



Pharmacy Site Quality Assurance

Todd Mereniuk, B.Sc., B.Sc. (Pharm)
Assistant Registrar – Field Operations
College of Pharmacists of Manitoba



Disclosure

- I am an employee of the College of Pharmacists of Manitoba, specifically the Assistant Registrar for Field Operations.
- I conduct inspections and investigations for the College of Pharmacists as per the *Pharmaceutical Act of Manitoba*
- I do not have any other financial interest or arrangements that could be perceived as a related or apparent conflict of interest in the context of the subject of this presentation



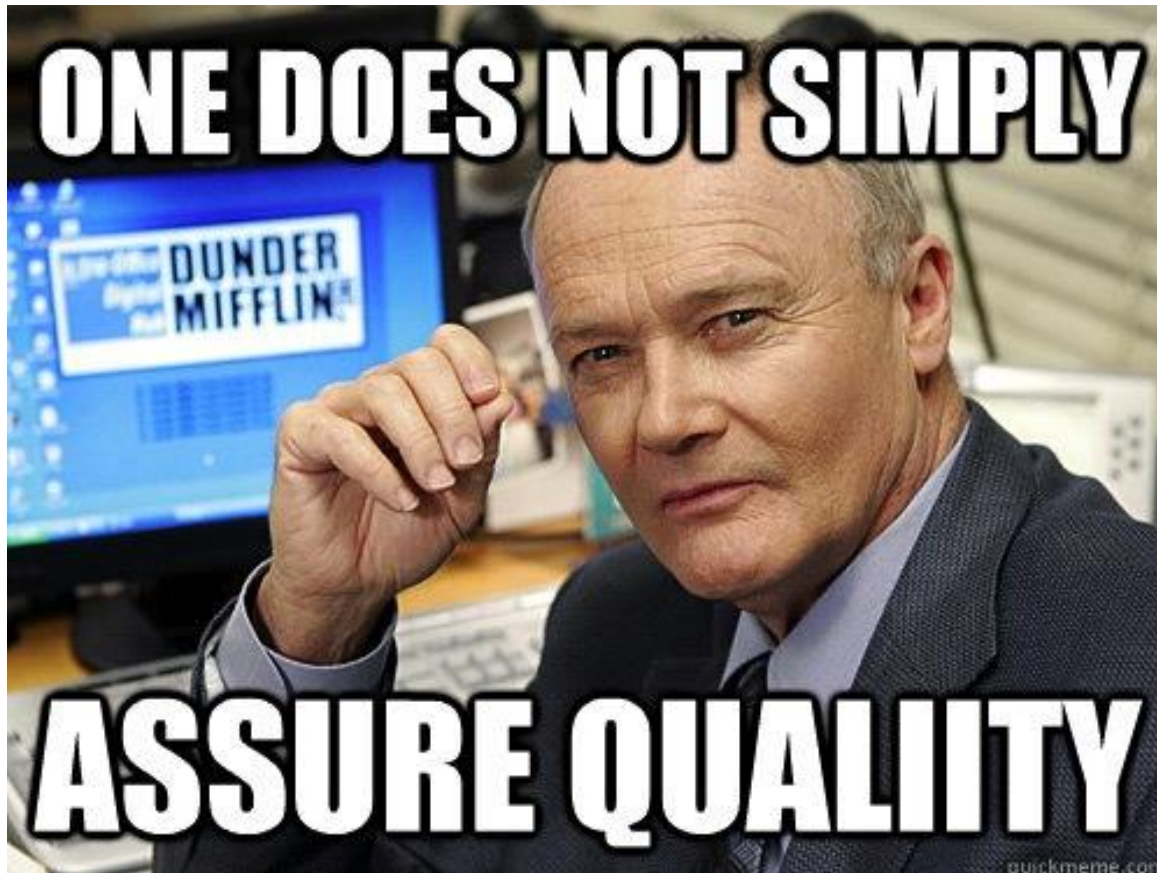
Inspections

Pharmacy Site Quality Assurance



Inspections

Pharmacy Site Quality Assurance



+ Inspections



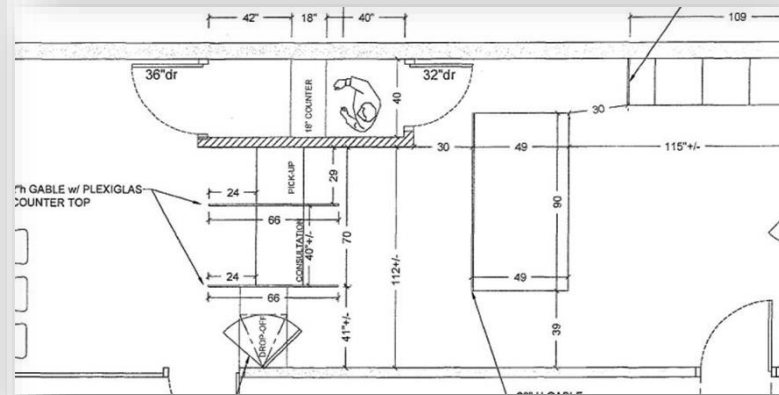
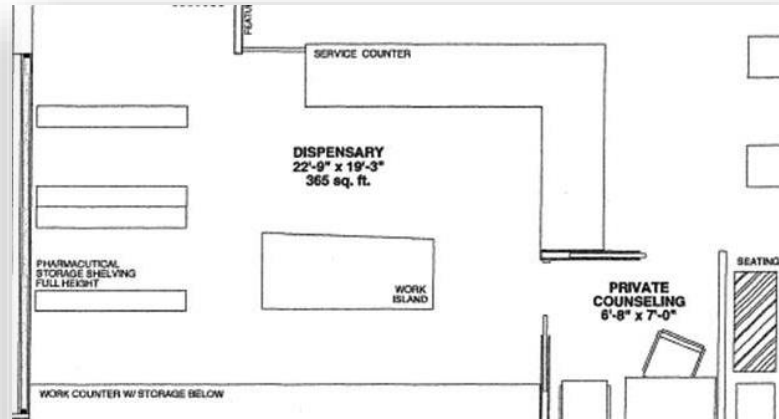
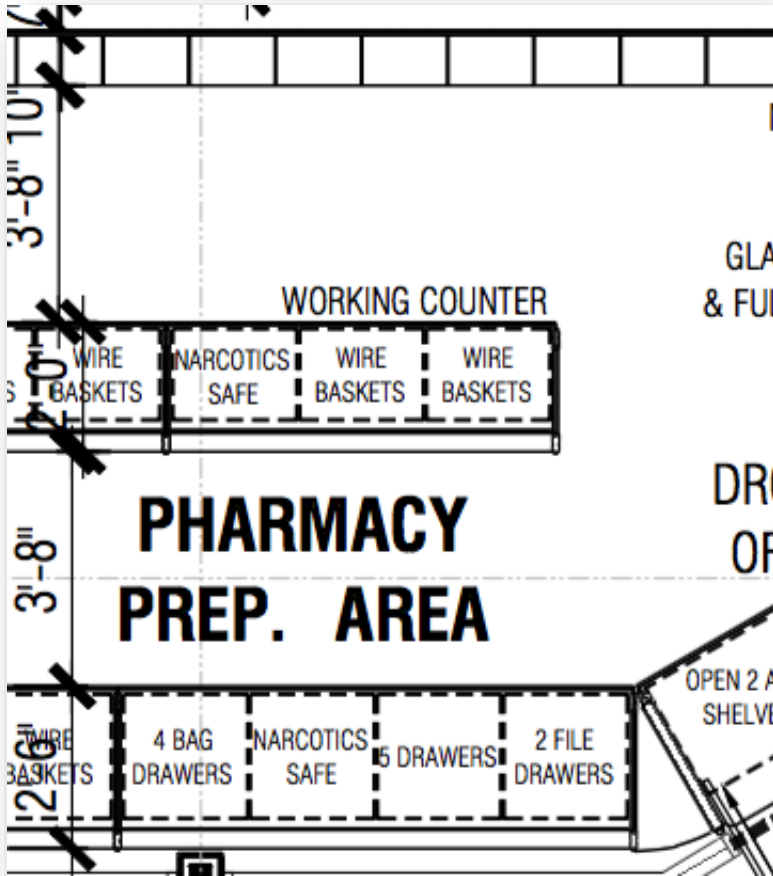
- New Store
- Regular Rotation
- Renovations
- Relocations
- Follow-ups
- Drop In Visits
- Inspections Due to Investigations

+ Inspections



- New Store
- Regular Rotation
- Renovations
- Relocations
- Follow-ups
- Drop In Visits
- Inspections Due to Investigations

+ New Store Inspections



+ New Store Inspections

Preliminary Inspection



+ New Store Inspections

Preliminary Inspection



College of Pharmacists of Manitoba

200 Tache Avenue, Winnipeg, Manitoba R2H 1A7
Phone (204) 233-1411 | Fax: (204) 237-3468
E-mail: info@cphm.ca | Website: www.cphm.ca

Practice Direction Standard of Practice # 15: Pharmacy Facilities

1.0 Scope and Objective:

1.1 Expected Outcome

This document is a practice direction by Council concerning the requirement to provide appropriate and accessible pharmacy facilities.

1.2 Document Jurisdiction (Area of Practice)

+ New Store Inspections

Preliminary Inspection

Important Points

- Ventilation, lighting

PDir: Pharmacy Facilities



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All licensed pharmacies must comply with this practice direction.

1.3 Regulatory Authority Reference

Section 56(1) of regulations to the Act allows Council to create this practice direction.

2.0 Practice Direction

2.1

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+ New Store Inspections

Preliminary Inspection

Important Points

- Ventilation, lighting
- 150 square feet dispensary

PDir: Pharmacy Facilities



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2.0 Practice Direction

2.1 7'

D'

'

+ New Store Inspections

Preliminary Inspection

Important Points

- Ventilation, lighting
- 150 square feet dispensary
- 12 square feet free counter space

PDir: Pharmacy Facilities



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2.1 Title

D

