Newfoundland and Labrador Pharmacy Board

Standards of Practice

Standards for the Safe and Effective Provision of Compliance Packages

September 2015

1) Introduction

Compliance packaging is available in various formats including single medication blister cards, multi-medication blister cards, hard packs and strip packaging. Multi-medication compliance packaging offers a safe and effective approach to managing medication therapy by placing different medications in the same compartment, organized by dosing intervals. These compliance packages are generally appropriate for patients who have difficulty remembering to take medications correctly, but who are otherwise deemed capable of self-administration or for those with complex drug regimens when other methods to improve compliance have been unsuccessful. Some of the benefits of this approach to treatment include:

- Effective treatment of a condition requiring multiple medications through optimal dosing and incorporation of several medications (prescription and non-prescription) in one place;
- Better clarity and transparency of treatment through more effective communications between health professionals and patients; and
- Improved drug utilization.

Standards of Practice are minimum standards that all registrants are expected to meet. Regardless of position or practice environment, when a registrant performs a specific role, they must perform it to the level specified in the Standards of Practice and meet all of the standards associated with that role. These Standards describe the minimum expectations for pharmacists involved in the provision of compliance packages to patients and are intended to promote consistency in the provision of this service to the people of this province.

2) Operational Standards

Before deciding to participate in compliance packaging services, the pharmacist-in-charge must ensure that the following requirements are in place:

a) *Pharmacy Layout and Design*. The pharmacy must have the appropriate physical space and equipment including a preparation area that is free of distractions.

b) *Staff Complement*. The staffing of the pharmacy must be sufficient to meet the additional time requirements necessary for the safe and organized preparation of the compliance packages and clinical assessment.

c) *Staff Education*. All professional staff have the necessary knowledge and skills to participate in compliance packaging services.

d) *Policies and Procedures*. The pharmacy must develop, maintain and regularly review policies and procedures that outline workflow, documentation requirements, and how to handle special situation such as medication changes, etc.

3) Practice Standards

3.1. Patient Assessment

a) Prior to initiating the service, pharmacists should consider whether or not the patient would benefit from this type of package. Compliance packaging services should only be offered to those individuals for whom the benefits outweigh the inherent risks. Appropriateness of compliance packaging should be assessed though consultation with the patient (or the patient's agent) and his or her physician. This conversation should include an overview of the risks and benefits of the package, expectations respecting ordering refills, and notification of medication changes as well as any other circumstances the pharmacist feels the patient should be aware of up front. (Many of these elements will be discussed again when the patient picks up the packages for the first time. See section 3.5 for more on Pharmacist-Patient Consultation). This conversation as well as the patient's consent should be documented and retained as part of the patient record.

3.2. Packaging Requirements

a) When preparing compliance packages, the pharmacists shall ensure:

i) the drugs in each compartment are physically and chemically compatible;

ii) no drug interactions are likely to occur if the drugs are administered simultaneously;

iii) adequate steps are taken to protect the integrity of the dosage form by considering physical and chemical characteristics of the drug (e.g. heat or light sensitivity);

iv) awareness and implementation of any special packaging requirements;

v) professional judgment is utilized with respect to:
- the quantity dispensed;
- the number of medications contained in each compartment; and
- the inclusion of medications that are administered 'prn' (ideally, these medications should not be included in the package, but dispensed in a separate vial or compliance package);

vi) proper hygiene is used while packages are prepared (hand washing, use of disposable gloves, etc.);

vii) each drug can be visually identified without removing it from the package;

viii) each package is tamper-evident;

> **NOTE**: Cutting and resealing compartments to change their contents is not advisable as the practice makes evidence of tampering more difficult to determine. If a situation arises that require cutting and resealing compartments, the resealing must restore the package to that of being tamper-evident.

ix) there are sufficient checks implemented throughout the process to prevent errors or deficiencies (e.g. stock bottle check, label checks, DIN checks); and

x) that a final check of the package contents is performed including a visual verification of the contents of each compartment.

b) Medications should be packaged as soon as possible after being removed from the stock bottle to minimize atmospheric exposure and protect the integrity of the medication. If the packages are not going to be prepared right away, medications can be counted into prescription vials with all necessary DIN checks being performed. This allows for the stock bottles to be removed if needed to fill other prescriptions.

c) Once packages have been prepared, they must be stored appropriately until released to the patient.

