COLLEGE OF PHARMACISTS OF MANITOBA

Practice Direction: Controlled Substance Accountability

Scope and Objective

1.0 Expected Outcome

1.1 This document is a practice direction by Council concerning controlled substance accountability. This practice direction establishes requirements for pharmacy professionals to deter drug diversion and to promote controlled substance security and accountability.

1.2 Controlled substances must be secured by all reasonable steps necessary. This practice direction establishes minimum requirements. The pharmacy manager is required to implement additional polices, procedures and security measures when required to maintain the security of controlled substances.

2.0 Document Jurisdiction

2.1 All pharmacists and pharmacy owners are expected to adhere to this practice direction.

3.0 Definitions

3.1 "Controlled Drug" is a substance set out in schedule 2 of the Controlled Substances Regulations.
3.2 "Controlled Substance" is any narcotic, controlled drug or targeted substance as laid out in Schedules I, II, III, IV or V of the *Controlled Drugs and Substances Act*.
3.3 "Discrepancy" is any deviation (higher or lower) between the pharmacy's perpetual inventory, and the actual counted inventory of a controlled substance.
3.4 "Facility" is the licensed community pharmacy, or the hospital containing a licensed hospital pharmacy.
3.5 "Licensed dealer" is the holder of a licence issued under subsection 12(1) of the Controlled Substances Regulations.
3.6 "Narcotic" is a substance set out in schedule 1 of the Controlled Substances Regulations.
3.7 An "other person" refers to an individual described in section 64 of the Pharmaceutical Regulation.
3.8 "Perpetual Inventory" is a real-time inventory recording document that accurately records the quantities of controlled substances received, on hand, dispensed, otherwise distributed, or destroyed.
3.9 "Targeted Substance" is a substance set out in schedule 3 of the Controlled Substances Regulations.

3.10 "Unserviceable stock" is drug product containing a controlled substance that is unused, expired, and/or that cannot be dispensed for some reason.

3.11 "Patient returns" are drug product containing controlled substances that are returned to the pharmacy by a member of the public for the purpose of destruction.

3.12 "Reconciliation" is the process of matching and comparing different sets of records to ensure they agree. It is meant to identify any discrepancies between the records.

Practice Direction

4.0 Access, Accountability, and Supervision

4.1 All pharmacists must ensure the security of all controlled substances in their possession.

4.2 The pharmacy manager must establish, implement, and maintain polices and procedures to ensure the security of controlled substances and to prevent, identify, and respond to theft, loss, or diversion.

4.3 Access to controlled substances must be limited to dispensary staff authorized by the pharmacy manager or pharmacist on duty. Pharmacists must directly supervise cleaning or maintenance staff if they are accessing an area where controlled substances are stored.

4.4 Access to controlled substances cannot occur in the absence of a pharmacist.

4.5 A pharmacist must supervise all activities involving access to controlled substances. The pharmacist(s) providing supervision and pharmacy manager remain responsible for the security of controlled substances even when activities, where appropriate and permitted by legislation, are conducted by a pharmacy technician, student or other person.

4.6 All pharmacists on duty are jointly responsible for ensuring appropriate supervision of pharmacy technicians or other persons.

5.0 Security and Storage

5.1 The pharmacy owner must ensure the pharmacy is equipped with physical security measures as outlined in the Practice Direction: Pharmacy Facilities.

5.2 The pharmacy manager must ensure physical security measures are utilized appropriately and policies and procedures for their use are established, implemented and maintained when required.

DRAFT

5.3 All pharmacy inventory of narcotics and controlled drugs, including unserviceable stock and patient returns, must be stored in the dispensary's safe when not in use. The safe must comply with the requirements of the Pharmacy Facilities Practice Direction.

5.4 All pharmacy inventory of targeted substances, including unserviceable stock and patient returns, must be stored in a secure location in the dispensary.

5.5 Passwords, codes and electronic signatures etc., for ordering and/or receiving controlled substances must be limited to the authorized individual they are issued to and cannot be shared.

6.0 Ordering Controlled Substances

6.1 Only pharmacists are permitted to order controlled substances.

7.0 Receiving Controlled Substances

7.1 All controlled substances, including those from a licensed dealer, another pharmacist or a hospital, must be received by a pharmacist or pharmacy technician and accounted for in the pharmacy's perpetual inventory.