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+ New Store Inspections

Preliminary Inspection

Important Points

- Ventilation, lighting
- 150 square feet dispensary
- 12 square feet free counter space
- Sink, equipment, security

PDir: Pharmacy Facilities



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Important Points

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- 150 square feet dispensary
- 12 square feet free counter space
- Sink, equipment, security
- Privacy, privacy, privacy

PDir: Pharmacy Facilities



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+ New Store Inspections

Pre-Opening Inspection



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Pre-Opening Inspection



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Pre-Opening Inspection



+ New Store Inspections

Pre-Opening Inspection



+ New Store Inspections

Pre-Opening Inspection



+ New Store Inspections

Pre-Opening Inspection



+ New Store Inspections

Pre-Opening Inspection



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Pharmacy Quality Assurance Self-Assessment

(Community and Hospital Outpatient Pharmacy)

Report #

Pharmacy:		CPhM Licence		Date:	
Address:		City		Postal Code	
Phone	#1	Fax	#1	E-Mail Address	#1
Phone	#2	Fax	#2	E-Mail Address	#2
Website	#1	Website	#2		
Last Inspection Date:		Pharmacare #:		Pharmacy Licence Posted <input type="checkbox"/>	
Computer System:		Pharmacy Manager:		Licence Number	Full Time <input type="checkbox"/>
Store Business Hours:				Part Time <input type="checkbox"/>	Posted <input type="checkbox"/>
Mon to Fri:		Staff Pharmacist(s):			
Sat:				<input type="checkbox"/>	<input type="checkbox"/>
Sun:				<input type="checkbox"/>	<input type="checkbox"/>

+ New Store Inspections

Pre-Opening Inspection

Important Points

- Assesses most, if not all, aspects of the pharmacy site requirements & practice support

Q/A Self-Assessment



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Please list components of community pharmacy licence (Check and Fill, Second Party, etc.) if any					

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Pre-Opening Inspection

Important Points

- Assesses most, if not all, aspects of the pharmacy site requirements & practice support
- Intent is for manager to perform annually

Q/A Self-Assessment



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Sat:				Posted
Sun:				
Holidays:				
Dispensary Hours (i.e. Lock and Leave):				
Mon to Fri:				
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Sun:				
Holidays:				
Please list components of community pharmacy licence (lock and key) if applicable. Full, Second, or Special Services.				