3.3. Labelling Requirements

a) In addition to the labelling requirements outlined in the *Standard of Pharmacy Operation – Community Pharmacy*, the following information must be recorded on the compliance package label:

i) a description of each drug including dosage form, color, shape and other identifying characteristics;

ii) the dosing specifications for each medication, including time of administration (exact time or breakfast, lunchtime, afternoon, etc.) with emphasis on any medications that are taken at different frequencies (such as once a week); and

iii) in addition to the regular prescription numbers, each compliance package shall be numbered sequentially (i.e. “1 of 4”, “2 of 4”, etc.), if applicable.

> **NOTE:** If the package allows for the removal or separation of the individual compartments, each compartment must be individually labelled to identify each solid oral dosage form contained within.

3.4. Record Keeping

A recording system, either manual or computerized, for each patient must be in place and shall include information regarding the dosing specifications, the number of packages prepared and their sequence and any other information necessary to ensure consistent packaging and location of doses in the package, from refill to refill.

a) For each patient, a record of each prepared package must be maintained and include, at a minimum:

i) all prescription information for each drug in the package;
ii) the date prepared;
iii) the number of compliance packages prepared for the patient on that date;
iv) special instructions, if any;
v) dosage adjustments, if any;
vi) a printed grid (or similar illustration) that clearly depicts how medications are to be organized in each package to serve as a visual aid when preparing the packages and performing the final check; and
vii) the names of all pharmacy staff involved in the dispensing, preparation and final check of the package;

> **NOTE**: Although expiry dates and lot numbers are not required for the prescription label, it is a recommended practice to document both in the patient’s record, in the event the patient returns the medication for re-packaging following a dosage change or in the event of a manufacturer product recall.

3.5. Pharmacist-Patient Consultation

a) Prior to providing the compliance packages to the patient for the first time, the pharmacist must appropriately counsel the patient on the medication contained in the package (if applicable) as well as on the use and limitations of the package itself. This counselling should include, at a minimum:

i) instructions for using the package;
ii) storage requirements, including the fact that the package is not child-resistant;
iii) handling of lost or missed doses;
iv) ordering routines for refills; and
v) handling of changes to drug therapy (new drugs, dosage changes, etc.).

b) Subsequent to this initial conversation, the pharmacist should “check in” with the patient from time to time to ensure that no issues have been identified and that the patient’s understanding continues.

NOTE: In accordance with the *Standard of Operation – Community Pharmacy*, all applicable counselling, as well as the patient's (or agent's) consent to provide compliance packaging services, should be documented and retained as part of the patient's record.

3.6. Changes to Drug Therapy

a) If the pharmacy is notified of a change to the patient's drug therapy, the change must be assessed by a pharmacist to ensure the change does not affect the compatibility of the contents of the affected compartment and that the patient will not be adversely affected.

b) In case of a change to drug therapy, new packages should not be issued until the old packages are returned for repackaging or destruction.

3.7. Medication Returns

a) Medications previously packaged in a compliance package, but returned by the patient, may not be returned to inventory or used for another patient.

b) Medications previously packaged in a compliance package may be repackaged for use by the SAME patient in cases where a change in therapy has occurred. Should such repackaging occur, steps must be taken to ensure the integrity of the drugs with respect to packaging methods (heat seal, cold seal) and that the date of dispensing of the original package is documented.

NOTE: Medications previously packaged in a compliance package may only be used for repackaging if the expiry date and lot numbers were originally recorded and can be confirmed prior to repackaging.