Department of Legislative Services

Maryland General Assembly
2008 Session

FISCAL AND POLICY NOTE

House Bill 772 (Delegate Robinson, *et al.*)
Health and Government Operations

Pharmacists - Substitution of Generic Drugs or Device Products - Consent of Consumers or Authorized Prescribers

This bill requires pharmacists to obtain written consent from the consumer or authorized prescriber before substituting a generically equivalent drug or device.

Fiscal Summary

State Effect: While Medicaid expenditures (50% general funds, 50% federal funds) could increase in FY 2009 and future years by a potentially significant amount due to an increase in the number of brand-name drugs dispensed rather than generics, any such increase cannot be reliably estimated at this time. No direct fiscal or operational impact on the State Employees and Retirees Prescription Drug Benefits Program. No effect on revenues.

Local Effect: Any impact on local government is anticipated to be minimal.

Small Business Effect: Potential minimal.

Analysis

Current Law: A pharmacist may substitute a generically equivalent drug or device product, of the same dosage form and strength, for any brand-name drug or device product prescribed, if • the authorized prescriber does not state expressly 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 drug or device products

with therapeutic equivalence evaluations; and • the consumer is charged less for the substituted drug or device than the price of the brand-name drug or device.

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 that primarily serves public or private institutional recipients; or • when the cost of the prescription is reimbursed by a third-party payer, including Medicaid.

Background: Authorized prescribers currently provide implicit written consent for generic substitutions when they do not expressly indicate that a medication should be dispensed as written. The bill would require explicit written consent from either the prescriber or consumer.

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 $8.0 to $10.0 billion a year at retail pharmacies. In fiscal 2007, Maryland Medicaid saved approximately $16.0 million as a result of preferred drug list and prior authorization policies, including $7.2 million from the market shift from top-shelf brand-name drugs to generics and less expensive brand-name drugs.

Under the State prescription drug program, members that do not consent to a generic substitution are dispensed the brand-name drug. However, members must pay the difference in cost as the program will only pay the cost of the available generic. The program has an out-of-pocket annual copayment maximum of $700. Thus, when the total amount of standard copayments an enrollee and their covered dependents pay during the plan year reaches $700, no additional copayments are required. If a member chooses to purchase a brand-name drug when a generic is available, the amount of the generic copayment is counted toward the $700 maximum, while the difference in cost between the drugs is not.

State Fiscal Effect: Medicaid expenditures (50% general, 50% federal) could increase in fiscal 2009 and future years due to an increase in the number of brand-name drugs that

would be dispensed rather than the available generic version under the bill, which could undermine Medicaid's preferred drug list and prior authorization policies. However, any such increase cannot be reliably estimated at this time but could be significant.

Additional Comments: To the extent that members of the program do not provide written consent to generic substitutions under the bill and are dispensed more brand-name drugs, the $700 annual copayment maximum may be reached more quickly and could increase Department of Budget and Management expenditures for the State prescription drug program.

Additional Information

Prior Introductions: None.

Cross File: None.

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

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