+ New Store Inspections

Pre-Opening Inspection

Important Points

- Answer as accurately as possible

Q/A Self-Assessment



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+ New Store Inspections

Pre-Opening Inspection

Important Points

- Answer as accurately as possible
- No. 1 – represents - “We are confident in our compliance;”

Q/A Self-Assessment



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Please list components of community pharmacy licence (lock and key) if applicable. Full-Fill, Second Party, etc. (if applicable)					

+ New Store Inspections

Pre-Opening Inspection

Important Points

- Answer as accurately as possible
- No. 1 – represents - “We are confident in our compliance;”
- No. 2 – represents - “We are not sure if we are compliant;”

Q/A Self-Assessment



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Holidays:				<input type="checkbox"/>	<input type="checkbox"/>
Please list components of community pharmacy licence (lock and leave) if applicable		Full-Fill, Second Party, Special Services			

+ New Store Inspections

Pre-Opening Inspection

Important Points

- Answer as accurately as possible
- No. 1 – represents - “We are confident in our compliance;”
- No. 2 – represents - “We are not sure if we are compliant;”
- No. 3 – represents - “We need help to be compliant”

Q/A Self-Assessment



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Sun:				<input type="checkbox"/>	<input type="checkbox"/>
Holidays:				<input type="checkbox"/>	<input type="checkbox"/>
Please list components of community pharmacy licence (check and fill if applicable):					
<input type="checkbox"/> Home Care Home Delivery <input type="checkbox"/> Community Pharmacy <input type="checkbox"/> Pharmacy Licence (Check and fill if applicable) <input type="checkbox"/> Mail-Fill, Second Party <input type="checkbox"/> Special Services					

+ New Store Inspections

Pre-Opening Inspection



+ New Store Inspections

Pre-Opening Inspection



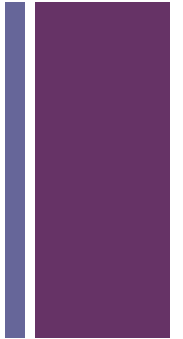
- Submit to the Registrar

+ New Store Inspections

Pre-Opening Inspection



- Submit to the Registrar
- Registrar has final approval



+ New Store Inspections

Pre-Opening Inspection



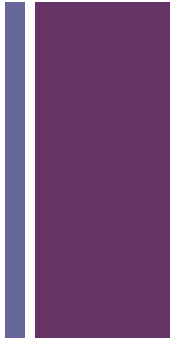
- Submit to the Registrar
- Registrar has final approval
- Any outstanding deficiencies?

+ New Store Inspections

Pre-Opening Inspection



- Submit to the Registrar
- Registrar has final approval
- Any outstanding deficiencies?
- Licensure!



+ New Store Inspections

Pre-Opening Inspection



- Submit to the Registrar
- Registrar has final approval
- Any outstanding deficiencies?
- Licensure!
- Effective date = can now order drugs

+ New Store Inspections

Pre-Opening Inspection



- Submit to the Registrar
- Registrar has final approval
- Any outstanding deficiencies?
- Licensure!
- Effective date = can now order drugs
- Third party's contacted by College with effective date

+ New Store Inspections

**Please
note!**

+ New Store Inspections



APPLICATION FOR DPIN REGISTRATION

Please Print Clearly

Manitoba Health
Provincial Drug Programs
300 Carlton St.
Winnipeg MB R3B 3M9
(204) 786-8000
Fax (204) 786-6634



DPIN REQUIRES 4-6 WEEKS NOTICE

1) Pharmacy Information

Change of information - Please indicate effective date

New application - Please indicate opening date

Day	Month	Year

Trade Name of Pharmacy/Dispensary		Pharmacare Number	P				
Legal Name of Pharmacy/Dispensary		Pharmacy License No. (as shown on M.Ph.A. License certificate)					
Site Address (Location of Pharmacy/Dispensary)				Mailing Address (different)			
City		Postal Code		City		Postal Code	
Telephone No. (Pharmacy) ()		Fax No. (Pharmacy) ()		Name of Contact		Telephone No. ()	

2) Ownership

Legal Name of Head Office		Mailing Address			MH Use Only
City	Postal Code	Telephone No. ()	Fax No. ()	Name of Contact	

3) Type of Pharmacy

Organization	<input type="checkbox"/>	Indep. Cont.	<input type="checkbox"/>	One	Own	<input type="checkbox"/>	Trade Name of
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+ New Store Inspections

Post-Opening Inspection

30 – 90 Days Post-Opening

- Pharmacy Manager submits Q/A Self-Assessment within 30 days of opening

Q/A Self-Assessment



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Post-Opening Inspection

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- Appointment for full inspection is made 30 to 90 days post-opening
- Use Self-Assessment as guide

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Sat:				<input type="checkbox"/>	<input type="checkbox"/>
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Holidays:				<input type="checkbox"/>	<input type="checkbox"/>
Dispensary Hours (i.e. Lock and Leave):				<input type="checkbox"/>	<input type="checkbox"/>
Mon to Fri:				<input type="checkbox"/>	<input type="checkbox"/>
Sat:				<input type="checkbox"/>	<input type="checkbox"/>
Sun:				<input type="checkbox"/>	<input type="checkbox"/>
Holidays:				<input type="checkbox"/>	<input type="checkbox"/>
Please list components of community pharmacy licence (Check and Fill, Second Party, Special Services, etc.) if any.					

