College of Pharmacists of Manitoba

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Practice Direction: Compliance Packaging

Scope and Objective

1.0 Expected Outcome

1.1 This document is a practice direction by Council concerning compliance packaging through the authority of the Pharmaceutical Regulation to *The Pharmaceutical Act* and *The Pharmaceutical Act*.

2.0 Document Jurisdiction

2.1 All community pharmacies providing compliance packaging are expected to adhere to this practice direction.

3.0 Regulatory Authority Reference

3.1 Sections 56(1) and 56(2) of the Pharmaceutical Regulation to *The Pharmaceutical Act* allows Council to create this Practice Direction.

4.0 Definitions

4.1 "Compliance packaging" is a medication packaging system prepared by pharmacy staff that arranges a patient's medications in a manner that facilitates the convenient and straightforward self-administration of the medications.

Practice Direction

5.0 Initiating compliance packaging services

5.1 The pharmacy manager must establish policies and procedures for compliance packaging.

5.2 When initiating compliance packaging services for a patient, a pharmacist must:

- 5.2.1 provide the patient or caregiver with appropriate education regarding compliance packages and their proper use,
- 5.2.2 inform the patient and/or caregiver that compliance packaging is not child resistant, and
- 5.2.3 obtain and document permission from the patient or caregiver for using non-child resistant packaging.

6.0 Compliance Packaging Preparation

6.1 Only medications that are deemed sufficiently physically and chemically stable for compliance packaging can be packaged.

6.2 Multiple medications packaged together in a dosage compartment must be compatible under specified storage conditions.

6.3 Proper hygiene and where applicable procedures to limit cross contamination must be followed when placing dosages in the compliance packaging.

6.4 The pharmacy must have a readily retrievable recording system in place, manual or electronic, to ensure current, consistent packaging and location of doses in the package, from refill to refill of the same drug.

7.0 Final Check

7.1 The final check of a compliance package must include visual verification of each dosage compartment and that the labelling reflects the package contents.

8.0 Compliance Packaging Labeling

8.1 All compliance packaging must be labelled with a label affixed directly to the compliance package.

8.2 A compliance packaging label must:

- 8.2.1 comply with section 71(1) of the Regulation to *The Pharmaceutical Act*,
- 8.2.2 include a physical description of each drug contained in the package, and
- 8.2.3 identify where each drug can be found in the package (e.g. morning, noon, evening, or at bedtime).

8.3 "Not child resistant" must indicated on the compliance package.

9.0 Repackaging of returned drugs:

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

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

9.3 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.

9.4 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.

10.0 Changes in drug or dosage regimens:

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

11.0 Compliance Adjudication

11.1 All documentation must be readily accessible and open to regulatory review.

12.0 Appendices

12.1 Compliance Packaging Guidelines

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:	Standards of Practice Committee
Regulatory Reference:	Section XX and XX, The Pharmaceutical Regulations
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