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

Guideline: Compliance Packaging

1.0 Purpose

1.1 The purpose of this guideline is to elaborate on the Compliance Packaging Practice Direction and support pharmacy professionals in providing safe and quality compliance packaging. Not all elements of the Compliance Packaging Practice Direction are covered in this guidance document. This guideline applies to community pharmacy practice.

2.0 Initiating compliance packaging services

2.1 Policy and procedure: The pharmacy must establish policies and procedures for compliance packaging within their pharmacy. Compliance packaging policies and procedures should include a standardized work process and be regularly reviewed.

2.2 Equipment and training: When providing compliance packaging services, the pharmacy manager must ensure staff have the necessary knowledge and the pharmacy has appropriate equipment and physical space to properly provide compliance packaging services.

2.3 Patient Education: When a patient is starting compliance packaging for the first time, the patient or their agent must be informed that compliance packages are not child resistant and given appropriate education regarding the safe and proper use of compliance packages. The information provided is subject to professional judgement and may differ depending on the type of compliance packaging and the patient's circumstances.

2.4 Not child resistant containers: drugs can only be dispensing in non-child resistant containers if the requirements of section 81 of the Pharmaceutical Regulation are met. When dispensing drugs in compliance packaging permission from the patient or their agent for using non-child resistant packaging must be obtained in writing.

3.0 Compliance Packaging Preparation

3.1 Hygiene: 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.

3.2 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.

3.3 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.

3.4 Medication Administration Record: A Medication Administration Record (MAR) will be supplied a minimum of once per cycle when MAR's are in use. When there is a change in drug or dose, an updated MAR will be provided when they are in use; within a reasonable timeframe and in keeping with professional judgment.

4.0 Compliance Packaging Labeling

4.1 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.

4.2 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).

4.3 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.

4.4 Not child resistant: Compliance packaging must indicate that it is not child resistant. "Not child resistant" can be pre-printed on the compliance packaging, the pharmacy label or on auxiliary label that is placed on the package.