12-508. SUBSTITUTION OF GENERIC EQUIVALENT FOR BRAND NAME DRUG PRODUCTS.

(A) DEFINITIONS.

(1) IN THIS SECTION, THE FOLLOWING WORDS HAVE THE MEANINGS INDICATED.

(2) "BRAND NAME" MEANS THE PROPRIETARY NAME A MANUFACTURER PLACES ON A DRUG PRODUCT OR ITS CONTAINER.

(3) "COMMISSIONER OF FOOD AND DRUGS" MEANS THE COMMISSIONER OF FOOD AND DRUGS OF THE UNITED STATES FOOD AND DRUG ADMINISTRATION.

(B) IN GENERAL.

A PHARMACIST MAY SUBSTITUTE A GENERICALLY EQUIVALENT DRUG PRODUCT, OF THE SAME DOSAGE FORM AND STRENGTH, FOR ANY BRAND NAME DRUG PRODUCT PRESCRIBED, IF:

(1) THE AUTHORIZED PRESCRIBER DOES NOT STATE EXPRESSLY THAT THE PRESCRIPTION IS TO BE DISPENSED ONLY AS DIRECTED;

(2) THE SUBSTITUTION IS RECOGNIZED IN THE FORMULARY OF AUTHORIZED SUBSTITUTIONS PUBLISHED BY THE DEPARTMENT UNDER SUBSECTION (D) OF THIS SECTION; AND

(3) THE CONSUMER IS CHARGED LESS FOR THE SUBSTITUTED DRUG THAN THE PRICE OF THE BRAND NAME DRUG.

(C) REQUIREMENTS ON SUBSTITUTION.

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) FORMULARY OF AUTHORIZED SUBSTITUTIONS.

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:

(1) SHALL LIST ALL DRUG PRODUCTS THAT THE COMMISSIONER OF FOOD AND DRUGS HAS:

(I) APPROVED AS SAFE AND EFFECTIVE; AND