

PHARMACY PRACTICE POLICY

Compliance Packaging

Introduction

Patient compliance with medication therapy has the potential to significantly impact patient health outcomes. Compliance packaging has been widely recognized by patients, caregivers and health care professionals to enhance patient compliance. Although advances in automation and delivery of compliance packaging have benefited patients, automation has the potential to introduce unique risks to the process and added checks and balances are required to provide for patient safety. Continuous quality assurance (CQA) programs should be in place to develop, maintain and enforce policies and procedures for compliance packaging services that comply with the NSCP Standards of Practice: Continuous Quality Assurance Programs in Community Pharmacies.

After consultation with, and with the consent of the patient (or patient's agent), a pharmacist may provide compliance packaging where appropriate.

Pharmacy professionals using automated equipment or centralized fill in the provision of compliance packaging are also responsible to comply with the NSCP Position Statement Automated Pharmacy Systems and the NSCP Policy Centralized Prescription Processing.

Purpose

This policy sets the expectations of community pharmacies, pharmacists and pharmacy technicians when providing compliance packaging. When a pharmacy is providing medication to an institution, such as a long-term care facility, provision of compliance packaging must also be consistent with the specific needs of the facility, local policies and procedures to ensure patient safety while preserving a patient's autonomy.

Definitions

Compliance package – A medication packaging system that arranges a patient's medications in a manner that facilitates the convenient and straightforward self-administration of the medications. The package is designed and labeled to indicate the day and time (or period of time) that the contents are to be taken by the patient. For the purpose of this policy, refillable dosettes that cannot be sealed such that individual blisters/compartments are tamper evident and /or which cannot be labelled appropriately are not considered to be "compliance packaging".

Tamper evident – a product that is packaged in such a way that it is obvious whether the product has been tampered with in any way after release from the pharmacy or supplier so that the accuracy and integrity of the contents of the package is in doubt.

Policy

I. Provision of Service – roles and accountability

I.1. Pharmacy managers:

- Ensure a standardized work process has been developed to dispense medications in compliance packages, including but not limited to:
 - a process to address mid-cycle and between cycle changes (including when packages are prepared in advance);
 - enabling pharmacy software alerts if available;
 - reviewing medications dispensed in the previous fill (e.g., the previous month if filling monthly); and
 - reviewing the patient profile to ensure verification with the most current prescription(s).
- Ensure that compliance packaging is part of the ongoing Continuous Quality Assurance process within the pharmacy.

I.2. Pharmacists:

- Comply with the processes established by the pharmacy manager as described in Section I.1.
- Complete an assessment of initial and ongoing appropriateness of drug therapy which also includes assessment of the optimal placement of the medication in the schedule.
- Be involved in the management of mid-cycle changes as they occur.
- Assess compliance and evaluate the patient for signs and symptoms of too high/too low of a dose when starting compliance packages, as previous medication non-compliance may have resulted in inconsistent ingestion of medications.

I.3. Pharmacists and pharmacy technicians when performing technical checks:

- Ensure each drug can be visually identified without removing it from the compartment.
- Ensure packaging is tamper-evident (refer to Definitions). Note: cutting and resealing blisters to change their contents is not advisable as the practice makes evidence of tampering more difficult to determine. However, situations may arise that require cutting and resealing blisters. In such situations, if a compliance package is opened, the resealing must restore the package to that of being tamper-evident, i.e., the patient or patient's agent can be confident of the accuracy and integrity of the contents of the package.
- Employ strategies to ensure accuracy when preparing packaging that includes uncommon dosage schedules (e.g., once weekly or tapering schedules).
- Ensure that the contents of each package/compartment is correct.

I.4. Pharmacists and pharmacy technicians provide technical information that includes but is not limited to:

- Instructions for using the packaging including how to interpret and navigate the label;
- Information on the placement of medication with unique dosing instructions (e.g., once weekly or alternate day dosing);
- Information on handling of missed or lost doses;
- Ordering routines for refills;

- Changes in drug therapy (new drugs, dosage changes, etc.);
- Storage requirements [avoid heat, light (package may not be UV protective) and humidity], and keeping out of reach of children, as compliance packages are not 'child resistant'; and
- The importance of returning any packages with unused drugs (so the pharmacist can follow-up with the patient or caregiver).

2. Return of Medications and Repackaging

- 2.1. Drugs returned by one patient cannot be re-dispensed for another patient. However, a pharmacy may accept the return of a compliance package from a patient for repackaging for the same patient in cases where a change in the therapy has occurred and where the pharmacist is satisfied that the integrity of the drugs has not been compromised.

3. Record Keeping

- 3.1. A system to record compliance packaging information for each patient must be in place and must record the information to ensure consistent packaging and location of doses in the package, from refill to refill.
- 3.2. Any records generated from compliance packaging are subject to the requirements set out in the Registration, Licensing and Professional Accountability Regulations.
- 3.3. The record of compliance packages prepared shall include the number of compliance packages prepared for each patient and the start date of the cycle.

4. Labelling

- 4.1. Each compliance package shall bear a label for each drug contained in the package that meets the requirements of the Prescription Labels Policy.

References

NSCP Automated Pharmacy Systems Position Statement

NSCP Policy: Centralized Prescription Processing

[Hand Hygiene Practices in Healthcare Settings, Health Canada](#)

NSCP Return of Medication Policy

NSCP Prescription Label Policy