College of Pharmacists of Manitoba

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

Practice Direction
Standards of Practice #6: Drug Distribution and Storage

1.0 Scope and Objective:

1.1 Expected Outcome

This document is a practice direction by Council concerning drug distribution through the authority of the *Pharmaceutical Regulations* to *The Pharmaceutical Act* and *The Pharmaceutical Act*.

1.2 Document Jurisdiction (Area of Practice)

Compliance is expected from all pharmacies in Manitoba.

1.3 Regulatory Authority Reference

Sections 56(1) and 56(2) of the *Pharmaceutical Regulations* to the *Pharmaceutical Act* empowers the Council to create a practice direction for drug distribution.

2.0 Practice Direction

2.1 Receiving and Storage

2.1.1 All products regulated by the *Controlled Drugs and Substances Act* (e.g. narcotic, controlled, and targeted substances, etc.) shall be delivered to the dispensary directly or, where applicable, to the receiving area and subsequently delivered to the dispensary forthwith;

2.1.2 The pharmacy manager shall be responsible to ensure established policy and procedures provide for the security of all drugs received during the time elapsed from the actual receiving until the drug is stored properly by dispensary staff;

2.1.3 The pharmacy manager shall be responsible to ensure established policy and procedures provide for the safe and secure storage of drugs when storage within the dispensary is not possible.

2.1.4 The pharmacy manager must ensure that drugs are stored in the pharmacy at the appropriate temperatures and under the appropriate conditions and in accordance with any manufacturer's requirements to ensure stability.

2.2 Temperature Sensitive Drug Distribution

2.2.1 The pharmacy must have a policy and procedure for ensuring the integrity of temperature-sensitive drugs during the transport, storage and handling of all temperature-sensitive drugs.

2.2.1.1 The pharmacy manager and pharmacy staff should review and follow *Manitoba Health Cold Chain Protocol – Vaccines and Biologics* for best practices.

2.2.2 Procedures and equipment must be in place within the pharmacy to ensure that pharmacists, pharmacy technicians and other pharmacy staff are trained and have the resources to protect the potency and effectiveness of these drugs.

2.2.3 Temperature sensitive drugs must also be appropriately maintained between time of dispensing and administration of the drug. Patients should be provided with education and instruction on proper storage and its importance in maintaining the integrity of the drugs. Protocols should also be in place for delivery personnel in this regard.

2.3 Security

2.3.1 The pharmacy manager must ensure all drugs are secured against theft, loss or diversion.

2.3.2 The pharmacy manager must ensure adequate procedures are in place to identify theft, loss or diversion of narcotic and controlled drugs, including but not limited to:

2.3.2.1 Maintaining a perpetual inventory of each drug listed under the Manitoba Prescribing Practices Program,

2.3.2.2 Performing and recording a physical count of both these drugs and expired and/or patient returned CDSA drugs at least once every three months.

2.3.2.3 Investigating any discrepancies identified,

2.3.2.4 Evaluating whether procedure changes or preventative measures are required to prevent future discrepancies,

2.3.2.5 Reporting any loss or theft of narcotic or controlled substances to Health Canada and the College within 10 days of discovery.

2.4 Disposal of Drugs

2.4.1 A pharmacy manager must ensure that:

2.4.1.1 All drugs and devices are checked for expiration dates as often as deemed necessary.

2.4.1.2 All expired drugs and devices are kept separately from other inventory until they are destroyed or returned to the supplier.

2.4.1.3 The pharmacy has procedures for safe and proper disposal of expired drugs and devices as required by provincial and federal legislation.

2.4.1.4 The pharmacy disposes of patients' returned drugs as required by provincial and federal legislation. The pharmacy accepts the return of unused or expired drugs and needles or other sharps used in the

administration of drugs for proper disposal unless doing so would pose a health risk or hazard to the pharmacy staff.

2.5 Drug recall procedures

2.5.1 The pharmacy manager should ensure there are policy and procedures in place for the handling of drug recalls.

2.5.2 All inventory of the affected lot numbers in the drug recall must be quarantined from other inventory as soon as possible.

