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

Frequently Asked Questions: Compliance Packaging

These Frequently Asked Questions (FAQ) accompany the Guideline: Compliance Packaging. The responses provide expansion on the outcomes expressed within the Guideline.

**The FAQs below follow the presentation and order of the Outcomes within the Guideline: Compliance Packaging.*

Outcome #1:

Q1: Do I need to establish separate policies and procedures for compliance packaging?

A: There is a requirement for specific policies and procedures relating to the provision of compliance packaging. Pharmacy managers may wish to review all dispensing policies and procedures at their practice site with a compliance packaging lens. Policies and procedures could be integrated within existing documents or be stand-alone.

Specific policies and procedures for compliance packaging must minimally include:

- Appropriate patient/caregiver assessment and education (See Outcome 2&3).
- A thorough description of tasks involved in the preparation of medications in compliance packaging (See Outcome **#**4).
- Detailed description of checking procedures (See Outcome **#**4).
- Labelling (See Requirement 4.3).
- Documentation (See Outcome **#**5).
- Safe management of changes to therapy/dosage (See Outcome **#**2 and #4).
- Safe return of medications in compliance packaging (See Outcome **#**2).
- Quality Management processes, so that incidents and near-misses are consistently recorded and then used for practice improvement (See Outcome **#**1).

Outcome #3:

Q2. What should we do when a patient requests a change in the dosing schedule (time of administration or dosing frequency) of a particular medication in their compliance package?

A. If a patient is requesting a change in the dosing schedule of a particular medication in their compliance package, this presents an opportunity for the pharmacist to engage the patient in a discussion. It is important to understand why the request was made, what the patient's medication experience is and for the pharmacist to assess, within their scope of practice, if this change is appropriate and in the best interest of the patient's health. The pharmacist may decide to proceed in a variety of ways, including:

- Advise the patient the change is not appropriate and that it is best not to change the regimen. This requires thorough communication, listening and collaborating with the patient to determine the best strategy. If the patient is not satisfied, the pharmacist may implement a follow-up plan with the patient that could also include the patient's primary care provider.
- Prescribe the change themselves if a change is appropriate and within the pharmacist's scope of practice. Requirements set out in the Regulations, Standards of Practice and Code of Ethics must be adhered to.
- Contact the primary care provider to discuss the patient's concerns. This may result in an order to change the medication schedule.

Whichever manner the request is addressed, the pharmacist must actively work to respond to the patient's need, better their health and prevent harm. All discussions and interventions need to be properly documented (See Outcome #5) and appropriate monitoring and follow-up implemented. It is essential that the label and pharmacy electronic records reflect what is being put in the packages.

Outcome #4:

Q3: What measures are sufficient to prevent contamination of compliance packaging?

A: Important measures to prevent contamination include:

- **Hand hygiene** - between handling an individual patient's compliance packaging and medication and other items such as phones, pens and stock bottles.
- Use of properly cleaned tools such as long-nosed tweezers are considered a better practice, to minimize touching the medications.
- Donning of latex/rubber-free gloves and changing those between each patient. Refer to NIOSH recommendations for safe practices when handling hazardous drugs.
- Cleaning countertops and counting equipment regularly and in between each patient's compliance packaging.

Please refer to Pharmaceutical Society of Australia: Guidelines for Pharmacists Providing Dose Administration Aids Appendix 7 – Hand hygiene procedures

Q4: Do I need a separate area to prepare compliance packaging?

A: This will depend on the number of patients being supplied with compliance packaging, the types of technologies used and the prescription volume of the practice site. The pharmacy manager must ensure there is appropriate physical space and equipment for the type of packaging used.

Please refer to Pharmaceutical Society of Australia: Guidelines for Pharmacists Providing Dose Administration Aids "Preparation Area" for greater detail.

Q5: Our pharmacy staff has identified the potential for medication errors subsequent to patients presenting with a need for immediate changes to their compliance packages. The risk appears to be related to time pressures (whether actual or perceived) associated with changes to compliance packaging. Any tips for managing these scenarios?

A: Patient expectations are more easily managed if they are addressed when the patient or caregiver is initially introduced to compliance packaging (See Outcome #2). Investing that time may eliminate the need for rushed preparations and potential errors. Please refer to Pharmaceutical Society of Australia: Guidelines for Pharmacists Providing Dose Administration Aids "Communication" for examples.

Open communication with the patient's primary care provider may help streamline processes, by alerting them of simple actions that can assist in ensuring the compliance packages are prepared accurately and on time (e.g., a note on the prescription that a medication change must occur immediately or at the start of the next package) (See Outcome #2).

