

## **ARTICLE X DRUG PRODUCT SELECTION**

When a generic equivalent drug product is available, drug product selection by the pharmacist shall be made in accordance with this regulation.

For purposes of this ARTICLE, "drug product selection" shall mean the dispensing of a generic equivalent drug product in lieu of the brand name drug product ordered by the prescriber.

1. Each prescription written in this state shall contain two signature lines, either of which, when signed by the prescriber, shall validate the prescription and, depending upon which line the prescriber's signature appears, will indicate the prescriber's approval or denial of drug product selection by the pharmacist. The two line provision of the prescription and the prescriber's approval or denial of drug product selection shall be as follows:

- A. There shall be a signature line in the lower right-hand corner of the prescription form beneath which shall be imprinted the words "Substitution Permitted".
- B. There shall be a signature line in the lower left-hand corner of the prescription form beneath which shall be imprinted the words "Dispense as Written".

If the prescriber utilizes a prescription form which does not contain the two signature lines, the prescriber must write in his own handwriting the words "Dispense as Written", otherwise the pharmacist may select a generic equivalent drug product.

On electronically transmitted prescriptions, the prescriber must specify if the brand name drug must be dispensed.

The requirements of this paragraph shall not apply to the dispensing of medication for Medicaid recipients. Pharmacists must comply with current Division of Medicaid guidelines regarding the dispensing of medications for Medicaid recipients.

2. When drug product selection is made under the provisions of this ARTICLE, the purchaser shall be informed of the drug product selection.
3. If a generic equivalent drug product is available, a pharmacist may select and dispense a generic equivalent drug product when the following three conditions are present:
  - A. The purchaser requests the selection of a generic equivalent drug product;
  - B. The prescriber has not prohibited drug product selection;
  - C. Drug product selection will result in a lower cost to the purchaser.
4. Unless the prescriber indicates that the name of the drug product shall not appear on the label of the dispensed medication container, the pharmacist, having made product selection of a drug, shall place on the label of the finished dispensed container one of the following:
  - A. The proprietary name of the generic product dispensed;
  - B. The generic name of the product dispensed and the name of the manufacturer or repackager, either written in full or appropriately abbreviated.
5. In addition to the labeling described in A. and B. of the previous paragraph, the pharmacist

may add a statement such as "Substituted for \_\_\_\_\_" and add to this statement the brand name of the prescribed drug product.

6. The pharmacist shall not select a generic equivalent drug product when the purchaser requests the drug product to be dispensed as ordered by the prescriber. Pharmacists must abide by Medicaid regulations concerning Brand and generic drugs for Medicaid Recipients.
7. A pharmacist may not select a drug product to substitute for a prescribed brand name drug unless such drug product is the generic equivalent of the prescribed brand name and has been manufactured under the Federal Food and Drug Administration's current Good Manufacturing Practice Regulations and meets U.S.P. or other official specifications, and has an approved New Drug Application (NDA) or Abbreviated New Drug Application (ANDA), or Antibiotic Form 5 or 6 Application approved by the U. S. Food and Drug Administration under the provisions of Section 505 and 507 of the Federal Food, Drug and Cosmetic Act (21 U.S.C.A., 301, et seq.).

Generic equivalent drugs shall include, but not be limited to, any drug listed by the Food and Drug Administration list of therapeutically equivalent drugs as contained in APPROVED DRUG PRODUCTS.

For purposes of this ARTICLE, the term "if available" means if the generic drug product is available in the pharmacy at the time the prescription is presented.

Nothing in this ARTICLE shall be construed to prohibit the implementation of a drug formulary system within an institution.