2.5.3 When warranted, the pharmacy should identify and contact all of the pharmacy's patients affected by the recall, advise patients of the recall, address any concerns patients may have about the recall and counsel patients on the best way to mitigate any safety risks identified in the recall.

2.5.4 Pharmacy managers and key pharmacy staff should stay informed of Health Canada advisories and recalls by subscribing to Health Canada's MedEffect e-notice service.

2.6 Delivery (applicable to Community Pharmacies that provide the service)

2.6.1 A pharmacy providing a delivery service should have a policy and procedure for delivery of prescription and non-prescription drugs.

2.6.2 For all deliveries of prescription drugs, the pharmacist must ensure that the standards of practice for patient counselling are met.

2.6.3 If a drug pursuant to a prescription is to be picked up at a location other than the licensed pharmacy, the location must be under the control of a trustee (as defined in PHIA) or in a location as described in the practice direction entitled *Delegation of Dispensing to Other Health Professionals,* and the pharmacy manager must ensure that patient counselling has been provided as well as ensure the security and safe storage of the drugs.

2.6.4 Ensure proper storage of drugs that are being delivered and, in default of delivery, the drugs are returned to the pharmacy within 24 hours or as soon as possible.

2.6.5 In the interest of patient and public safety, the pharmacy should arrange delivery when the patient or an agent will be present to accept the delivery. Delivery receipts should be signed by the patient or agent to confirm receipt of drugs. Requests for leaving delivered drugs in a mailbox or doorway should only be honoured under extenuating circumstances, with documentation of professional judgment and rationale for the decision. The possible safety risks must be discussed with the patient.

2.6.6 Mail Service or Courier (applicable to Community Pharmacy)

2.6.6.1 The pharmacist must use a courier service, delivery service or postal method that has available signed proof of delivery, registered mail (or equivalent) for all narcotic, controlled and targeted substance prescriptions and retain the shipping receipt information for 60 days.

2.7 Drug Programs Information Network (DPIN) (applicable to Community Pharmacy)

The following must occur under DPIN:

2.7.1 "Days Supply" field must be filled in the DPIN system. Where dosages are suffixed by "prn" or indicate "ut dict", the day's supply should be calculated using professional judgment or calculated using the maximum dose resulting in a lower number of days supply;

2.7.2 When accessing the DPIN patient profile, as permitted under the Pharmaceutical Act of Manitoba and privacy legislation, without receiving a prescription for the patient, the pharmacist must:

2.7.2.1 confirm the identity of the person requesting the access and their authority to do so;

2.7.2.2 clarify the inquiry with respect to patient care;

2.7.2.3 document the name of the person and reason for inquiry in a readily retrievable manner;

2.7.2.4 retain this information for a period of 5 years.

2.7.3 Where critical patient care codes, MY (duplicate drug other pharmacy) or MZ (duplicate therapy other pharmacy), appear, either separately or in addition to other codes, from the DPIN with the filling of a prescription, the pharmacist must intervene and document the interventions on the DPIN and the patient record in the pharmacy;

2.7.4 Where all other patient care codes appear from the DPIN with the filling of a prescription, the pharmacist shall use professional judgment in the review, intervention and documentation of the response. If the review reveals that an intervention is critical to patient care, or results in a change in the prescription, the pharmacist shall document the response in the DPIN and the patient record in the pharmacy;

2.7.5 Where a pharmacist has become aware of an individual that is receiving a drug that is excessive or inconsistent with good medical care and where the pharmacist has not been able to solicit satisfactory response through consultation with the prescriber(s), the identity of the patient and circumstance is to be forwarded in writing to the office of the College of Pharmacists.

2.8 Other Electronic Systems

Access to personal health information must comply with the Pharmaceutical Act of Manitoba and privacy legislation.