7.2 All controlled substances must be delivered and received at the dispensary directly, or where direct delivery to the dispensary is not possible, delivered to a separate receiving area in the facility and immediately transferred to the dispensary.

7.3 When direct delivery to the dispensary is not possible, the pharmacy manager must ensure there are polices and procedures in place that ensure chain of custody is documented, the controlled substances are immediately brought to the pharmacy in the original container unopened, and a pharmacist or pharmacy technician receives the controlled substances.

7.4 A record of acquisition must be accurate, traceable and maintained for all controlled substance received, including those from another pharmacy (where permitted by the Controlled Substances Regulations), and must include:

- 7.4.1 the date the controlled substance(s) were received,
- 7.4.2 the printed name and signature/initials of the pharmacist or pharmacy technician who received the controlled substance(s),
- 7.4.3 the printed name and signature or initials of the person who entered the controlled substance(s) into the perpetual inventory,
- 7.4.4 in the case of a compounded controlled substance the name, form and quantity of the substance

DRAFT

7.4.5 in the case of a commercial product, the name, brand name (if applicable), the name of the controlled substance it contains, the form, strength, number of containers, the number of units per container (if applicable), and the Drug Identification Number (if any)

8.0 Perpetual Inventory

8.1 An accurate perpetual inventory must be established and maintained for all controlled substances.

8.2 A separate inventory must be maintained for unserviceable stock and patient returns.

8.3 All manual adjustments to the perpetual inventory must be authorized by a pharmacist and clearly documented. The documentation must include:

- 8.3.1 the reason for the adjustment,
- 8.3.2 the person who made the adjustment,
- 8.3.3 if the person who made the adjustment is not a pharmacist, the pharmacist who approved the adjustment, and
- 8.3.4 the date the adjustment was made.

8.4 The pharmacy manager must review all manual inventory adjustments at least once every three months for trends consistent with diversion or non-compliance with this practice direction. The review must be documented and include the printed name and signature/initials of the pharmacy manager and the date of the review.

8.5 Any concerns identified during the review of adjustments must be promptly reported to the pharmacy manager, investigated, and addressed with documentation that includes:

- 8.5.1 the concern(s) identified,
- 8.5.2 findings of the investigation,
- 8.5.3 corrective action taken, and
- 8.5.4 the date.

9.0 Physical Inventory and Reconciliation

9.1 The pharmacy manager must ensure all controlled substances, including unserviceable stock and patient returns, are physically counted and promptly reconciled against the pharmacy's perpetual inventory:

- 9.1.1 at least once every three months,
- 9.1.2 as soon as possible before and after a pharmacy relocation,

DRAFT

9.1.3 as soon as possible before a change in pharmacy manager if done jointly by the incoming and outgoing pharmacy mangers, or if a joint count and reconciliation are not possible, it must be done as soon as possible before and after the change in pharmacy manager,

9.1.4 as soon as possible before and after a change in pharmacy ownership, and

9.1.5 immediately after any event where controlled substances security was compromised.

9.2 The physical count must be supervised by a pharmacist, and the reconciliation must be completed by a pharmacist.

9.3 The physical count and reconciliation must be documented and reviewed by the pharmacy manager. The documentation must include:

9.3.1 the date the count and reconciliation were completed,

9.3.2 the perpetual inventory of each controlled substance, the counted inventory of each controlled substance, and the details of the reconciliation between the two if required,

9.3.3 the printed name and signature/initials of the person who completed the count and supervising pharmacist, if different,

9.3.4 the name and signature/initials of the pharmacist who performed the reconciliation if different from the pharmacist who performed or supervised the count, and

9.3.5 the name and signature/initials of the pharmacy manager.

9.4 Any identified discrepancies must promptly be dealt with as per section 10.

10.0 Investigating and Responding to Inventory Discrepancies

10.1 When a discrepancy between the actual inventory/physical count of a controlled substance and the perpetual inventory (or any other controlled substance inventory discrepancy) is discovered, it must be reported to the pharmacist on duty immediately and reported the pharmacy manager as promptly as possible.

10.2 The pharmacy manager must ensure all controlled substance inventory discrepancies are promptly investigated with documentation that is reviewed by the pharmacy manager. Documentation must include:

10.2.1 the concern(s) identified,

10.2.2 the results of the investigation,

10.2.3 the pharmacy manger's signature/initials,

10.2.4 any corrective actions taken, and

DRAFT

10.2.5 the date.