+ New Store Inspections

Post-Opening Inspection

30 – 90 Days Post-Opening

- Pharmacy Manager submits Q/A Self-Assessment within 30 days of opening
- Appointment for full inspection is made 30 to 90 days post-opening
- Use Self-Assessment as guide
- Post-Opening similar to Regular Rotation Inspection

Q/A Self-Assessment



The College of Pharmacists of Manitoba
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TELEPHONE (204) 233-1411 FAX: (204) 237-3468 E-MAIL: info@cphm.ca

Pharmacy Quality Assurance Self-Assessment (Community and Hospital Outpatient Pharmacy)

		CPhM Licence		Date:	
Pharmacy:					
Address:		City		Postal Code	
Phone #1	Fax #1	E-Mail Address #1			
Phone #2	Fax #2	E-Mail Address #2			
Website #1	Website #2				
Last Inspection Date:		Pharmacare #:		Pharmacy Licence Posted	
Computer System:		Pharmacy Manager:		Licence Number	Full Time
Store Business Hours:		Staff Pharmacist(s):		Part Time	Posted
Mon to Fri:				<input type="checkbox"/>	<input type="checkbox"/>
Sat:				<input type="checkbox"/>	<input type="checkbox"/>
Sun:				<input type="checkbox"/>	<input type="checkbox"/>
Holidays:				<input type="checkbox"/>	<input type="checkbox"/>
Dispensary Hours (i.e. Lock and Leave):				<input type="checkbox"/>	<input type="checkbox"/>
Mon to Fri:				<input type="checkbox"/>	<input type="checkbox"/>
Sat:				<input type="checkbox"/>	<input type="checkbox"/>
Sun:				<input type="checkbox"/>	<input type="checkbox"/>
Holidays:				<input type="checkbox"/>	<input type="checkbox"/>
Please list components of community pharmacy licence (check and fill if applicable):				Full-Fill, Second Party, Special Services	

+ Inspections



- New Store
- Regular Rotation
- Renovations
- Relocations
- Follow-ups
- Drop In Visits
- Inspections Due to Investigations

+ Regular Inspections



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Inspection Reply Form

Pharmacy:	License No.	Report No.
Address:	Date:	
Pharmacy Manager:		
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+ Regular Inspections

How to Prepare?

Inspection Reply Form



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Part 1: Correct the following Conditions within 30 days:

Distribution:

- 1) Premises and Management:
- 2) Dispensary Equipment:
- 3) Pharmacy Library:
- 4) Lock and Leave Enclosure:
- 5) Pharmacy Security:
- 6) Prescription Records:
- 7) Faxed Prescriptions:
- 8) Refill reco

+ Regular Inspections

How to Prepare?

- Complete the Q/A Self Assessment

Inspection Reply Form



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+ Regular Inspections

How to Prepare?

- Complete the Q/A Self Assessment
- Address any deficiencies prior to inspection

Inspection Reply Form



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- 5) Pharmacy Security:
- 6) Prescription Records:
- 7) Faxed Prescriptions:
- 8) Refill reco

+ Regular Inspections

How to Prepare?

- Complete the Q/A Self Assessment
- Address any deficiencies prior to inspection
- Identify topics of conversation

Inspection Reply Form



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- 5) Pharmacy Security:
- 6) Prescription Records:
- 7) Faxed Prescriptions:
- 8) Refill reco

+ Regular Inspections

How to Prepare?

- Complete the Q/A Self Assessment
- Address any deficiencies prior to inspection
- Identify topics of conversation
- Gather up documentation