2.9 Returned Drugs – refer to Section 85 of the Regulations

2.10 Compliance packaging (applicable to Community Pharmacy)

2.10.1 The pharmacy must establish a policy and procedure for compliance packaging within their pharmacy.

2.10.2 Proper hygiene procedures must be followed when placing dosage in the compliance packaging. Ongoing hand washing with a hypoallergenic soap, the use of rubber or latex free gloves and prevention of cross contamination, for patients with known anaphylactic responses to certain drugs, must be addressed in established policy.

2.10.3 Labeling of compliance packaging:

2.10.3.1 Drug appearance: The description of the drug must include the shape and colour of the dosage and may also include size, form and identifiable markings. The description must appear on the package or on a label affixed to the package.

2.10.3.2 Placement of labels: All labels must be affixed to the package.

2.10.3.3 Labeling requirements: All labeling information must be in compliance with section 71(1) of the Regulations to the Pharmaceutical Act.

2.10.3.4 Dosing time: Information must appear on the package indicating where the individual doses of the various prescriptions are to be found in the blister package (e.g. morning, noon, evening, or at bedtime). Further, the pharmacy must have a readily retrievable recording system in place, manual or on computer, to ensure current, consistent packaging and location of doses in the package, from refill to refill of the same drug.

2.10.3.5 Lot number and expiry date: The lot number and expiry date does not have to be identified if the packages are prepared pursuant to a prescription and have not been prepared in anticipation of receiving a prescription.

2.10.4 Child resistant closures: The pharmacy is responsible for informing the patient and caregivers that compliance packaging is not child resistant. Permission from the patient or caregiver for using non child resistant packaging must be documented and kept on file. The pharmacy should place an auxiliary label on the compliance packaging indicating the package is not child resistant if not preprinted on the packaging.

2.10.5 Packaging of specialized dosages: If a patient requires drugs over a shorter period of time than the total time span of the other drug(s) dispensed in the cycle, it is important the packages are numbered in order for them to be used in the correct sequence. If a drug is introduced that requires a special dosing regimen during the drug packaging cycle (i.e. 4,8,12 weeks) an additional package is recommended. The pharmacist should use their professional judgment in the packaging of drugs used on an “as needed” basis.

2.10.6 Type of packaging: The pharmacy must not dispense in compliance packaging any drug which is not appropriate for such packaging, according to the

manufacturer's directions, compendia sources or the pharmacist's professional judgment. Policy must be established for the appropriate packaging of drugs where physical and chemical form, light sensitivity, therapeutic incompatibility or risk of interaction with another drug in the compartment, could potentially reduce the effectiveness of the drug. When using a heat-sealing system, care must be taken not to disrupt the integrity of the dosage form.

2.10.7 Repackaging of returned drugs:

2.10.7.1 Any compliance packaged drug released to the patient and later returned to the pharmacy **cannot** be repackaged for **another** patient.

2.10.7.2 A pharmacist **may** accept the return of drugs to be repackaged for the **same** patient in incidents when a change in dosage has occur.

2.10.7.2.1 The pharmacy may repackage the drugs only **once** if using either the heat seal method of compliance packaging **or** does not track lot numbers and drug expiration dates.

2.10.7.2.2 The pharmacy may repackage the drugs until the drug expiration date if they use the cold seal method **and** track the lot numbers and drug expiration dates.

2.10.7.3 Changes in drug or dosage regimens: Upon notification of a change in drug or dose, the licenced pharmacist must use professional judgment in how the new dosage regimen is provided.

2.10.7.4 Provide an updated MAR (Medication Administration Record) when they are in use; within a reasonable time frame and in keeping with professional judgment.

2.10.8 A Medication Administration Record (MAR) will be supplied a minimum of once per cycle when MAR's are in use.

3.0 Documentation

3.1 Documentation is to be recorded in a readily retrievable manner either electronically or in written form.

4.0 Compliance Adjudication

4.1 All documentation must be readily accessible and open to regulatory review

5.0 Appendices

Not applicable

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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 been published on the College website.

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