

(2) [The substitution is recognized in the formulary of authorized substitutions published by the Department under subsection (d) of this section] **THE SUBSTITUTION IS RECOGNIZED IN THE UNITED STATES FOOD AND DRUG ADMINISTRATION'S CURRENT LIST OF APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS;** and

(3) The consumer is charged less for the substituted drug than the price of the brand name drug.

(c) If a drug product is substituted under this section, the pharmacist shall:

(1) Notify the patient in writing that the drug product dispensed is a generic equivalent of the prescribed drug product; and

(2) Record on the prescription and keep a record of the name and manufacturer of the substituted drug product.

(d) [(1) The Department shall publish and, at least every 6 months, update a formulary that lists those substitutions that may be made under this section. The formulary:

(i) Automatically shall list all drug products that the Commissioner of Food and Drugs has:

1. Approved as safe and effective; and
2. Determined to be therapeutically equivalent;

(ii) Automatically shall list all drug products that:

1. Were not subject to premarketing approval for safety and effectiveness under the Federal Food, Drug, and Cosmetic Act;

2. Are manufactured by firms meeting the requirements of that Act;

3. Are subject to pharmacopoeial standards that are adequate to assure product quality; and

4. Have been determined by the Commissioner of Food and Drugs to meet any other requirements necessary to assure therapeutic equivalence; and

(iii) **THE DEPARTMENT [May] MAY list any additional drug products that are determined by the Department to meet requirements that are adequate to assure product quality and therapeutic equivalence, AFTER AN OPPORTUNITY FOR PUBLIC COMMENT AS PROVIDED IN TITLE 10, SUBTITLE 1 OF THE STATE GOVERNMENT ARTICLE.**

[(2) The Department may remove a drug product from the formulary, after opportunity for public comment, that the Department determines is therapeutically nonequivalent or has a negative physical or biological effect on the consumer of that drug product.]