Inspection Reply Form



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- 8) Refill reco

+ Regular Inspections



+ Regular Inspections

First Impressions



+ Regular Inspections

First Impressions



+ Regular Inspections

First Impressions



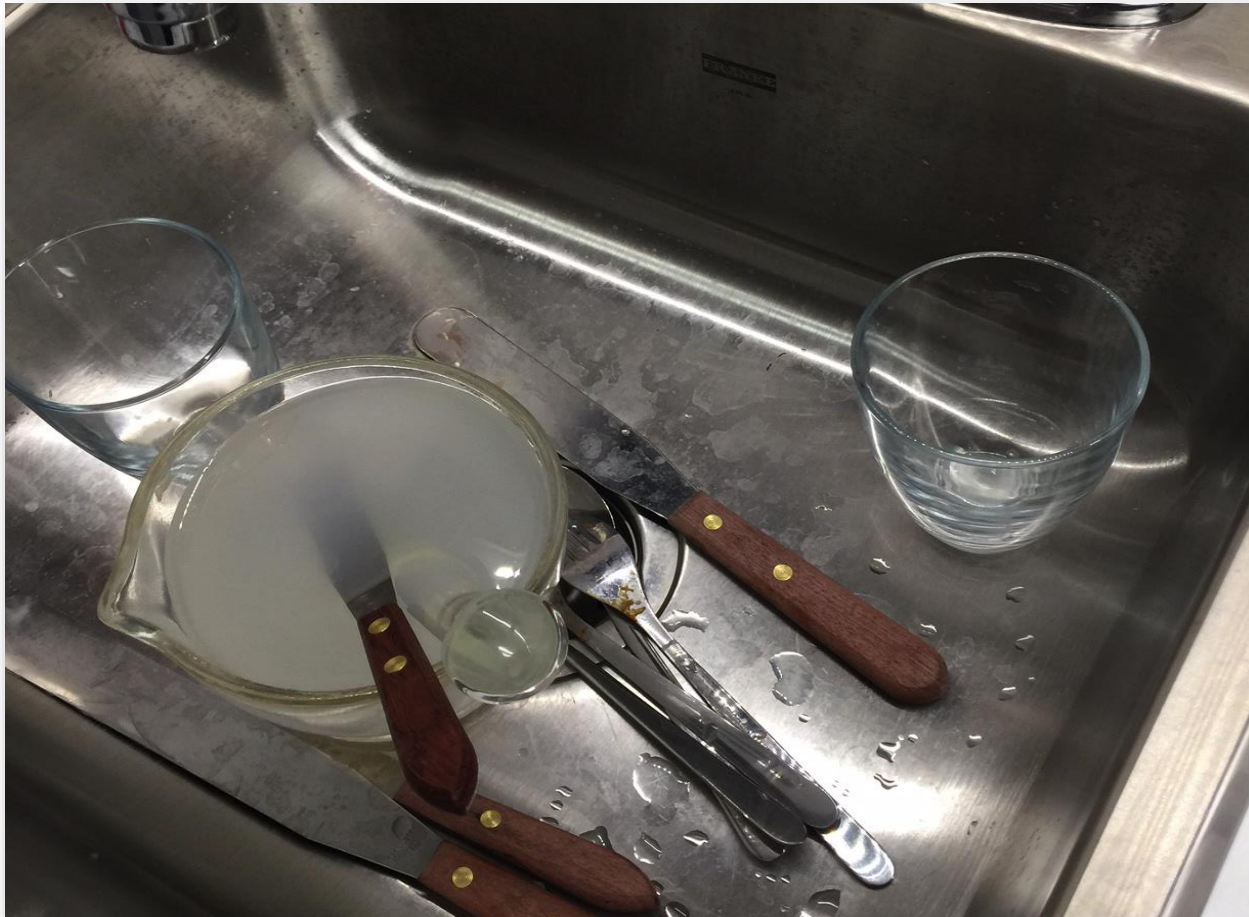
+ Regular Inspections

First Impressions



+ Regular Inspections

First Impressions



+ Regular Inspections

General Layout



+ Regular Inspections

General Layout



+ Regular Inspections

Documentation



+ Regular Inspections

Documentation

- General Documentation



+ Regular Inspections

Documentation

- General Documentation
 - “MY/MZ”



+ Regular Inspections

Documentation

- General Documentation
 - “MY/MZ”
 - DPIN checks



+ Regular Inspections

Documentation

- General Documentation
 - “MY/MZ”
 - DPIN checks
 - Continued Care



+ Regular Inspections

Documentation

- Patient Care



+ Regular Inspections

Documentation

- Patient Care
- Conversations with patients?



+ Regular Inspections

Documentation

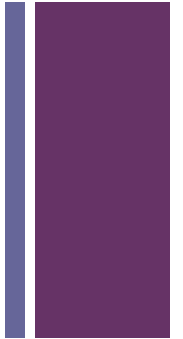
- Patient Care
- Conversations with patients?
 - Disease states



+ Regular Inspections

Documentation

- Patient Care
- Conversations with patients?
 - Disease states
 - Monitoring?



+ Regular Inspections

Documentation

- Patient Care
- Conversations with patients?
 - Disease states
 - Monitoring?
 - Interventions?



+ Regular Inspections

Documentation

- Patient Care
- Conversations with patients?
 - Disease states
 - Monitoring?
 - Interventions?
 - Documentation?



+ Regular Inspections

Documentation

- Narcotic prescriptions
- Conversations with patients?



+ Regular Inspections

Documentation

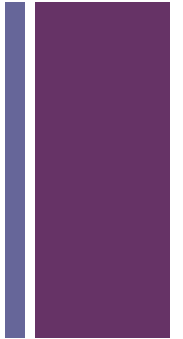
- Narcotic prescriptions
- Conversations with patients?
 - Indication?



+ Regular Inspections

Documentation

- Narcotic prescriptions
- Conversations with patients?
 - Indication?
 - Early fills?



+ Regular Inspections

Documentation

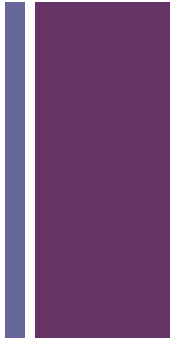
- Narcotic prescriptions
- Conversations with patients?
 - Indication?
 - Early fills?
 - Rationale?



+ Regular Inspections

Documentation

- Narcotic prescriptions
- Conversations with patients?
 - Indication?
 - Early fills?
 - Rationale?
 - Prescriber?



+ Regular Inspections

Documentation

- Narcotic prescriptions
- Conversations with patients?
 - Indication?
 - Early fills?
 - Rationale?
 - Prescriber?
- “Just fill it?”



+ Regular Inspections

Documentation – Narcotic Audits



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NARCOTIC & CONTROLLED DRUG ACCOUNTABILITY GUIDELINES

Goal: To establish self monitoring procedures for pharmacy managers, which will provide accountability for narcotic and controlled drug transactions, detect drug diversion, and deter pilferage.

Required Procedures:

The specific drugs included shall be all products covered under the Manitoba Prescribing Practices Program (M3P) previously known as the triplicate prescription program, and other such drugs as determined by Council and the College of Physicians and Surgeons.

Perpetual Inventory Records

Either manual count sheets or the equivalent in computer software may be used. Each pharmacy will establish a start count by completing a full physical count.


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Regular Inspections

Documentation – Narcotic Audits

- Perpetual Inventory



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Regular Inspections

Documentation – Narcotic Audits

- Perpetual Inventory
- Physical Inventory



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Regular Inspections

Documentation – Narcotic Audits

- Perpetual Inventory
- Physical Inventory
- Expired Narcotics and Patient Returns



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Regular Inspections

Documentation – Narcotic Audits

- Perpetual Inventory
- Physical Inventory
- Expired Narcotics and Patient Returns
- Change of Manager Inventory Count



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Regular Inspections

Documentation – Narcotic Audits

- Perpetual Inventory
- Physical Inventory
- Expired Narcotics and Patient Returns
- Change of Manager Inventory Count
- Reporting Discrepancies



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Regular Inspections

Documentation – Narcotic Audits

- Perpetual Inventory
- Physical Inventory
- Expired Narcotics and Patient Returns
- Change of Manager Inventory Count
- Reporting Discrepancies
- Acquisition Records



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Regular Inspections

Documentation – Narcotic Audits

- Perpetual Inventory
- Physical Inventory
- Expired Narcotics and Patient Returns
- Change of Manager Inventory Count
- Reporting Discrepancies
- Acquisition Records
- Random count



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+ Regular Inspections

Counselling Logs



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Practice Direction Patient Counselling

1.0 Scope and Objective:

1.1 Expected Outcome

This document is a practice direction by Council concerning implementation of concept of patient counselling through the authority of *The Pharmaceutical Regulations to The Pharmaceutical Act* and *The Pharmaceutical Act*.

1.2 Document Jurisdiction (Area of Practice)

he col all practi

+ Regular Inspections

Counselling Logs

Important Points

Practice Direction

Circumstances in which a dialogue is required

2.2 A ... pharmacist ... must enter into a dialogue with a patient:

2.2.1 when a Schedule I drug is dispensed to a patient...

