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Board of Registration in Pharmacy

Policy 2022-08: Compliance Packaging

A pharmacy or pharmacist may utilize compliance packaging, including oral-liquid-single-dose packaging, single-drug-single-dose packaging, and multi-drug-single-dose packaging provided the following requirements are met:

1. The pharmacy designates a space that allows for the orderly placement of equipment, materials, and medications, for the proper preparation of the compliance packaging, and for the prevention of cross contamination.
2. The pharmacy maintains policies and procedures pertaining to each type of compliance packaging utilized that include cleaning, labeling, dispensing, proper hand hygiene, quarantine, and reverse distribution.
3. The compliance packaging does not conflict with the USP-DI monograph or FDA-approved labeling.
4. The medications are compatible with packaging components and with each other.
5. The compliance packaging is designed to prevent the container from being re-closed, to show evidence of having been opened, and in such a manner that the label cannot be altered or removed.
6. A licensee may not place a quantity of drugs in compliance packaging that exceeds the capacity of the container or that may cause damage to the individual dosage forms.
7. The compliance packaging must adhere to USP requirements for containers and packaging.
8. A licensee may not place more than one commercially available medication into an oral-liquid-single-dose package unless compounded pursuant to a prescription.
9. A licensee shall label each oral-liquid-single-dose, single-drug-single-dose, and multi-drug-single-dose package with the following information:
    a. information required by M.G.L. c. 94C, § 21 and USP for each medication in the package;

b. the name, strength, physical description, and total quantity of each drug dispensed;
c. the dispensing or preparation date;
d. a beyond-use date, which may not exceed the shortest expiration date on the original manufacturer's container or 60 days, for each drug contained in a multi-drug-single-dose package; and
e. the telephone number of the pharmacy.

10. If the compliance package has removable cells, a pharmacy shall label each cell with a label of sufficient size to properly and clearly label each cell with each drug name and strength.

Single-Drug-Single-Dose Packaging

1. A pharmacy or pharmacist may utilize single-drug-single-dose packaging for solid oral dosage forms.
2. If a pharmacy or pharmacist places a medication in a single-drug-single-dose package prior to the receipt of a patient specific prescription, the pharmacy and pharmacist shall properly label the package and utilize bar-code scanning or similar technology to ensure proper identification of the pre-packaged medication at the time of dispensing.

Multi-Drug-Single-Dose Packaging

A pharmacy or pharmacist may utilize multi-drug-single-dose packaging for solid oral dosage forms provided the following requirements are met:

1. A licensee may not dispense more than a 60-day supply of medication in a multi-drug-single-dose package.
2. A licensee may not dispense Schedules II or III controlled substances in a multi-drug-single-dose package.
3. A licensee may not dispense medications to be taken on an as needed basis in a multi-drug-single-dose package.

Return and Repackaging of Multi-Drug-Single-Dose Packaging

1. A pharmacy or pharmacist may accept a return of a multi-drug-single-dose package that the pharmacy previously dispensed for the purpose of repackaging and re-dispensing to that same patient.
    a. If a patient's medication was discontinued, a pharmacy may remove the discontinued drug(s) from the multi-drug-single-dose package and re-

dispense the remaining medications in the multi-drug-single-dose package to the same patient.

b. If a patient's drug therapy has changed, a pharmacy may remove the discontinued drug(s) from the multi-drug-single-dose package(s) and may add a new medication(s) to the multi-drug-single-dose package and re-dispense the multi-drug-single-dose package to the same patient.
c. Prior to re-dispensing, if the compliance package has removable cells, a pharmacy shall re-label each cell with a label of sufficient size to properly and clearly label each cell with each drug name and strength.
d. A pharmacy shall implement policies and procedures pertaining to security and accountability of controlled substances during return and repackaging.

2. A licensee may not return any medication removed from a multi-drug-single-dose package to inventory. A licensee may not dispense any medication removed from a multi-drug-single-dose package to any patient other than the patient who returned the multi-drug-single-dose package.
3. A pharmacy shall maintain a record that accounts for and documents any repackaging, removal, or re-dispensing of any medication it previously dispensed in a multi-drug-single-dose package. The record shall identify the pharmacist making the change.

Supersedes Policy 98-011

Please direct any questions to: **Pharmacy.Admin@mass.gov**