

Compliance Packaging

ISSUES AND CONSIDERATIONS

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Compliance packaging helps address the need for patients to adhere to their medication schedule and is a practice that's been in place in long term care pharmacies for years. It is also becoming more common in community practice. This article is the first of two in a series focusing on compliance issues facing a community practice.

The basic objective behind dispensing medications in compliance packs is to assist patients (or their agents) in maintaining an administration schedule and thus optimizing the effectiveness of treatment.

Compliance packaging is one option that can be introduced when treating certain disease states, addressing cognitive impairment, managing a large number of medications, improving ease/efficiency of administration and convenience. Compliance packaging is available in various formats: single medication blister cards, multi-medication blister cards, hard packs and strip packaging. Each device is designed with compartments representing day of week and administration time; typically morning, noon, dinner and evening. It is important to note that, when



dispensing in compliance packs, the pharmacist assumes the responsibility and accountability for organizing the patient's medications in addition to dispensing and counselling functions associated with traditional prescriptions.

Another form of packaging

Compliance packaging is considered another form of packaging and, like the use of vials, must meet the minimum labelling requirements of the *Drug and Pharmacies Regulation Act* (DPRA). All compliance packs must therefore be labelled with the information that would appear if each drug had been dispensed in individual vials. However, when dispensing medications in compliance aids, OCP policies specify additional labelling and operational requirements, above and beyond those involved with the dispensing of traditional prescriptions. One purpose of this article is to promote adherence with all the labelling and record keeping requirements in an efficient, consistent and functional manner.

The decision to initiate dispensing medications in compliance packaging is usually made by the patient and/or family members/care giver in consultation with the primary treating physician. The circumstances prompting the need for compliance packaging must be established when initiating this treatment option or subsequently confirmed for patients currently receiving compliance packs. The reason(s) for introducing compliance aids will determine treatment objectives, quantities to dispense and whether compliance monitoring is necessary. The additional labelling requirements apply to all dispensed compliance packs, regardless of type or the condition(s) necessitating their use.

Labelling

While the traditional prescription label can be used, most dispensing software systems offer the option to generate a chart or grid prescription label. The chart label is designed to meet regulatory requirements as well as the added information requirements of the OCP policy. Associated with the chart label, most software systems also offer the option to generate a hardcopy report that records multiple prescriptions on a single page while satisfying the DPRA hardcopy requirements. Advantages to utilizing these options include condensing and simplifying labelling

and record keeping requirements while reducing waste and meeting legal obligations.

OCP policy requires that each drug be labelled with an identifier or descriptor. The identifiers should describe the shape, colour, relative size and unique markings of the tablet or capsule. The identifiers can be abbreviated to address the space constraints encountered with various label configurations provided the abbreviations provide enough detail that would enable the patient or caregiver to differentiate between medications contained in the compliance aid. Further, each drug should be labelled with the generic drug name. To facilitate adherence with the labelling requirements, most software systems have the identifiers and generic labelling programmed into the drug files. It is recommended that the pharmacy contact their software vendor for direction with selecting the correct format.

Other considerations

The dispensing of compliance packs introduces some operational considerations related to the filling of the packs, facilitating dose changes and managing medications that, due to dosage form or administration requirements, cannot be dispensed in the compliance pack. OCP policy requires that the pharmacy employ sanitary procedures when filling the compliance packs to prevent staff from having direct contact with the drugs. The main concern with direct contact is the potential risk to staff from absorption of drugs through the skin. The use of gloves is the most common solution to this requirement.

When dispensing compliance aids, "PRN" or "when needed" medications present special consideration. PRN medications must be dispensed in a separate container as they cannot be placed in the compliance pack. The quantities of PRN medications to dispense will be influenced by the patient's needs and should best be established up front, in collaboration with the physician. In some circumstances, there is a greater potential for misuse of the PRN medications by the patient simply because they are not placed in the pack. Similar concerns apply to the dispensing of creams and liquids.

Patient-specific filing system

To simplify record keeping, promote consistency and improve access to related documents, it is advantageous to

create a patient specific filing system for compliance pack patients. Each patient file would contain all documentation related to the patient (with the exception of the hardcopy which should be filed with the other prescription hardcopies). To improve ease of access to the patient information, consider organizing patient files alphabetically in a three ring binder(s). To improve functionality, the compliance pack binder(s) can be further organized by day the packs are processed and consulted when filling the compliance packs. A typical patient file could include, among other things, the current content of the compliance pack, authorizations for reductions in quantity, limited use forms, progress notes, lab test results, etc. In future, it may be possible to adopt a fully electronic filing system. However, as some physical documents are still required in some instances, it is advisable, at present, to maintain a physical file.

Authorization letters

The dispensing of compliance packs often requires direction from either the patient or the physician to authorize a reduction in the quantities of drugs dispensed. While it is a common practice to have the patient sign a letter for the reductions in quantities there are additional issues that can be incorporated into the letter. To condense record keeping requirements and promote collaboration and transparency, consider developing a three section letter that would be signed by the patient/agent, the primary treating physician and the Designated Manager; each section covering topics relevant to each signatory. A three part letter could be customized to each patient's circumstances and could include the following:

Patient/agent section:

- Direction with respect to reduction in quantity
- Direction with respect to who can accept delivery of prescriptions
- Acknowledgement that prescriptions are being dispensed in non-child safe packaging
- Patient consent for pharmacist to access test results ordered by the physician related to prescribed drug therapy
- Acknowledgement/outline of the pharmacy's "take back" program (to monitor compliance)
- Provision emergency contact numbers (family,

caregiver, etc)

- Approval/acknowledgement of pharmacy adding non-prescription drugs into compliance aid
- Issuance of receipts and other billing details including clear information about billing to third-party plans (if applicable)

Prescriber section:

- Acknowledgement/direction for the reductions in quantities dispensed and the condition necessitating dispensing medications in a compliance aid
- Acknowledgement of pharmacist's need to access relevant test results
- Define the number of doses to provide for PRN drugs (eg. analgesics, sleep aids, etc), creams and liquids

Pharmacist section:

This section should outline what the patient can expect from the pharmacist

- Pick-up and delivery times
- Destruction of drugs and personal health information
- Quality assurance procedures, use of gloves, checking of meds, review of program
- Meds-Check evaluations, how many or how often
- Consultation with physicians
- Any reports that pharmacist could provide (if applicable)

While obtaining authorizations from the prescriber for weekly quantities is an acceptable and legal approach to dispensing reduced quantities, the approach has one major drawback. If (when) the pharmacy is required by a third party payer to justify dispensing the reduced quantities, the pharmacy will be required to retrieve every authorization for the patient for potentially the last two years. Not only will this be labour intensive, the pharmacy will not be compensated for the time spent to retrieve each authorization. Using the three section letter detailed above will provide the necessary authorization(s) in one document that should be transparent and readily accessible.

The second part of this article will appear in the next Pharmacy Connection. It will show how the information and procedures discussed here can form the basis of a comprehensive compliance and monitoring program. 