+ Regular Inspections

Counselling Logs

Important Points

- Pharmacist must talk to the patient

Practice Direction

Circumstances in which a dialogue is required

2.2 A ... pharmacist ... must enter into a dialogue with a patient:

2.2.1 when a Schedule I drug is dispensed to a patient...

+ Regular Inspections

Counselling Logs

Important Points

- Pharmacist must talk to the patient
- Refills

Practice Direction

Circumstances in which a dialogue is required

2.2 A ... pharmacist ... must enter into a dialogue with a patient:

2.2.1 when a Schedule I drug is dispensed to a patient...

2.14 For ... refill(s), the ... pharmacist ... may exercise professional judgment as to the content of the dialogue.

+ Regular Inspections

Counselling Logs

Important Points

- Pharmacist must talk to the patient
- Refills ≠

Practice Direction

Circumstances in which a dialogue is required

2.2 A ... pharmacist ... must enter into a dialogue with a patient:

2.2.1 when a Schedule I drug is dispensed to a patient...

2.14 For ... refill(s), the ... pharmacist ... may exercise professional judgment as to the content of the dialogue.

+ Regular Inspections

Counselling Logs

Important Points

- Pharmacist must talk to the patient
- Refills ≠ “do you have any questions for the pharmacist?”

Practice Direction

Circumstances in which a dialogue is required

2.2 A ... pharmacist ... must enter into a dialogue with a patient:

2.2.1 when a Schedule I drug is dispensed to a patient...

2.14 For ... refill(s), the ... pharmacist... may exercise professional judgment as to the content of the dialogue.

+ Regular Inspections

Counselling Logs

Important Points

Practice Direction

3.0 Documentation

3.1 Patient counselling must be documented and the information contained in the record would be dependent upon the judgment of the pharmacist performing the counselling.

+ Regular Inspections

Counselling Logs

Important Points

- Protection of Pharmacist

Practice Direction

3.0 Documentation

3.1 Patient counselling must be documented and the information contained in the record would be dependent upon the judgment of the pharmacist performing the counselling.

3.2 ...the ... pharmacist...must ensure that the refusal ... is documented in the record.

+ Regular Inspections



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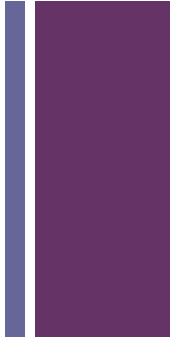
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+ Inspections



- New Store
- Regular Rotation
- Renovations
- Relocations
- Follow-ups
- Drop In Visits
- Inspections Due to Investigations

+ Inspections



- New Store
- Regular Rotation
- Renovations
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- Inspections Due to Investigations

+ Inspections

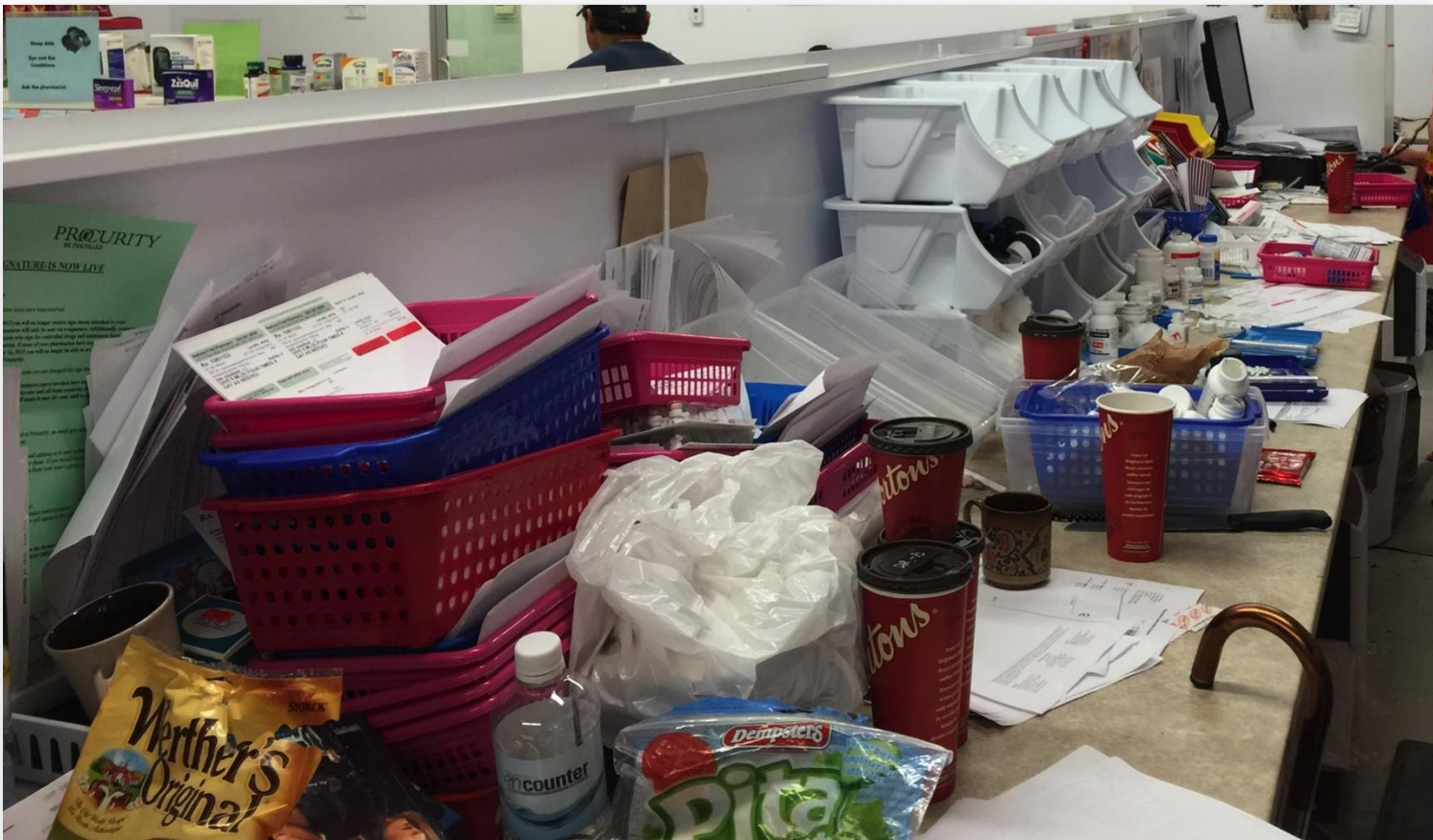


- New Store
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- Renovations
- Relocations
- Follow-ups
- Drop In Visits
- Inspections Due to Investigations

