Newfoundland and Labrador Pharmacy Board
Standards of Practice

Standards for the Provision of Compliance Packages

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Table of Contents

1) Introduction

Compliance packaging is a common service provided by pharmacies to assist patients with medication adherence. This form of packaging simplifies medication self-administration for patients managing complex drug regimens or who struggle with medication self-administration due to specific cognitive, physical, or sensory impairments. Other common benefits of this treatment approach include:

- optimization of dosing schedules, allowing for more effective treatment;
- integration of all medications (prescription and non-prescription) into a single package;
- better clarity and transparency of treatment through improved 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 registrants 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 met:

a) *Pharmacy Layout and Design*. The pharmacy must have the appropriate physical space and equipment for compliance packaging activities. The area in which compliance packages are prepared and verified must be well lit, organized and of sufficient size as well as being free from distractions, including other dispensary activities.

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 compliance packaging. This must take into account the need for appropriate, uninterrupted time at each stage of the preparation and verification process and the need for independent double checks at various stages of the compliance packaging process.

c) *Staff Education*. The pharmacist-in-charge must ensure that all staff involved in compliance packaging activities have the necessary knowledge and skills to do so. This includes training in the pharmacy's policies, procedures and standardized work processes for compliance packaging.

d) *Policies and Procedures*. The pharmacy must develop, maintain and regularly review policies and procedures related to the provision of compliance packaging services, including a defined, standardized workflow.

By definition, *policies* are clear statements that guide processes, procedures, and decision-making related to compliance packaging services; they are often based on standards of practice, but may extend beyond them. *Procedures* describe how each policy will be put into action in the pharmacy. For example, procedures should outline:

i) Who will do what;

ii) What steps they need to take;

iii) Which forms or documents to use; and

iv) How documentation is retained.

3) Practice Standards

3.1 Patient Assessment and Initial Consultation

a) Compliance packaging services should only be offered to those individuals for whom the benefits outweigh the inherent risks. Particular consideration should be given to the patient's cognitive and physical ability to self-administer medications within the packaging, or the presence of a designated caretaker to assist with administration. Appropriateness of compliance packaging should be assessed though consultation with the patient (or the patient's agent) and their physician.

> **PLEASE NOTE**: There may be various patient factors that contribute to non-adherence to prescribed medication regimens; for example, a patient may be uncertain of the benefits of a medication or concerned about adverse effects. As such, when assessing patients for provision of compliance packaging, pharmacists should discuss the patient's understanding of their medication regimen, as well as any concerns they may have, to prevent continued, intentional non-adherence.

b) Through consultation with the patient (or their designated agent) and a review of the patient's local and electronic health records, pharmacists must be reasonably assured that they are aware of all medications the patient is currently taking. Pharmacists should ask patients to bring all medications from home, including any OTC/herbal supplements, to the pharmacy prior to initiating compliance packaging so that all regular, long-term items may be included, where appropriate. This also allows used, expired and discontinued medications to be discarded safely.

c) Prior to initiating the service, a **pharmacist** must provide the patient with appropriate education regarding compliance packages and their proper use. **This conversation, as well as the patient's consent, must be documented and retained as part of the patient record**. This information should include, at a minimum:

i) instructions for using the package;

ii) safe storage requirements, including the fact that the package is not child-resistant;

iii) ordering routines for refills;

iv) how lost or missed doses should be handled;

v) how regimen changes, including mid-cycle changes, are handled; and

vi) how "as needed", short-term (e.g. antibiotics), and irregular dosing medications (e.g. warfarin) will be packaged.

3.2 Packaging Requirements

a) Upon review of the prescription, a **pharmacist** must determine the appropriate dosing schedule for each medication. When determining this administration schedule, the pharmacist is expected to consider whether:

i) the number of medications in each compartment is appropriate;

ii) the timing of doses are appropriate based on each medication's mechanism of action, duration of action, compatibility with other medication(s) administered at the same time, and the patients daily activities; and

iii) the medications within each compartment and the package as a whole are physically and chemically compatible with each other and with the packaging method (e.g. heat seal).

b) As with all dispensed medications, in accordance with Section 3.1 a) of the *Standards of Pharmacy Operation - Community Pharmacy*, a **pharmacist** must carry out a clinical check for each medication contained within a compliance package **each time** the packages are prepared. This should be done prior to packaging and not be carried out during the final check of the packages, if these checks are performed by the same individual.

c) Prior to packaging medications, a **pharmacist or pharmacy technician** must also verify that the printed grid (or similar guide) that depicts how medications are to be organized in each pack, is accurate and reflective of the most recent prescription on file.

d) When preparing compliance packages, it must be ensured that:

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

   ii) proper hygiene is used while packages are prepared (hand washing, use of appropriate PPE, etc.);

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

   iv) each package is tamper-evident.

e) 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 stock bottles to be removed if needed to fill other prescriptions.

f) A final check of each package, including a visual verification of the contents of each compartment, must be performed by a **pharmacist or pharmacy technician**.

g) Once packages have been prepared, they must be labelled (see section 3.3 below) and stored appropriately until released to the patient.

3.3 Labelling Requirements

a) The compliance package label must include the following information:

   i) pharmacy name, phone number, and street address (if available, or, if not, a way of uniquely identifying the pharmacy location);

   ii) patient's first and last name;

   iii) prescriber's full name, or first initial and last name;

   iv) for single-entity products,
      - the strength and generic name of the drug and either:
        - the brand name;
        - the manufacturer; or
        - the Drug Identification Number;

   v) for multiple-entity products,
      - the brand name and strength (if applicable), or all active ingredients and their strengths, and either:
        - the manufacturer; or
        - the Drug Identification Number;

   vi) prescription number for each medication contained therein;

vii) date of dispense;

viii) quantity of medication dispensed;

ix) the directions for use 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);

x) identifying features of each medication in the package, including dosage form, color, shape and other identifying characteristics;

xi) quantity of medication remaining, or number of refills remaining;

xii) expiry date of prescription (one year from the date the prescription was written); and

xiii) appropriate auxiliary labels, as indicated.

PLEASE 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 Package Release

a) When releasing packages for the first time, pharmacists are expected to meet the usual patient counselling requirements, as stated in Section 3.8 of the *Standards of Pharmacy Operation - Community Pharmacy*. Additionally, a **pharmacist** should re-review the information provided as per section 3.1 c) above, at this time.

b) Subsequent to these initial conversations, the pharmacist should "check in" with the patient from time to time to ensure that the patient continues to understand the proper use of the package and that no issues have been identified.

3.5 Record Keeping

a) A recording system, either manual or computerized, must be in place for each patient. This must include any information necessary to ensure that prepared packages are consistent with the patient's current medication regimen. The preparation of each set of packages must be documented, including:

i) all prescription information for each medication in the package;

ii) lot number and expiry date of each medication in the package;

iii) the date prepared;

iv) the number of compliance packages prepared for the patient on that date;

v) special instructions, if any;

vi) dosage adjustments, if any;

vii) a printed grid, illustration, or image 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

viii) the names of all staff involved in the dispensing, preparation and final check of the package.

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 all components of Section 3.2 a) continue to be met.

b) For changes mid-cycle the patient should be requested to return the current pack for repackaging or exchange it for the updated packaging, prepared in advance.

c) If packages for the next cycle have already been prepared in advance and are awaiting pick-up, a process should be in place to "quarantine" the packages, ensuring they are not accidentally dispensed to the patient.

d) In all cases, pharmacy staff should avoid cutting and resealing compartments to change their contents

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.