

REGULATION POLICY

Guidelines for Implementation of Oral Multiple Medication/Compliance Packaging Regulations

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INTRODUCTION

Noncompliance can significantly impact health outcomes. Compliance packaging has been widely recognized by patients, caregivers and allied health care professionals to enhance patient compliance. After consultation with, and with the consent of the patient (or patient's caregiver), a pharmacist may provide compliance packaging where appropriate. The customized compliance package is a package of drugs comprised of a series of blisters or individually sealed compartments containing one or more prescribed solid oral dosage forms. The package is so designed and/or each compartment is so labeled as to indicate the day and time, or period of time that the contents within each compartment are to be taken.

These guidelines are directed towards pharmacies servicing patients within the community. They may also have applications in the institutional settings, however additional controls with respect to labeling, packaging and record keeping consistent with the policies of these institutions should be considered.

The goal of these guidelines is to provide patients with consistent, user-friendly compliance packaging.

I. PROVISION OF SERVICE

In addition to the points included in these guidelines, pharmacists must comply with all of the requirements pertaining to the provision of medication as stated in the *Pharmacy Act* and its regulations.

Pharmacists who are contemplating providing compliance packaging for their patients shall:

- Ensure they and their professional staff have the necessary knowledge and skills to properly provide compliance packaging services
- Ensure the pharmacy has the appropriate physical space and equipment
- Ensure the staffing of the pharmacy is sufficient to meet the additional time requirements necessary for the safe and organized preparation of the compliance packages

When preparing a compliance package, pharmacists shall:

- Take into account any drug interactions that may occur if drugs are administered simultaneously
- Ensure 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)
- Visually check the contents of each blister/compartment prior to sealing the package

- Be aware of and implement special packaging requirements
- Use professional judgment with respect to the number of medications provided in each blister/compartment
- Ensure each drug can be visually identified without removing it from the compartment
- Use professional judgment before including specialized doses such as prn drugs
- Ensure proper hygiene is used when preparing packages (frequent hand washing, use of disposable gloves, etc.)

Counseling shall include but not be limited to:

- instructions for using the package;
- handling of missed or lost dosages;
- ordering routines for refills;
- changes in drug therapy
- storage requirements

II. LABEL

- Each compliance package shall bear a label for each drug contained in the package that meets the requirements of legislation for prescription labeling.
- The label shall visually identify each drug in a manner that meets the needs of the patient.
- The label shall indicate the dosing specifications for each medication (i.e. the day and time (or period of time) that the contents are to be taken by the patient).
- In addition to the regular prescription numbers, each compliance package shall be sequentially numbered (e.g. 1/4, 2/4, 3/4, etc) where appropriate.
- In accordance with current legislation, expiry dates and lot numbers do not have to be identified on the label if the prescription has been prepared pursuant to a prescription and has not been prepared in anticipation of receiving a prescription. However, compliance packages cannot be repackaged for the same patient if the expiry date and lot number have not been recorded.

III. REPACKAGING

In compliance with standards of practice, drugs returned by one patient cannot be redispensed for another patient. However, a pharmacist may accept the return of a compliance package from a patient for the SAME patient in cases where a change in therapy has occurred. Should repackaging for the same patient occur, steps must be taken to ensure the integrity of the drugs with respect to packaging methods (heat seal vs. cold seal) If expiry dates/lot numbers have not been recorded, repackaging shall not occur.

IV. RECORD KEEPING

A recording system, either manual or computerized, for each patient must be in place and shall include information conforming to the dosing specifications (e.g. am, noon, pm, hs), 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 log of compliance packages prepared shall be maintained and include:

- the name of the patient
- the date prepared
- the number/dates of compliance packages prepared for each patient on that date
- the names of the pharmacy personnel that prepared and checked the compliance packages

V. FINAL CHECK

- As with all prescriptions, the pharmacist shall sign or initial the prescription hard copy indicating a final check of the completed compliance package
- Pharmacists shall take necessary steps to ensure the parcel released to the patient contains the correct compliance packages.