+ Drop-In Visits



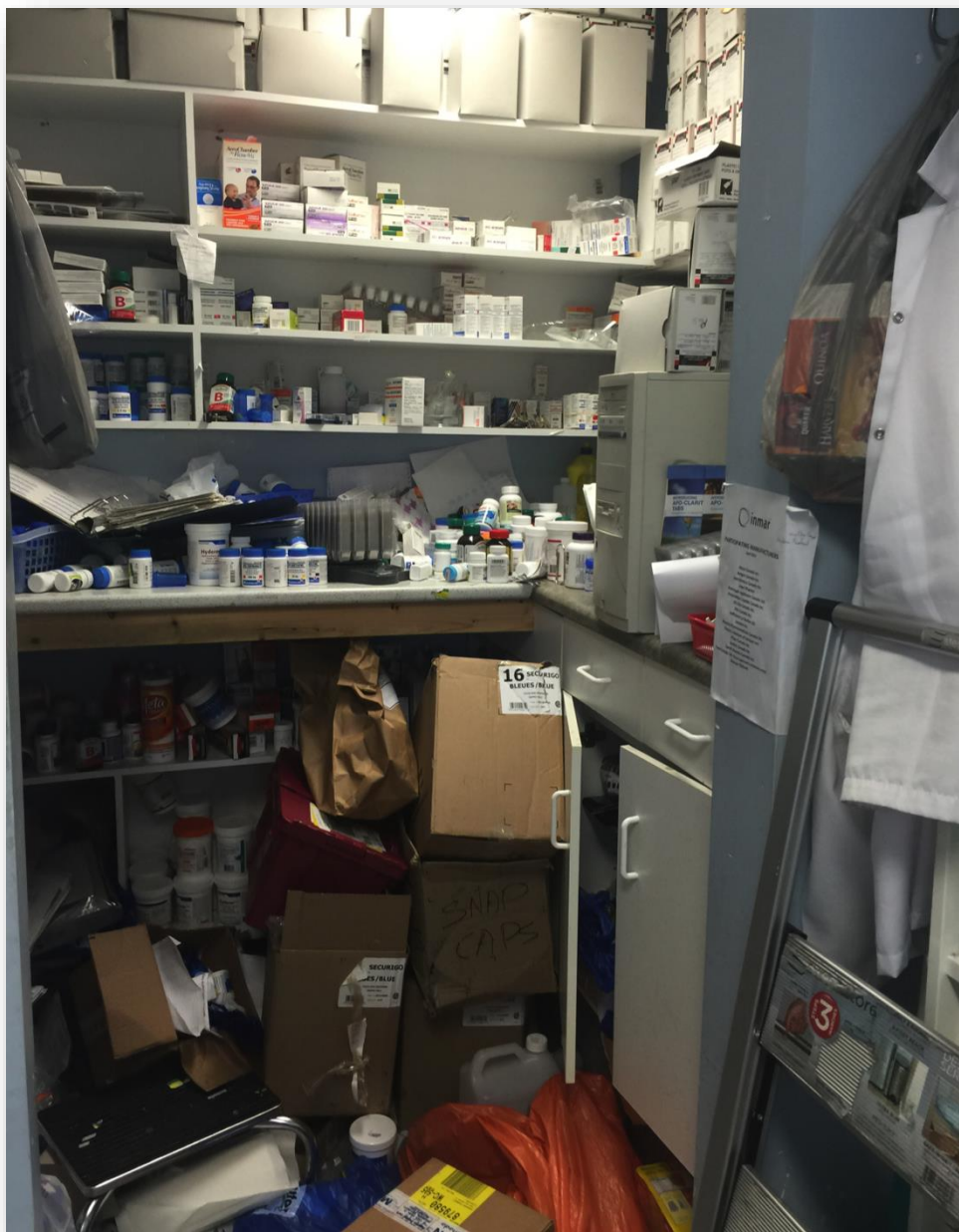
+ Drop-In Visits



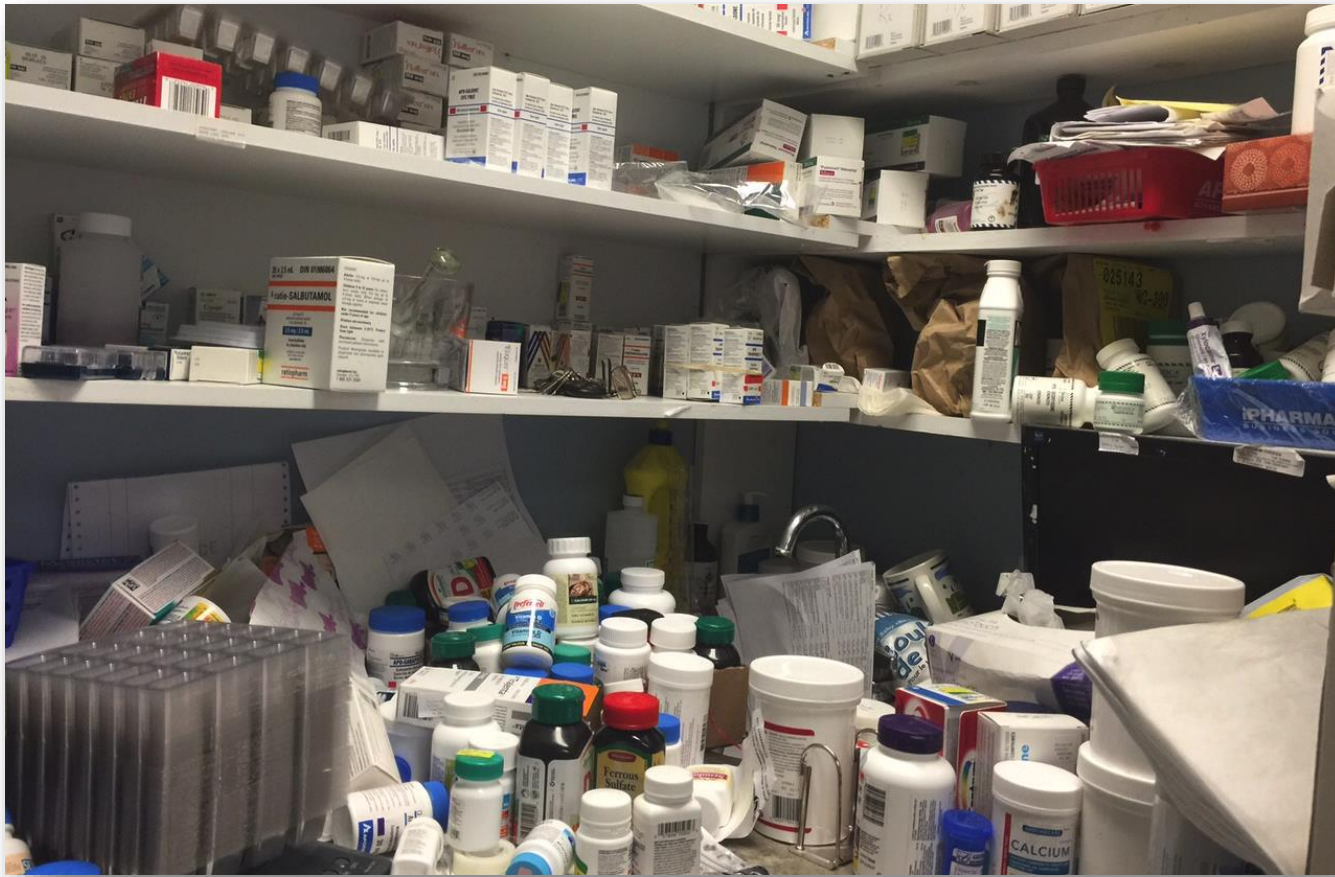


Drop-In Visits

