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| POLICY CATEGORY: | Governing the Membership |
| POLICY NAME: | Compliance Packaging |
| POLICY NUMBER: | GM-PP-CP-01 |
| ORIGINAL APPROVAL DATE: | November 22, 2021 |
| ORIGINAL MOTION NUMBER: | C-21-11-03 |
| LATEST REVISION DATE: | November 22, 2021 |
| LATEST MOTION NUMBER: | C-21-11-03 |

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New Brunswick College of Pharmacists
Ordre des pharmaciens du Nouveau-Brunswick

# GUIDELINE: COMPLIANCE PACKAGING

This Compliance Packaging Guideline is meant to support pharmacy professionals in providing quality compliance packaging in alignment with the New Brunswick College of Pharmacists' mission, *Governing the practice of pharmacy for a healthier New Brunswick.*

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## DEFINITIONS/ACRONYMS

**Beyond-Use-Date (BUD)**: Date before which the patient is advised to use the medication. This is different than the expiry date assigned by the pharmaceutical manufacturer.[1]

**Compliance Package**: A tamper-evident, well-sealed device or packaging system that allows for organizing doses of medicine according to the time of administration.[2] A "reusable dosette" is ***not*** a compliance package due to its inability to be tamper-evident (see definition below).

**ISMP Canada:** The Institute for Safe Medication Practices Canada is an independent national not-for-profit organization committed to the advancement of medication safety in all healthcare settings.

**NBCP/the College:** The New Brunswick College of Pharmacists

**Quality**: The degree to which a service increases the likelihood of desired health outcomes and is consistent with current professional knowledge focusing on effectiveness, efficiency, accessibility, patient-centredness, equity and safety.[3, 4]

**Quality Management Program (QMP)**: A program implemented to ensure and document ongoing quality management within pharmacy operations. This includes, but is not limited to, evaluating staff performance, equipment, facilities and adherence to Standards of Practice, including medication incident reporting and protection of patient confidentiality. Please refer to NBCP Regulations 14.2 & 20.2 and the College's QMP Guidance Document for further information.

**Tamper-Evident**: A package that has an indicator or barrier to entry which, if breached or broken or missing, provides visible evidence that alterations may have occurred after being dispensed.

## INTRODUCTION

Compliance packaging can be a means to improve safety, medication adherence and overall patient care. It reduces manual dexterity, cognition or vision required for the patient or caregiver to successfully administer the correct medication regimen. Production factors (required attention to detail, repetitive nature, environmental distractions) coupled with patient vulnerability (elderly, poor health and/or cognitive issues) introduces unique risks to the service. Compliance packaging may be beneficial for some, yet not suitable for all patients as it does not overcome all barriers to optimal medication management. A 2014 Multi-Incident Analysis by ISMP Canada has identified several specific medication errors in compliance packaging, including incorrect medication discontinuation, missed new prescriptions, incorrect times of administration and errors in labelling.[5,6] Provincial incident reports also affirm the need for added checks and balances to ensure safety and accuracy in compliance packaging.[7]

**GUIDELINE**

Provision of compliance packaging involves multiple steps. The Compliance Packaging Guideline (the Guideline) aims to enhance pharmacy professionals' understanding of the **Outcomes** (below) that support provision of safe, quality compliance packaging. Each **Outcome** in this document directs pharmacy professionals to existing applicable legislation, standards of practice, QMP policy and Code of Ethics they are responsible for while providing compliance packaging. Pharmacy professionals are also expected to apply relevant clinical practice guidelines, such as Pharmaceutical Society of Australia: Guidelines for Pharmacists Providing Dose Administration Aid Services

## Outcome 1: A Quality Management Program is established for safe compliance packaging

**Responsibility: Pharmacy Manager**

NBCP Regulations 14.2 & 20.2
MSOPs for Canadian Pharmacists: (3) Safety & Quality: 7-9
NBCP Quality Management Program Document
NBCP Mandatory Medication Incident Reporting Practice Directive

As established in the College's Quality Management Program (QMP) requirements, pharmacy managers must develop a QMP to ensure a quality compliance packaging program exists and is adhered to by staff. This includes:

1.1 Develop, implement, monitor, document and regularly update pharmacy's compliance packaging procedures

1.2 Establish adequate equipment, staffing, training, supervision and environment to ensure safe and effective compliance packaging

1.3 Establish and adhere to a process for documenting known, alleged, suspected medication errors, discrepancies, near misses and the steps taken to resolve them

## Outcome 2: Patients/caregivers receive orientation & education and are invited to collaborate in their care

**Responsibility: Pharmacist & Pharmacy Technician**

NBCP Regulations 17.16
MSOPs for Canadian Pharmacy Technicians: (1) Expertise in drug distribution systems: Section 27

Providing initial orientation, along with follow-up education and collaboration with patient and/or caregiver may help facilitate effective and continued safe use of compliance packaging.

