Department of Legislative Services

Maryland General Assembly
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FISCAL AND POLICY NOTE
Revised

Senate Bill 167 (Senator Pinsky, *et al.*)

Finance Health and Government Operations

Prescription Drugs - Canadian Mail Order Plan

This bill provides that by November 1, 2004, the Department of Health and Mental Hygiene (DHMH), in consultation with the Office of the Attorney General, must seek approval of a waiver from the federal Food and Drug Administration (FDA) that would permit the State to operate a program to purchase and import prescription drugs from Canada and certify the safety and efficacy of any prescription drugs imported from Canada. DHMH also must seek approval from the federal Centers for Medicare and Medicaid Services (CMS) to allow the State to use matching funds to operate a Canadian mail order plan for the purchase and importation of prescription drugs.

Fiscal Summary

State Effect: Assuming federal approval, DHMH prescription drug expenditures could decrease by as much as $4.8 million and State plan prescription drug expenditures could decrease by as much as $2.7 million, beginning in FY 2006. Future year estimates reflect 18% annual prescription drug cost inflation.

($ in millions)	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009
Revenues	$0	$0	$0	$0	$0
GF Expenditure	0	(2.4)	(2.9)	(3.4)	(4.0)
FF Expenditure	0	(2.4)	(2.9)	(3.4)	(4.0)
GF/SF/FF Exp.	0	(2.7)	(3.2)	(3.7)	(4.4)
Net Effect	$0	$7.5	$8.9	$10.5	$12.3

Note:() = decrease; GF = general funds; FF = federal funds; SF = special funds; - = indeterminate effect

Local Effect: None.

Small Business Effect: Potential minimal.

Analysis

Bill Summary: By January 1, 2005, DHMH must develop a plan to implement a Canadian mail order plan. The plan must provide prescription drugs to the following individuals: (1) State Employee and Retiree Health and Welfare Benefits Program (State plan) enrollees; (2) Medicaid recipients; (3) enrollees and recipients of any other State prescription drug program as the Secretary of Health and Mental Hygiene deems appropriate; and (4) any individuals in the State without health insurance or prescription drug coverage. DHMH must implement the plan within 30 days of waiver approval from FDA and CMS.

DHMH must contract with a pharmacy benefits manager (PBM) to operate the plan. The PBM must incorporate patient safety features into the plan. The cost to both the State and the participant for a prescription drug provided through the plan must be less than the cost to both the State and the participant through retail purchase. DHMH must provide a financial incentive, such as the elimination or reduction of a copayment to participants, to purchase drugs through the Canadian mail order plan.

DHMH must submit a report comparing the costs of purchasing drugs through the Canadian mail order plan against the costs of purchasing drugs in the U.S.

Current Law: The U.S. Federal Food, Drug, and Cosmetic Act (21 U.S.C. sections 331(d), and 355(a)), administered by the U.S. Food and Drug Administration (FDA), prohibits the interstate shipment (which includes importation) of unapproved new drugs. Unapproved new drugs are any drugs, including foreign-made versions of U.S. approved drugs, that have not received FDA approval to demonstrate they meet the federal requirements for safety and effectiveness. It is the importer's obligation to demonstrate to FDA that any drugs offered for importation have been approved by FDA.

21 U.S.C. Section 384 allows drug wholesalers and pharmacists to import prescription drugs under certain circumstances. However, that section is not in effect. This provision only becomes effective if the U.S. Secretary of Health and Human Services (HHS) certifies to Congress that the section's implementation will "pose no additional risk to the public's health and safety" and will "result in a significant reduction in the cost of covered products to the American consumer." To date, the HHS Secretary has declined to make such findings.

Background: As prescription drug costs continue to escalate, a variety of state and local governments have explored the possibility of implementing formal prescription drug importation programs to access cheaper drugs sold in Canada and other foreign countries.