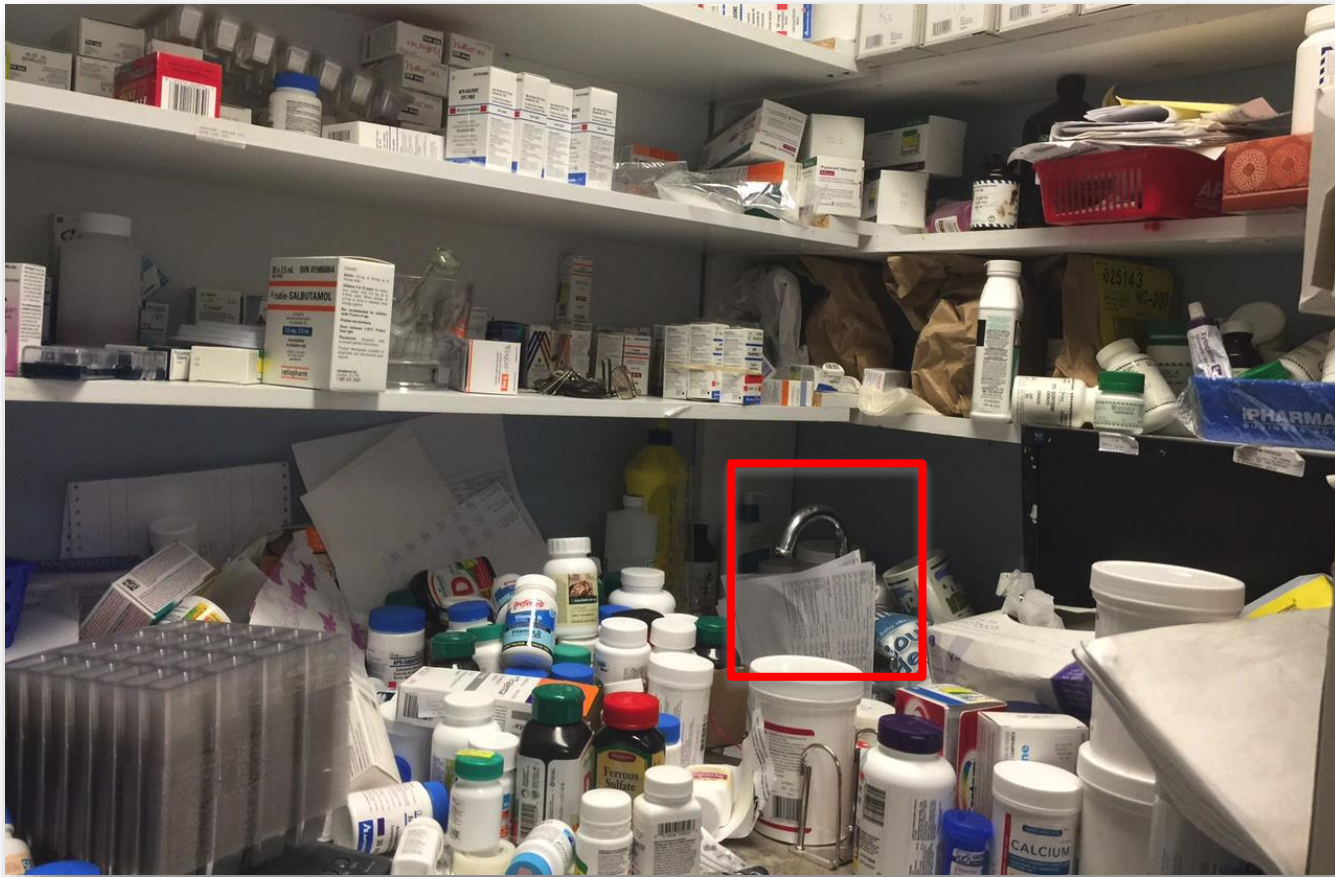
Is this safe?



+ Drop-In Visits



+ Drop-In Visits



+ A pharmacy in Alberta

It was shut down!

