HB 231

Department of Legislative Services

Maryland General Assembly
2005 Session

FISCAL AND POLICY NOTE

House Bill 231 (Delegate Rudolph)
Health and Government Operations

Prescription Drugs - Canadian Mail Order Plan

This bill requires the Department of Health and Mental Hygiene (DHMH), subject to federal waiver approval, to implement a Canadian Mail Order Plan for: (1) State Employee and Retiree Health and Welfare Benefits Plan enrollees; (2) Medicaid and Maryland Pharmacy Assistance Program enrollees; (3) any other State prescription drug program that DHMH considers appropriate; (4) any local jurisdiction that requests participation for local government employees and retirees; and (5) any individual in the State without health insurance or prescription drug coverage.

The bill takes effect July 1, 2005.

Fiscal Summary

State Effect: Assuming federal waiver approval, State expenditures (all funds) could decrease by as much as $9.9 million in FY 2007. Board of Pharmacy revenues and expenditures could increase from the regulation of foreign pharmacies. Future year estimates reflect 15.4% annual prescription drug cost inflation.

($ in millions)	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010
Revenues	$0	$0	$0	$0	$0
GF Expenditure	0	(2.8)	(3.3)	(3.8)	(4.3)
FF Expenditure	0	(2.8)	(3.3)	(3.8)	(4.3)
GF/SF/FF Exp.	0	(4.2)	(4.9)	(5.6)	(6.5)
Net Effect	$0	$9.9	$11.4	$13.1	$15.1

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

Local Effect: To the extent local jurisdictions request to participate in the mail order plan, local jurisdiction prescription drug expenditures could decrease. Revenues would not be affected.

Small Business Effect: Potential minimal.

Analysis

Bill Summary: By November 1, 2005, DHMH must (1) apply for a waiver from the federal Food and Drug Administration (FDA) that would permit the State to import prescription drugs from Canada; and (2) apply for a waiver from the federal Centers for Medicare and Medicaid Services (CMS) to use federal matching funds for the mail order plan.

By January 1, 2006, DHMH must complete a plan to implement the Canadian Mail Order Plan; the plan must be implemented within 30 days after the waivers are approved. DHMH must contract with a pharmacy benefits manager (PBM) to operate the plan; the PBM must incorporate specified safety features into the plan. The cost of the plan must be less than the cost to the State and the participant through retail purchase.

If FDA denies DHMH a waiver, the Attorney General's Office must file suit in the appropriate court to seek appropriate relief.

If, by December 31, 2006, the waiver approvals have not been granted, DHMH does not have to implement the Canadian Mail Order Plan.

Current Law: The U.S. Federal Food, Drug, and Cosmetic Act (21 U.S.C. sections 331(d), and 355(a)), administered by 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 that demonstrates 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.

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 importation 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. The U.S. Department of Health and Human Services (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 Medicare Prescription Drug Improvement and Modernization Act of 2003 (Medicare Modernization Act or MMA) permits the importation of prescription drugs if the Secretary of Health and Human Services certifies that drugs imported from Canada pose no risk to public health and safety and that importation would provide significant cost savings to consumers. To that end, MMA requires HHS to conduct a study on the importation of drugs. In December 2004, the task force issued its findings. In particular, it estimates that savings from importation would range from 1-2%.

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.

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 imported to the U.S., the actual price spread would be smaller due to importation costs and changes in distribution practices by manufacturers.

Last year Vermont applied to FDA seeking a waiver to import drugs legally from Canada for its state employees. FDA denied the request, and Vermont subsequently filed suit on August 19, 2004 against HHS and FDA in the U.S. District Court for the District of Vermont. The lawsuit seeks declaratory and injunctive relief based on FDA's denial of Vermont's December 4, 2003 citizen petition requesting that the Vermont State Employee Medical Benefit Plan be allowed to establish a program for the importation of prescription drugs from Canada.

Massachusetts, Wisconsin, and Minnesota are some of the states that have drug reimportation programs; however, none has been approved by FDA, and most drugs imported under these programs are considered illegal under federal law.

State Fiscal Effect: Assuming both waivers are approved, State prescription drug expenditures could decrease by an estimated $9.9 million (total funds), beginning in fiscal 2007. If FDA denies a waiver, no savings would be achieved and the Office of the Attorney General (OAG) expenditures could increase by an estimated $231,236 in fiscal 2007 because the State would be required to file suit against the federal government. Both scenarios are discussed below.

Waiver Approval

State prescription drug expenditures could decrease by an estimated $9.9 million, beginning in fiscal 2007. Assuming waiver approval by FDA, DHMH would implement a Canadian mail order drug plan that covers Medicaid and State plan enrollees. According to two recent federal studies of prescription drug importation, such programs reduce prescription drug expenditures by about 1%. Projected fiscal 2005 expenditures for prescription drugs are $424 million for Medicaid and $316 million for the State plan. It is assumed the earliest DHMH could implement a mail order plan would be fiscal 2007. Assuming 15.4% annual inflation for prescription drugs, prescription drug expenditures could be as much as $985 million total funds in fiscal 2007. Accordingly, expenditures could decrease by $9.9 million in fiscal 2007 from savings achieved under the mail order plan.

Medicaid expenditures are 50% federal funds, 50% general 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 inflation.

Board of Pharmacy special fund revenues and expenditures could each increase, beginning in fiscal 2007. Board revenues could increase from pharmacy permit fees sought by foreign pharmacies. Expenditures could increase depending on the number and scope of investigations the board would have to conduct if any foreign pharmacy violates State or federal laws. The amount of any increases cannot be determined at this time.

Waiver Denial

If FDA denies the waiver, OAG expenditures could increase by $184,185 in fiscal 2007, which assumes OAG files suit against FDA by July 1, 2006. This estimate reflects the cost of hiring one contractual assistant attorney general and one contractual paralegal to file suit in federal court. It includes salaries, fringe benefits, one-time start-up costs, and ongoing operating expenses.

Salaries and Fringe Benefits	$102,382
Litigation Expenses	75,000
Other Operating Expenses	6,803
Total FY 2007 State Expenditures	**$184,185**

Future year expenditures reflect: (1) full salaries with 4.6% annual increases and 6.8% contractual employee turnover; (2) 1% annual increase in ongoing operating expenses; and (3) assumes the contractual employees are only needed for fiscal 2007 and 2008 to litigate the case.

Additional Information

Prior Introductions: None.

Cross File: SB 742 (Senator Pinsky, *et al.*) – Finance.

Information Source(s): Department of Health and Mental Hygiene (Medicaid, Board of Pharmacy, Maryland Health Care Commission, Heath Services Cost Review Commission), Maryland Insurance Administration, Department of Budget and Management (Employee Benefits Division), Office of the Attorney General, Department of Legislative Services

Fiscal Note History: First Reader - February 11, 2005
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