Drug reimportation is attractive to many due to potential cost savings. Many industrialized countries have very strict price controls for prescription drugs, effectively shifting the research and development costs to U.S. consumers. HHS has refused to permit importation in most cases due to drug safety and counterfeiting concerns. Proponents argue, however, that many drugs bought in Canada are manufactured in the U.S. and approved by FDA before being shipped to Canadian wholesalers. Thus, the risk of potential medication errors is reduced.

The federal Congressional Budget Office (CBO) conducted a fiscal estimate on H.R. 2427, a bill passed by the U.S. House of Representatives on July 25, 2003 that would permit the importation of prescription drugs from 25 countries, including Canada. CBO estimates that if the bill had been enacted, total prescription drug expenditures in the U.S. would be reduced by about 1%, or $40 billion, over the 2004-2013 period. Those savings would result primarily from the importation of brand-name drugs that are protected by patents in the U.S. Savings to federal programs would be lower, about one-half of a percent of federal spending on prescription drugs, because those programs generally already pay among the lowest prices in the market. CBO estimates that enacting H.R. 2427 would reduce federal spending for Medicaid, the Federal Employees Health Benefits program, TriCare for Life, and Medicare Part B by $100 million in 2005 and $2.9 billion over the 2004-2013 period.

Currently, foreign prices for prescription, brand-name drugs are between 45% and 65% of U.S. manufacturer prices. However, if large numbers of prescription drugs are reimported to the U.S., the actual price spread would be smaller due to importation costs and changes in distribution practices by manufacturers.

Faced with significant revenue losses from reimported drugs, U.S. drug manufacturers would have incentives to restrict the supply of drugs available for importation from Canada. Manufacturers would earn less if domestic sales at relatively high prices are displaced by drugs originally sold in other countries at lower prices. Manufacturers could pursue multiple strategies to restrict that supply, including: limiting the quantity shipped to foreign countries to the expected level of each country's domestic consumption; establishing and enforcing contracts with wholesalers that restrict the sale of drugs to entities that export to the U.S.; and raising the price of drugs sold in foreign countries. The price differential could be further eroded by transaction and shipping costs incurred by importers and the need for purchasing additional liability insurance.

State Fiscal Effect: DHMH expenditures could decrease by about $4.84 million, and State plan expenditures could decrease by about $2.67 million, beginning in fiscal 2006. Assuming waiver approval from both FDA and CMS, DHMH will contract with a PBM to implement and manage a Canadian mail order drug plan that covers Medicaid enrollees, State plan enrollees, and any State residents without prescription drug coverage. According to the CBO estimate, reimportation programs reduce prescription drug expenditures by about 1%. Projected fiscal 2006 prescription drug expenditures are $484 million for Medicaid and other related prescription drug coverage programs and $267 million for the State plan. Accordingly, DHMH expenditures could decrease by $4.84 million and State plan expenditures could decrease by $2.67 million in fiscal 2006.

DHMH would incur additional expenses to contract with a PBM to manage the plan. There are insufficient data at this time to reliably estimate contractual expenses, which would depend on the terms and length of the contract. However, it is assumed the additional expenditures could be covered with the projected savings from the mail order plan.

DHMH expenditures are 50% general funds, 50% federal funds. State plan expenditures assume a fund mix of 60% general funds, 20% federal funds, and 20% special funds; and 20% of expenditures are reimbursable through employee contributions. Future year estimates reflect 18% annual prescription drug cost inflation.

Small Business Effect: To the extent that Canadian mail order plan enrollees choose to purchase prescription drugs through mail order rather than at local pharmacies, local pharmacy revenues could decrease.

Additional Information

Prior Introductions: None.

Cross File: None.

Information Source(s): *Congressional Budget Office Cost Estimate on the Pharmaceutical Market Access Act of 2003* (November 19, 2003); U.S. Food and Drug Administration, U.S. Centers for Medicare and Medicaid Services; Department of Health and Mental Hygiene (Medicaid, Board of Pharmacy), Department of Budget and Management (Employee Benefits Division), Department of Legislative Services

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