If a medication change occurs before the next set of compliance packages are due, the pharmacist must use professional judgement on how to address it. Whether the current package is altered, a new one is made, or an interim supply is provided using traditional vials, packaging must be accurate and provide clear instructions for dosing. Documentation must be sufficient to ensure that the next set of packages will be produced accurately, including notation of upcoming changes (See Outcome #5).

Q6: Can returned medication be repackaged for the same patient?

A: Dispensing returned medications to a new/distinct patient is considered unethical and contrary toregulation. A patient's **own** medication may be repackaged for themselves under specific conditions:

- The returned packages must be handled according to policy regarding quarantine and cleaning, as they are potential infectious disease vectors.
- The medication must appear intact and integrity of medication maintained, as assessed by the pharmacist or pharmacy technician to the best of their ability.
- Documentation must link the new package with the returned package for traceability and auditing and investigative purposes (See Outcome #5).

Q7: Our pharmacy prepares many compliance packages each day, and the same stock bottles are often needed for multiple packages. During final product check, there may be no stock bottles left with the packages. How can we create a safer process, and allow the person performing the final check to trust previous steps in the process?

A: Some pharmacy software systems have tablet identification programs and pharmacists or technicians performing visual checks can refer to the picture on the screen for comparison.

Other pharmacies have added a step, where tablets are counted out into labelled vials prior to packaging. In this scenario, a pharmacist or pharmacy technician will check the contents of the vial against the stock bottle and record that on the documentation, which frees up the stock bottle for the next order.

At the time of the final check, the pharmacist or pharmacy technician knows the stock bottle, DIN, lot number and expiry date have already been checked. This extra step also means the tablets/capsules are counted so if there is an extra or shortage of tablets when filling the packages, it prompts further investigation for the extra or missing dose, thereby decreasing the risk of error.

Q8: Does the package need to include a description (i.e., size, shape, colour, markings) of each medication?

A: Physical descriptions may allow patients to accurately identify the contents of compliance packages. The College does not require however, that compliance packaging include a description of the characteristics of the contents within the compliance package.

Q9: How do we consistently deal with packaging that requires uncommon dosing schedules? Patients are experiencing variations in how we prepare and label weekly doses and tapering regimens.

A: While compliance packaging is safest when patients are on stable medications, unusual dosing regimens (such as weekly or monthly frequency) and tapering doses can also be provided safely. Having a standard process for filling and labeling decreases the risk of errors (See Outcome #1). Documentation showing exactly how the medications were packaged in previous months ensures consistency and reduces error (See Outcome #5). Using copies of labelling, or even pictures of the packages from the previous month, may support that documentation.

Communication with the patient or caregiver to ensure their needs are being met will assist in preventing errors (See Outcome #2). Follow-up monitoring of returned packages should be implemented to guide ongoing decisions on how to package uncommon dosing schedules

Outcome #5:

Q10: What documentation is required beyond typical vial prescription dispensing documentation?

A: All details of the process must be documented; this may be done using a manual or electronic system. Additional documentation required beyond that of a "regular" prescription includes, at a minimum:

- lot number and expiry date from the stock bottle.
- the date packaging was prepared.
- number of compliance packages prepared for the patient on that date.
- special instructions, if any.
- description of the presentation of the package (such as a printed grid or similar illustration).
- names and signature of **any** pharmacy team member playing a role in **any** step of package preparation. Process must be auditable.

Associated with the label containing a grid/map of package contents, most software systems can generate a hardcopy report that records multiple prescriptions on a single page. Advantages to this option include condensing and simplifying record keeping requirements, meeting legal obligations and reducing waste. If these reports are used, they are to be treated as a refill hardcopy and retained as per Regulations 17.22 and 17.23.

Please refer to Pharmaceutical Society of Australia: Guidelines for Pharmacists Providing Dose Administration Aids "Documentation".

Q11: How should we best document changes?

A: The pharmacy manager must collaborate with staff to establish a process to record changes when initially moving from medications provided in vials/bottles to compliance packaging. There will be need for a separate process to record adjustments (i.e., medication, dose, frequency or time of administration) to ongoing compliance packaging.

When changes are made to medication regimens in the middle of a regular refill cycle, a process must be in place to ensure the change is made safely, reviewed by a pharmacist and documented such that the change is flagged for the subsequent refill. A discontinued or changed medication must be inactivated, and the drug file for the new medication reviewed so that labelling at the time of next refill is accurate.