

NEWFOUNDLAND AND LABRADOR PHARMACY BOARD

Standards of Pharmacy Practice



Customized Patient Drug Packaging

Approved by the Newfoundland and Labrador Pharmacy Board February 5, 1995

Forward

In compiling this document, the Newfoundland Pharmaceutical Association (now the Newfoundland and Labrador Pharmacy Board) utilized standards and guidelines developed by various health care organizations and groups. In some cases, the language and material is directly transposed from the original documents. The reference list outlines the source of this material.

Notes

1. The verb “shall” indicates a mandatory requirement; “should” indicates a recommendation or that which is advised but not mandatory.
2. The term “patient” is used generically to designate patient, resident, client or inmate.
3. “Pharmacist” in the body of the text refers to a pharmaceutical chemist as defined in the Pharmacy Act.
4. The standards apply to services provided from publicly funded or private sector pharmacies
5. ***These guidelines do not interfere with guidelines established by the Department of Health and Community Services or any other governing body.***

Introduction

The customized patient drug package is a package of drugs comprised of a series of compartments and containing one or more prescribed solid oral dosage forms in each compartment. 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. Packages are for a specific patient and are prepared by the pharmacist or under the direct supervision of a pharmacist.

Owing to the inherent dangers associated with customized patient drug packaging only those individuals for whom the benefits outweigh the risks should be included in the program.

A pharmacist may provide a multidose package, with the consent of the patient, or the patient’s guardian or the patient’s caregiver and the physician.

Assessments for program eligibility shall be made by the pharmacist in consultation with the patient, the patient’s guardian or the patient’s caregiver and the physician.

1. PROVISION OF SERVICE

- 1.1 The pharmacist providing the multidose package has added responsibilities and liabilities with regard to product identification.
- 1.2 Each patient and/or patient caregiver shall be counseled on the customized patient drug-packaging program by the pharmacist. This counseling shall include but not be limited to:
 - Instructions for using the package
 - Handling of lost or missed dosages
 - Ordering routines for refills
 - Addition of new medications
 - Handling of order changes
 - Storage requirements, including the fact that the multidose package is not a child proof container.
- 1.3 The pharmacist, when preparing a customized drug package shall:
 - Take into account any therapeutic incompatibilities that may attend the simultaneous administration of the drugs
 - Take into account any applicable compendial requirements or guidelines

- Take into account the physical and chemical compatibility of the solid oral dosage forms placed within each compartment.
- Assure that each drug can be visually identified without removing the drugs from the compartment.
- Be aware of and implement special packaging requirements
- Number the packages sequentially, where applicable
- Not repackage drugs from customized drug packages and
- Take precautions to assure hygienic packaging.

1.4 All customized patient drug packages shall have the information on each individual package or shall have an accompanying information sheet for all solid oral dosage forms contained therein that:

- Visually identifies each solid oral dosage form in a manner that meets the needs of the patient
- Designates the generic name, strength and manufacturer or brand name and strength of each solid dosage form
- Includes full directions for use
- Contains storage instructions or cautionary statements required by official compendia and
- Contains other information, statements or warnings

2. LABEL

2.1 Each customized patient drug package shall bear a label indicating:

- Patient's Name
- Pharmacy control number identifying the patients drug package and a separate identifying prescription number for each solid oral dosage form contained therein
- Each solid oral dosage form in the compartment by:
- Brand name and strength, or generic name and strength in which case the manufacturer shall be indicated by name or code. When a drug is ordered by brand name and an alternate brand is dispensed, both generic and brand names should appear on the label by using the generic name followed by "For – (name of drug as ordered)" or
- Drug Identification Number (DIN), when deemed appropriate by the pharmacist after consultation with the physician or
- Ingredients or descriptive name (i.e. for compounded products)

EXCEPTION: *In specific circumstances such as drug studies or investigational drug use, this section may be replaced with a special code.*

- Total quantity dispensed of each solid oral dosage form
- Full directions for use and cautionary statements, if any, contained in the prescription order for each drug therein.
- Name of the physician prescribing for each solid oral dosage form
- Date of preparation and the beyond use date; which is 60 days from the date of preparation
- Name, address and telephone number of the pharmacy
- Dispensing pharmacist's name or initials

2.2 If the package allows for the removal or separation of the individual compartments therefrom, each compartment shall be individually labeled to identify each solid oral dosage form therein.

3. RECORD KEEPING

3.1 Individual prescription requirements as defined in the Federal Food and Drug Act and/or Regulations and the Pharmacy Act, Regulations and/or Bylaws shall be fulfilled.

- 3.2 For customized patient drug packaging, a record of each package shall be made and filed and shall contain as a minimum:
- The name, address and phone number of the patient and care giver, if applicable
 - The pharmacy control number of the customized patient drug package and the prescription number for each solid oral dosage form contained therein
 - The drug name and the manufacturer's name
 - Date of preparation and the beyond use date assigned
 - Number of packages prepared
 - Special labeling instructions, if any
 - Dosage adjustment, if any
 - Name or initials of the pharmacist checking the drug package
 - Date of patient counseling and the initials of the counseling pharmacist
- 3.3 Workload statistics should include but not be limited to
- Repackaging
 - Patient counseling and follow-up

GLOSSARY

Beyond use date:	the date after which the product should not be used. For customized patient drug packaging this date shall not be later than 60 days from the preparation date ¹
Caregiver:	the individual responsible for providing care to a person who is unable to administer drugs as prescribed.
Pharmacy Control Number:	a number assigned sequentially to each customized patient drug package prepared in the pharmacy.
Physician:	a person who is registered and entitled under the laws of a province to practice the profession of medicine.
Repackaging:	removal of a drug from manufacturer's original package and placing the drug in another form of packaging (including blister packaging).

REFERENCES

1. Alberta Pharmaceutical Association: Principles of Good Pharmacy Practice – Institutional Pharmacy, 1992
2. Saskatchewan Pharmaceutical Association Guidelines – Customized Patient Medication Packages, 1988
3. United States Pharmacopoeia: Pharmacy Board Bulletin, Customized Patient Medication Packages.

¹ United States Pharmacopoeia, Pharmacy Board Bulletin. April 3, 1981.