2.1 This includes but is not limited to:

- Technical use and storage
- Alterations to medication regimens
- Lost or forgotten doses
- Unexpected changes to content or appearance

- Medications that cannot be provided in compliance pack (e.g., "as needed" medications, inhalers, patches)
- Return of unused doses to pharmacy for appropriate follow-up by pharmacist

## Outcome 3: Compliance Packaging is provided in the context of the patient care process

**Responsibility: Pharmacist**

Code of Ethics: Beneficence, Non-Maleficence and Respect for Persons
MSOPs for Canadian Pharmacists: (1) Expertise in medication & medication use: Sections 13 & 14
MSOPs for Canadian Pharmacy Technicians: (1) Expertise in drug distribution systems: Sections 7, 15 &16

Compliance packaging is a component of the overall patient care process.[8] Patient care processes must be applied in tandem with dispensing functions of compliance packaging. Pharmacists are expected to use their clinical skills and application of best available evidence to determine if compliance packaging is appropriate.[9]

3.1 Compliance packaging is provided to patients if it provides health benefit, honours patient's autonomy and does not increase risk of harm
- Patients must be initially assessed as requiring intervention to improve adherence
- Patients routinely receive follow-up assessment for clinical benefit and safe use of compliance packaging

3.2 Appropriate steps must be taken to solve compliance-aid/adherence related problems (e.g., collaboration with healthcare team, further patient education, adjustment of compliance packaging)

## Outcome 4: Dispense Safe Compliance Packaging

**Responsibility: Pharmacy Manager, Pharmacist & Pharmacy Technician**

NBCP Regulations 6.7(t), 17.30(1), 17.14, 20.6(d)
MSOPs for Canadian Pharmacists, Expertise in medications and medication use: Sections 40-42
MSOPs for Canadian Pharmacy Technicians: Expertise in drug distribution systems: Sections 25, 28, 29e, 33

It is imperative that compliance packages are produced to a standard of quality that ensures safety and accuracy of the product. This includes but is not limited to:

4.1 Cleaning
- Environment, equipment, supplies, work surfaces and hands must be cleaned frequently to prevent microbial contamination and cross-contamination
- Appropriate precautions taken when handling hazardous medications (NIOSH)

4.2 Packaging
- Only medications that are deemed sufficiently physically and chemically stable for compliance packaging can be packaged
- Stability and integrity of suitable medications must be maintained by minimizing exposure to air, heat and moisture during packaging
- Multiple medications packaged together in a dosage compartment must be compatible under specified storage conditions
- Each medication in multiple-medication packages must be visible for inspection

- Package must be tamper-evident
    - Pharmacist must use professional judgement if it is appropriate to modify existing package or create an entirely new package (i.e., mid-month dosage change)
    - Any modifications to package must be clearly identifiable as performed by the pharmacy (i.e., indicative auxiliary label or use of packaging repair tape)

4.3 Labelling

- Labelling must accurately reflect the prescription(s) and contents of each dosage compartment and be replicated in the directions displayed on the electronic health record
- In addition to requirements in NBCP Regulation 17.14, labelling must include:
- Clear directions for medications with unusual dosing schedules
    - A Beyond Use Date (BUD) of 60 days or the earliest expiry date of medications included if less than 60 days, when multiple medications are in the same package1
    - A BUD of one year or the expiry date of medication, whichever is sooner, when only one medication is in a package[1]
- When appropriate, packages must be numbered to indicate the order in which they should be taken (i.e., irregular dosing schedules)

4.4 Final Check

The final accuracy check must include visual verification of each dosage compartment and that the labelling, documentation and electronic health record reflects the package contents

## Outcome 5: Document steps in the clinical and technical processes

**Responsibility: Pharmacy Manager, Pharmacist & Pharmacy Technician**

NBCP Regulations 17.12, 17.20(1), 17.21-23

MSOPs for Canadian Pharmacists: (1) Expertise in medications and medication use: Sections 56-61MSOPs for Canadian Pharmacy Technicians: Expertise in drug distribution systems: Sections 37-44

Comprehensive documentation gives an accurate representation of a pharmacy's compliance packaging process.

5.1 All documentation must comply with established regulations and standards

5.2 Documentation must be in sufficient detail to permit accurate production of subsequent packages

5.3 Dispensing records (pharmacy software and provincial drug information system) must accurately reflect medications provided in compliance package

5.4 Final and interim accuracy checks must be documented

5.5 Documentation must be complete, readily retrievable, traceable and auditable to respond to potential subsequent:

- Medication incidents
- Quality Improvement initiatives
- Drug recall notices
- Inquiries from patient's healthcare team*

**Healthcare team includes patient and/or caregiver*

**RESOURCES**

New Brunswick College of Pharmacists Mandatory Medication Incident Reporting Practice Directive
New Brunswick College of Pharmacists Code of Ethics
NAPRA Model Standards of Practice for Pharmacy Technicians
NAPRA Model Standards of Practice for Pharmacists
Regulations of the New Brunswick College of Pharmacists
New Brunswick College of Pharmacists Quality Management Program Guidance Document
Institute for Safe Medication Practices (ISMP) Canada
Canadian Patient Safety Institute (CPSI)
NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016
Pharmaceutical Society of Australia: Guidelines for Pharmacists Providing Dose Administration Aid Services

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