

**Department of Legislative Services**  
Maryland General Assembly  
2006 Session

**FISCAL AND POLICY NOTE**

Senate Bill 568  
Finance

(Senator Pinsky, *et al.*)

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**Prescription Drugs - Canadian Mail Order Plan**

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This bill requires the Department of Health and Mental Hygiene (DHMH), in coordination with the Secretary of Budget and Management, to develop a Canadian Mail Order Plan for the purchase and importation of prescription drugs.

The bill takes effect June 1, 2006.

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**Fiscal Summary**

**State Effect:** Total State expenditures on drugs could increase or decrease by a significant amount, beginning in FY 2008, depending on whether the Canadian Mail Order Plan is approved by the federal Food and Drug Administration (FDA). No effect on revenues.

**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.

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**Analysis**

**Bill Summary:** The plan must provide prescription drugs to: (1) State Employee and Retiree Health and Welfare Benefits Program (State 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 or local boards of

education that requests participation for local government and board of education employees and retirees; and (5) any individual in the State without health insurance or prescription drug coverage.

The plan must contract with a pharmacy benefits manager to operate the plan, incorporate patient safety features, require the plan cost for a prescription drug to be less than the cost through retail purchase, and provide a financial incentive to participants to purchase prescription drugs through the plan.

The Secretary must report on the elements of the plan and a proposed process for implementing the plan on or before July 1, 2007. By December 1, 2006, the Secretary must submit the report to the Legislative Policy Committee for review and comment. After receiving the comments of the Legislative Policy Committee, the Secretary must implement the Canadian Mail Order Plan by July 1, 2007.

**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 United States 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 United States 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 United States, the actual price spread would be smaller due to importation costs and changes in distribution practices by manufacturers.

In 2004 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

Montgomery County also applied for a federal waiver to implement a Canadian mail order drug plan, but was denied in 2005.

**State Fiscal Effect:** Total State expenditures on prescription drugs could increase or decrease by a significant amount, depending on whether FDA grants approval for the program.

If FDA approves the mail order plan, total State expenditures could decrease by \$8,215,882 (total funds) in fiscal 2008. The information and assumptions used in calculating the estimate are stated below:

- State plan prescription drug expenditures are \$315,226,000 in fiscal 2008;
- Medicaid drug expenditures are \$506,362,204; and
- the mail order program saves 1% on prescription drug costs.

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. Medicaid expenditures are 50% general funds and 50% federal funds.

If FDA denies the waiver and a Canada mail order plan is still implemented, Medicaid would lose prescription drug rebates and federal matching funds for prescription drugs purchased from Canada. There are insufficient data to reliably estimate what types of drugs and what quantities would be purchased through the Canada mail order plan. Currently, the State receives approximately 24% in manufacturer rebates and receives a 50% federal fund match for prescription drugs in the Medicaid program.

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### **Additional Information**

**Prior Introductions:** Similar bills, SB 742 and HB 231, were introduced in 2005. SB 742 was not reported by the Senate Finance Committee. HB 231 was reported unfavorably by the House Health and Government Operations Committee. A similar bill, SB 167, was introduced in 2004. It passed both chambers with amendments, but no conference committee was appointed.

**Cross File:** None.

**Information Source(s):** Department of Health and Mental Hygiene, Maryland Insurance Administration, Department of Budget and Management, Department of Legislative Services

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