480-9-.03. Conditions

The conditions for allowing Multi-drug Single-dosing containers shall be as follows:

(a) The number of drugs placed in one package cannot exceed the capacity of the container in order to prevent damage to the individual dosage forms;

(b) The total quantity of drugs dispensed may not be more than a ninety-six (96) day supply;

(c) The labels must be of sufficient size to properly and clearly label each container of a ninety-six (96) days or less drug supply with all information required by state and federal law and rules;

(d) The integrity of each individual multi-drug single-dosing container shall be maintained until the last drug dose is administered to or taken by the patient;

(e) Once a multi-drug single-dosing container has been properly labeled and dispensed to a patient, and this same container is returned to the pharmacy, the drugs packaged in such container are considered adulterated and may not be returned to the pharmacy stock. Drugs may be redispensed only under the following conditions:

1. Drugs repackaged for and redispensed only to the same patient to which the drugs were originally dispensed or;
2. Whenever a patient has an allergic reaction to any drug contained in a multi-drug single-dosing container and this drug is discontinued from the patient's treatment, a pharmacy cannot repackage and redispense any drug(s) which were packaged with the discontinued drug in the single-dosing container, because any such drug is then considered to be adulterated as defined under O.C.G.A. 26-3.
3. Unopened unit-dose drugs packaged only by the original drug manufacturer dispensed to and returned only by a Long Term Care facility patient for Medicaid credit;
4. A multi-drug single-dosing container must be tamper evident in such a manner to prevent the container from being either reclosed or designed to show evidence of having been opened;

(f) Whenever a drug(s) in such a container previously dispensed to a patient has/have been discontinued, the remaining container(s) must be returned to the dispensing pharmacy for the removal of the discontinued drug(s) from the container for destruction. Except as provided for in paragraph 480-9-.03(5)(a)1, once the discontinued drug(s) has/have been removed, the pharmacy may repackage the drug(s) to be continued and once again only dispense them to the patient to whom they were originally dispensed. Under no circumstances may any of the remaining or discontinued drug(s) be returned to the drug stock of the pharmacy or dispensed to any patient other than the patient to whom the drugs were originally dispensed, as specified in 480-9-.03(5), (6) and (7).

(g) At the time of administration, nothing in this rule is meant to prevent a nurse or a patient specified caregiver from removing a discontinued drug(s) from a container to be wasted as directed by a pharmacist or from retaining up to a 72-hour supply of the continued drug(s) in the original container in order to maintain a patient on his or her continuing drug administration schedule;

(h) Any pharmacist or pharmacy using multi-drug single-dosing container must implement policies and procedures which will exclude any drug(s) which have the following characteristics from being utilized in such packaging:

1. The USP-DI monograph or official labeling requires dispensing in the original container;

2. The drugs are incompatible with packaging components or each other;
3. The drugs require special packaging.

Authority: O.C. G.A. Secs. 26-3-8, 26-3-16, 26-4-27, 26-4-80, 16-13-73, 16-13-15.