[12–508.] 12–504.

(a) In this section, "brand name" means the proprietary name a manufacturer places on a drug, OR DEVICE, ~~OR DIAGNOSTIC~~ product or its container.

(b) A pharmacist may substitute a generically equivalent drug, OR DEVICE, ~~OR DIAGNOSTIC~~ product, of the same dosage form and strength, for any brand name drug, OR DEVICE, ~~OR DIAGNOSTIC~~ 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 United States Food and Drug Administration's current list of approved drug, OR DEVICE, ~~OR DIAGNOSTIC~~ products with therapeutic equivalence evaluations; and

(3) The consumer is charged less for the substituted drug, OR DEVICE, ~~OR DIAGNOSTIC~~ than the price of the brand name drug, OR DEVICE, ~~OR DIAGNOSTIC~~.

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

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

(2) Record on the prescription and keep a record of the name and manufacturer of the substituted drug, OR DEVICE, ~~OR DIAGNOSTIC~~ product.

(d) The Department may list any additional drug, OR DEVICE, ~~OR DIAGNOSTIC~~ 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.

(e) The Department may disqualify a drug, OR DEVICE, ~~OR DIAGNOSTIC~~ product on the United States Food and Drug Administration's current list from being used in Maryland as a generic substitute if the Department determines that the drug, OR DEVICE, ~~OR DIAGNOSTIC~~ is therapeutically nonequivalent or has a negative physical or biological effect on the consumer of that drug, OR DEVICE, ~~OR DIAGNOSTIC~~ product:

(1) After providing an opportunity for public comment as provided in Title 10, Subtitle 1 of the State Government Article; or

(2) Prior to providing an opportunity for public comment, if the Department believes that a particular generic drug, OR DEVICE, ~~OR DIAGNOSTIC~~ product constitutes an imminent danger to the public health, safety or welfare, and the Department:

(i) Provides an opportunity for public comment as provided in Title 10, Subtitle 1 of the State Government Article within 30 days of disqualifying the DRUG, OR DEVICE, ~~OR DIAGNOSTIC~~ product; and

(ii) After providing an opportunity for public comment, determines whether the DRUG, OR DEVICE, ~~OR DIAGNOSTIC~~ product should remain disqualified.