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

ONE DOES NOT SIMPLY ASSURE QUALITY
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

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.
New Store Inspections
Preliminary Inspection

Important Points
- Ventilation, lighting

PDir: Pharmacy Facilities

College of Pharmacists of Manitoba
200 Tache Avenue, Winnipeg, Manitoba R2H 1A7
Phone (204) 233-1411 | Fax: (204) 237-5468
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)

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.
New Store Inspections

Preliminary Inspection

Important Points

- Ventilation, lighting
- 150 square feet dispensary

PDir: Pharmacy Facilities

College of Pharmacists of Manitoba

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2.0 Practice Direction

2.1...
New Store Inspections

Preliminary Inspection

Important Points

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

PDir: Pharmacy Facilities

College of Pharmacists of Manitoba
200 Tache Avenue, Winnipeg, Manitoba R3H 1A7
Phone: (204) 233-1411 | Fax: (204) 237-5408
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2.0 Practice Direction

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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

Practice Direction
Standard of Practice # 15: Pharmacy Facilities

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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
- Privacy, privacy, privacy

PDir: Pharmacy Facilities

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2.0 Practice Direction
New Store Inspections

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
New Store Inspections

Pre-Opening Inspection
The College of Pharmacists of Manitoba
200 TACHE AVENUE, WINNIPEG, MANITOBA R2H 1A7
TELEPHONE (204) 233-1411 FAX: (204) 237-3468 E-MAIL: info@cphm.ca

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

<table>
<thead>
<tr>
<th>Pharmacy:</th>
<th>CPhM Licence</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td>City</td>
<td>Postal Code</td>
</tr>
<tr>
<td>Phone #1</td>
<td>Fax #1</td>
<td>E-Mail Address #1</td>
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<tr>
<td>Phone #2</td>
<td>Fax #2</td>
<td>E-Mail Address #2</td>
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<td>Website #1</td>
<td>Website #2</td>
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</tbody>
</table>

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<thead>
<tr>
<th>Last Inspection Date:</th>
<th>Pharmacare #:</th>
<th>Pharmacy Licence Posted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Computer System:</td>
<td>Pharmacy Manager:</td>
<td>Licence Number</td>
</tr>
<tr>
<td>Store Business Hours:</td>
<td></td>
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<tr>
<td>Mon to Fri:</td>
<td>Staff Pharmacist(s):</td>
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<td>Sat:</td>
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<td>Sun:</td>
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</table>
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
**New Store Inspections**

**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**

The College of Pharmacists of Manitoba
200 Taché Avenue, Winnipeg, Manitoba, R2H 1A7
Telephone: (204) 233-1481 Fax: (204) 233-9408 E-mail: info@cpmh.ca

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<tr>
<td>Phone #1</td>
<td>Fax #1</td>
<td>E-Mail Address #1</td>
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<tr>
<td>Phone #2</td>
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<td>Website</td>
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</tbody>
</table>

Last Inspection Date: [ ]

Computer System:
- [ ] Pharmacy Manager:
  - License Validation: [ ] Full Time: [ ] Part Time: [ ]

Store Business Hours:
- Mon to Fri:
  - Staff Pharmacist(s):
    - [ ]
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Sundays:
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Holidays:
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Pharmaceutical Hours (i.e., Lock and Leave):
- Mon to Fri:
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Employee Services:
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Prescriptions:
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Mail Order Service:
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Delivery Service:
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Interprofessional Relations:
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Patient Care:
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Care Plan Development:
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Continuing Education:
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In-Service Training:
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Supervision:
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Performance Evaluation:
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Satisfaction Survey:
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Quality Improvement:
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Ongoing Monitoring:
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Patient Education:
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Survey Administration:
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Filling, Dispensing, and Service:
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Refill, Second Prescriptions:
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Other Services:
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Please list components of our pharmacy that you are not currently providing:
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New Store Inspections

Pre-Opening Inspection

Important Points

- Answer as accurately as possible

Q/A Self-Assessment
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

[Image of Q/A Self-Assessment form]

The College of Pharmacists of Manitoba
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Telephone: (204) 233-1481 Fax: (204) 237-3408 E-mail: info@cpbm.ca

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<td>E-Mail Address</td>
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<td>Home:</td>
<td>Fax</td>
<td>E-Mail Address</td>
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<tr>
<td>Website:</td>
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</tbody>
</table>

Last Inspection Date: 

Pharmacy #: 

Pharmacy Licenses Period: 

Computer System: 

Pharmacy Manager: 

License Status: 

Part Time: 

Full Time: 

Store Business Hours: 

Mon to Fri: 

Staff Pharmacist(s): 

Sat: 

Sun: 

Holidays: 

Dispensary Hours (i.e. Lock and Leave): 

Mon to Fri: 

Sat: 

Sun: 

Holidays: 

[Below is a list of components of a pharmacy's services, including refill, second prescription, etc.]

