# Department of Legislative Services

Maryland General Assembly
2008 Session

## FISCAL AND POLICY NOTE

House Bill 435 (Delegate Pena-Melnyk, *et al.*)
Health and Government Operations

**Pharmacists - Generic Drugs - Treatment of Epileptic Seizures**

This bill prohibits a pharmacist from substituting a generically equivalent drug or another brand name drug for an antiepileptic drug prescribed for the treatment of epileptic seizures without the prior notification and written consent of • the prescribing heath care practitioner; and • the patient, parent, legal guardian, or spouse.

## Fiscal Summary

**State Effect:** While Medicaid expenditures (50% general funds, 50% federal funds) could increase in FY 2009 and future years due to an increase in the number of brand name antiepileptic drugs dispensed rather than generics, any such increase cannot be reliably estimated at this time. No effect on revenues.

**Local Effect:** Any impact on local government expenditures is assumed to be minimal.

**Small Business Effect:** Potential minimal.

## Analysis

**Current Law:** A pharmacist has to inform a retail consumer about the availability of a generically equivalent drug and its cost difference compared to the brand name drug. This requirement does not apply • to a prescription written for a generic drug; • when the prescriber states that the prescription should be dispensed only as directed; • to a pharmacist who works in a pharmacy which primarily serves public or private institutional recipients; or • when the cost of the prescription is reimbursed by a third-party payer, including Medicaid.

A pharmacist can substitute a generically equivalent drug or device product for any brand name prescribed if • the prescriber does *not* state that the prescription is to be dispensed only as directed; • the substitution is recognized in the U.S. Food and Drug Administration's current list of approved products with therapeutic equivalence evaluations; and • the consumer is charged less for the substituted drug or device than the price of the brand name. If a drug or device is substituted, a pharmacist has to notify the patient of this fact in writing, record it on the prescription, and keep a record of the name and manufacturer of the substitute.

The Department of Health and Mental Hygiene can disqualify a drug or device product on FDA's current list from being used in Maryland as a generic substitute if DHMH determines that the drug or device is therapeutically nonequivalent or has a negative physical or biological effect on the consumer of that product.

**Background:** To obtain FDA approval, a generic drug has to • contain the same active ingredients as the innovator drug (inactive ingredients may vary); • be identical in strength, dosage form, and route of admission; • have the same use indications; • be bioequivalent; • meet the same batch requirements for identity, strength, purity, and quality; and • be manufactured under the same standards of FDA's good manufacturing practice regulations required for innovator products.

According to FDA, generic drugs are estimated to save consumers at least $8 billion to $10 billion a year at retail pharmacies. However, the Epilepsy Foundation – while noting that generic drugs can be used safely and effectively for most people with epilepsy – has expressed concern that some individuals might experience "breakthrough" seizures when switching from a brand to a generic drug.

Legislation has been introduced in New York that would prohibit a pharmacist from substituting any antiepileptic drug, brand or generic, without the signed informed consent of the physician and patient, parent, legal guardian, or spouse. The bill was referred to committee on January 9, 2008.

**State Fiscal Effect:** DHMH advises that the bill would affect Medicaid's ability to control expenditures for epileptic drugs. DHMH further advises that many antiepileptic drugs are scheduled to become available as generics in the near future. Therefore, Medicaid expenditures (50% general, 50% federal) could increase in fiscal 2009 and future years due to an increase in the number of brand name antiepileptic drugs that would be dispensed rather than the available generic version under the bill. However, any such increase cannot be reliably estimated at this time.

The Department of Budget and Management advises that since the State Employee/Retirees Prescription Drug Benefits Program does not require generic substitution for antiepileptic drugs, the bill would not affect the program.

## Additional Information

**Prior Introductions:** None.

**Cross File:** None.

**Information Source(s):** Department of Health and Mental Hygiene, Maryland Insurance Administration, Department of Budget and Management, U.S Food and Drug Administration, Epilepsy Foundation, Department of Legislative Services

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