#)
- [Policy documents/CDSA section 56 exemptions](#)
- [Drug Product Database](#) (DIN products)
- [Adverse reaction reporting](#)
- [Adverse reaction database](#)
- [Recalls and safety alerts](#)
- [Health Product InfoWatch publications](#)
- [Policy on Manufacturing and Compounding Drug Products in Canada \(POL-0051\)](#)
- [Portal FAQ](#); [Sign up for a GCKey](#) (Loss or theft reporting)
- [Unserviceable stock](#); [post-consumer returns](#) (Guidance for destructions)
- [Q&A Guidance](#); [Part A List of Opioids](#) (Opioid labelling)

[Pharmacy splash page](#)



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



CPhM Resources

- [CPhM Resource Library](#)
- [Pharmaceutical Regulation](#)
- [Drug Distribution and Storage Practice Direction](#)
- [Pharmacy Facilities Practice Direction](#)
- [Records and Information Practice Direction](#)
- [Narcotic and Controlled Drug Accountability Guidelines](#)
- [Guideline on Minimum Pharmacy Policy and Procedure](#)
- [Provincial Prescription Regulation Summary Chart \(M3P and non-M3P\)](#)
- [List of Drugs covered by the M3P Program](#)
- [M3P Q&A](#)
- [Companion Document to the CPSM Standards of Practice for Prescribing Opioids and Benzodiazepines and Z-Drugs](#)
- [Destruction and Return of Narcotic, Controlled and Targeted Drugs Forms](#)



Contact Information

Contact	Info
College of Pharmacists of Manitoba	Email: Info@cphm.ca Phone: 204-233-1411 Fax: 204-237-3468
CPhM Field Operations Team Chris Louizos, Assistant Registrar Field Operations Arleigh Andrushak, Quality Assurance and Field Officer Kevin Chaboyer, Quality Assurance and Field Officer	Email: Fieldops@cphm.ca Phone: 204-233-1411 ext. 240
Loss/Theft Reporting	Email: losstheft@cphm.ca Fax: 204-237-3468
<u>Attempted</u> Forgery Reporting	Via web form: https://forms.office.com/r/8abeQy3cf1



TO PROTECT THE HEALTH AND WELL-BEING OF THE PUBLIC.

Questions?

Thank you for your time and attention.



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