



Compliance Packaging - Customized Patient Medication Packaging Guidelines

Non-compliance can significantly impact patient health outcomes. Compliance packaging has been widely recognized by patients, caregivers and allied health care professionals to enhance patient medication adherence. However, there are inherent dangers that can be associated with customized patient medication packages when not prepared accurately.

The goal of these guidelines is to increase the quality and safety of pharmacy processes with respect to customized patient medication packages /compliance packaging to decrease the potential of errors and unintended adverse events.

Good communication should be established between the caregiver, home care, physician, pharmacist and pharmacy staff to ensure everyone has the same current and accurate information regarding the patient's medication. Medication changes need to be communicated to all team members in a timely manner.

Prior to instituting compliance packaging services, the pharmacy manager, along with the pharmacy staff, needs to ensure the following:

- they and their professional staff have the necessary knowledge and skills to properly provide compliance packaging services
- the pharmacy has the appropriate physical space and equipment, ensuring there is an area that is free of distractions
- the staffing of the pharmacy is sufficient to meet the additional time requirements necessary for the safe and organized preparation of the compliance packages and clinical assessment
- a standardized work process has been developed

Preparing the Cards

In lieu of dispensing prescribed drug products in separate containers (vials), a pharmacist may, after consultation with, and with the consent of the patient, the patient's caregiver, or a prescriber, provide a customized patient medication package (compliance package) for the purposes of increased medication adherence. A patient compliance package is prepared under a pharmacist's supervision for a specific patient, comprising of a series of blisters or compartments, which may contain more than one prescribed solid oral dosage form. The patient compliance package is so designed, or each compartment is so labelled, as to indicate the day and time, or period of time, that the contents are to be taken.

When preparing a compliance package, pharmacists shall:

- review the patient's medication profile and history for drug interactions and other drug related concerns

- ensure compatibility of the contents of each compartment to be administered at the same time
- 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)
- be aware of and implement special packaging requirements
- ensure each drug can be visually identified without removing it from the package
- ensure each package is tamper-evident
- maintain proper hygiene while packaging (frequent hand washing, disposable gloves, etc.)
- ensure there are sufficient checks implemented throughout the process to ensure that any errors or deficiencies are eliminated e.g. stock bottle check, label checks, DIN checks, and visually check the contents of each blister / compartment prior to and after sealing the package

If the cards are not going to be made right away, medications can be counted into a labeled prescription vials with all necessary DIN checks being performed before the stock bottles are returned to the shelf. This allows for the stock bottles to be removed, if needed, to fill other prescriptions. However the DIN needs to be checked before the stock bottle is removed.

Labeling

In recognition of the different delivery systems available, the packaging must clearly indicate the following:

1. The patient compliance package shall clearly indicate:
 - a) the name of the patient
 - b) the name of the prescriber for each prescription
 - c) the prescription number for each prescription
 - d) the date dispensed
 - e) the name, strength, description and quantity of each prescription
 - f) the directions for each prescription
 - g) the name, address and phone number of the pharmacy
 - h) the name or initials of the pharmacist

Most computer software systems contain the ability to print medications grids/maps that contains all the above information. Although prescription labels are allowed, the medication grid is preferred because it is easier for the patient to read and allows them to confirm the accuracy of the cards.

2. If the **drug name** and **strength** is abbreviated on the back of each blister, the label must show the full name of the product and the corresponding abbreviation.
3. A **description** of each medication **must** be provided, either on the label or compartment, or as separate written information.
4. The **quantity** of each product in a compliance package may be shown as, for example:

- a) the total number per package (7/card, 14/card)
 - b) the dosage each day (1/day, 2/day), or
 - c) label each blister
5. The **directions** for each prescription may be shown on the label, or with graphics (medication map/grid) on the packaging or as separate written information.
 6. The label and all auxiliary information must be clearly visible.
 7. Each patient compliance package must be numbered sequentially with respect to the number of packages dispensed at one time; i.e. - 1/4, 2/4, 3/4, 4/4.

Patient/Auxiliary Information

The pharmacist must ensure that the patient, or the patient's caregiver, receives sufficient information, either verbal or written, to achieve optimal benefit from the medications. Along with specific medication education, counseling shall include, but not be limited to:

- instructions for using the packaging
- handling of missed or lost doses
- ordering routines for refills / Automatic refills
- changes in drug therapy (new drugs, dosage changes, etc.)
- storage requirements

Recording System

1. A recording system (electronic or manual) must be in place and include
 - a) information confirming dosing specifications (time of day)
 - b) the number of packages prepared
 - c) special drug integrity information, and
 - d) the complete patient medication list dispensed, including the date of dispensing and total quantities dispensed to allow subsequent preparation of an identical patient compliance package for the patient
2. Dose or drug changes from one month to the next should be documented either in the computer or on a paper copy of the medication map to ensure any changes are made to any subsequent cards. It is important to document who made the change and the date.
3. A medication map (grid) or similar process should be used when filling the cards in order to have a visual tool to ensure the accuracy of compliance packaging cards when preparing them and performing the final check.
4. Although expiry dates and lot numbers do not have to be identified on the prescription label, it is a recommended practice to document both in the patient's record. In the event the patient returns the medication for repackaging, the medications safety and integrity can then be confirmed.

5. A record is recommended to be kept including the names of the pharmacy personnel that prepared and checked the compliance packages.

Medication Changes

When medication orders change, the orders need to be confirmed by the pharmacist to ensure the new medication is compatible with the other medications taken at the same time and that there are no drug interactions and that the goals of therapy for the patients will be met.

No new cards should be issued until the old cards are returned for repackaging or destruction. The time of day that doses will be given should be agreed upon by the pharmacist and the patient or their caregiver.

All compliance packages that have not been picked up need to be taken apart in a timely manner and segregated from finished packages waiting to be picked up.

Return of Medications

Medications returned in a patient compliance package may not be returned to inventory. (Section 15 of Part J of the SCPP Regulatory Bylaws).

A pharmacist may accept the return of a compliance package from a patient for repackaging 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, cold seal) and that the date of dispensing of the original package is documented.

Compliance packaged drugs should not be repackaged if the expiry date and lot numbers have not been recorded.

Other Issues

1. No medications should be provided in prescription vials unless specifically requested by the patient or their agent (i.e. prns, warfarin) or it is not possible to provide in the compliance cards (i.e. inhalers, insulin) and reference should be made to these medications on the compliance label or medication grid.
2. It is recommended to have a schedule set up as to when patients are due for their compliance packaging card, as opposed to having patients notifying the pharmacy. This allows for the pharmacy to prepare the cards during designated low volume times.
3. Review the NIOSH *List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2014* for potentially hazardous drugs to ensure pharmacy staff are adequately protected when handling these medications.

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