Care Hours
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;”
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”
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*

**DPIN REQUIRES 4-6 WEEKS NOTICE**

1) **Pharmacy Information**
   - Change of information - Please indicate effective date
   - New application - Please indicate opening date

<table>
<thead>
<tr>
<th>Trade Name of Pharmacy/Dispensary</th>
<th>Pharmacare Number</th>
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<tbody>
<tr>
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<table>
<thead>
<tr>
<th>Legal Name of Pharmacy/Dispensary</th>
<th>Pharmacy License No. (as shown on M.Ph.A. License certificate)</th>
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<tbody>
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<table>
<thead>
<tr>
<th>Site Address (Location of Pharmacy/Dispensary)</th>
<th>Mailing Address (different)</th>
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<thead>
<tr>
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<table>
<thead>
<tr>
<th>Telephone No. (Pharmacy)</th>
<th>Fax No. (Pharmacy)</th>
<th>Name of Contact</th>
<th>Telephone No.</th>
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2) **Ownership**

<table>
<thead>
<tr>
<th>Legal Name of Head Office</th>
<th>Mailing Address</th>
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</table>

3) **Type of Pharmacy**

<table>
<thead>
<tr>
<th>Organization</th>
<th>Independent</th>
<th>Own</th>
<th>Trade Name of</th>
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</table>
New Store Inspections
Post-Opening Inspection

30 – 90 Days Post-Opening

- Pharmacy Manager submits Q/A Self-Assessment within 30 days of opening
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
New Store Inspections
Post-Opening Inspection

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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
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
Inspections

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

College of Pharmacists of Manitoba
200 Tache Avenue, Winnipeg, Manitoba R2H 1A7
Phone (204) 233-1411 | Fax: (204) 237-3468
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Inspection Reply Form

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacy Manager:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Need form returned indicating compliance: Please indicate Y or N:</td>
<td></td>
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</tr>
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</table>

Upon resolution of the areas for improvement outlined below, please indicate that each item has been resolved by initialing each item separately. Prior to returning the Inspection Reply Form within the required 30 days, please ensure that the pharmacy manager signs the document as indicated in Part Five and return the document in full to the College by fax (204.237.3468) or email tmereniuk@cphm.ca.
Regular Inspections

How to Prepare?

Inspection Reply Form

Inspection Reply Form

Pharmacy: ___________________________ License No.: ___________________________
Address: ___________________________ Date: ___________________________
Pharmacy Manager: ___________________________
Need form returned indicating compliance: Please indicate Y or N: ___________________________

Upon resolution of the areas for improvement outlined below, please indicate that each item has been resolved by initiating each item separately. Prior to returning the Inspection Reply Form within the required 30 days, please ensure that the pharmacy manager signs the document as indicated in Part Five and return the document in full to the College by fax (204) 237-3468 or email inspection@cpmt.ca.

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 Records:

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Regular Inspections

How to Prepare?

- Complete the Q/A Self Assessment

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
Regular Inspections

How to Prepare?

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

Inspection Reply Form

College of Pharmacists of Manitoba
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Inspection Reply Form

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Pharmacy Manager:

Need form returned indicating compliance: Please indicate Y or N:

Upon resolution of the areas for improvement outlined below, please indicate that each item has been resolved by initializing each item separately. Prior to returning the Inspection Reply Form within the required 30 days, please ensure that the pharmacy manager signs the document as indicated in Part Five and return the document in full to the College by fax (204) 237-3468 or email info@cpmb.ca.

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
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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Inspection Reply Form

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<th>Report No.</th>
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<tbody>
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<td>Address:</td>
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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 Record:

...
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

College of Pharmacists of Manitoba
200 Tache Avenue, Winnipeg, Manitoba R2H 1A7
Phone (204) 233-1411 | Fax: (204) 237-3468
Email: info@cpmb.ca | Website: www.cpmb.ca

Inspection Reply Form

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7) Faxed Prescriptions:
8) Refill System:
9) Narcotic and Controlled Drug Record Keeping:
10) Storage and Disposal:

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Regular Inspections
Regular Inspections
First Impressions
Regular Inspections

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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?
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  - 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
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  - Indication?
  - Early fills?
  - Rationale?
Regular Inspections

Documentation

- Narcotic prescriptions
- Conversations with patients?
  - Indication?
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  - 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.

Received quantities (including medication dispensed, but not picked-up and returns from personal care home to the contract provider for re-dispensing) will be added to the start count, and dispensed drug will be subtracted from the total.
Regular Inspections

Documentation – Narcotic Audits

- Perpetual Inventory

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Regular Inspections

Documentation – Narcotic Audits

- Perpetual Inventory
- Physical Inventory
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

College of Pharmacists of Manitoba

NARCOTIC & CONTROLLED DRUG ACCOUNTABILITY GUIDELINES

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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
Regular Inspections

Documentation – Narcotic Audits

- Perpetual Inventory
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- Acquisition Records

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NARCOTIC & CONTROLLED DRUG ACCOUNTABILITY GUIDELINES

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Regular Inspections

Documentation – Narcotic Audits

- Perpetual Inventory
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- Expired Narcotics and Patient Returns
- Change of Manager Inventory Count
- Reporting Discrepancies
- Acquisition Records
- Random count
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)
## Important Points

<table>
<thead>
<tr>
<th>Practice Direction</th>
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<td><strong>Circumstances in which a dialogue is required</strong></td>
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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…
## 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

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# Regular Inspections

## Counselling Logs

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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:

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2.14 For …refill(s), the …pharmacist…may exercise professional judgment as to the content of the dialogue.
### 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.
### 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.
### Inspection Reply Form

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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
- Relocations
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Inspections

- New Store
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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!