10.3 Following the investigation, the pharmacy manager must ensure the perpetual inventory has been corrected and evaluate whether procedural changes or preventative measures are required to prevent future discrepancies.

11.0 Reporting Loss or Theft

11.1 If a pharmacy technician or other person becomes aware of loss or theft of a controlled substance, they must immediately report it to the pharmacist on duty.

11.2 The Pharmacist who becomes aware of any loss or theft of a controlled substance must report it to the pharmacy manager as soon as possible and to the Health Canada Office of Controlled Substances and the College of Pharmacists of Manitoba within 10 days of discovery.

11.3 A copy of the report sent to Health Canada and CPhM must be retained at the pharmacy.

11.4 Any theft of a controlled substance must also be promptly reported to law enforcement.

11.5 Dispensed prescription forgeries are to be treated as theft. Attempted prescription forgeries where no drug was dispensed are not considered theft but must be reported to CPhM.

12.0 Controlled Substance Sales

12.1 A record of controlled substance sales must be maintained.

12.2 The pharmacy manager must review controlled substance sales at least once a month for trends consistent with diversion, and inappropriate dispensing. The review must be documented and include the printed name and signature of the pharmacy manager and the date of the review.

12.3 Any identified concerns must be promptly reported to the pharmacy manager, investigated, and addressed with documentation that includes:

12.3.1 the date,
12.3.2 the concern(s) identified,
12.3.3 the results of the investigation, and
12.3.4 the corrective action taken.

DRAFT

13.0 Disposal of Controlled Substances

13.1 When disposing of controlled substances, pharmacists must ensure the controlled substances are destroyed locally at the pharmacy or sent to a licensed dealer who is authorized by Health Canada to destroy them.

14.0 Disposal by Local Destruction

14.1 When conducting local destruction, the controlled substances must be altered or denatured to the extent that consumption becomes impossible or improbable.

14.2 Local destruction of controlled substances must be performed by a pharmacist or a pharmacy technician, and a witness that meets the requirements of the Controlled Substances Regulations.

14.3 Each time a controlled substance is destroyed locally the following information must be documented:

- 14.3.1 the name and address of the pharmacy,
- 14.3.2 the name, form, strength, drug identification number (if applicable) and quantity of the controlled substance,
- 14.3.3 the date of destruction,
- 14.3.4 the method of destruction, and
- 14.3.5 the printed names and signatures of the pharmacist or pharmacy technician, and witness conducting the destruction with a joint statement that certifies the substances were altered or denatured to such an extent as to render consumption impossible or improbable.

15.0 Sending to a Licensed Dealer for Disposal

15.1 When sending controlled substances to a licensed dealer for destruction, the pharmacist or pharmacy technician must ensure the licensed dealer is licensed to destroy controlled substances, obtain a written and signed order from the licensed dealer authorizing the return, and document the following information:

- 15.1.1 name, strength, and quantity of drug,
- 15.1.2 name and address of the licensed dealer to whom the controlled substances were provided,
- 15.1.3 the date it was provided,
- 15.1.4 the name of the pharmacist or pharmacy technician requesting destruction, and
- 15.1.5 a copy of the authorization to return the controlled substance.

DRAFT

16.0 Compliance Adjudication

16.1 All documentation must be readily accessible in physical or electronic format and open to regulatory review.

16.2 Controlled substance prescriptions and prescription records must be filed separately from other prescriptions/prescription records.

16.3 All documentation required by this practice direction must be retained for five years after the day on which the last record is recorded in the document.

17.0 Appendices

17.1 Not applicable.

A Practice Direction is a written statement made by Council for the purposes of giving direction to members and owners about the conduct of their practice or pharmacy operations. Compliance with practice directions is required under the Pharmaceutical Act.

The process for development, consultation, implementation, appeal and review is published on the College website.

Development Source:	Professional Practice Committee
Regulatory Reference:	Section XX and XX, the Pharmaceutical Regulation
Consultation Close:	M/D/Y
Authorized by Council:	M/D/Y
Effective Date:	M/D/Y
Revised:	M/D/Y
Review Due:	M/D/Y

DRAFT