Department of Legislative Services
Maryland General Assembly
2007 Session

FISCAL AND POLICY NOTE

Senate Bill 670 (Senators Pinsky and Britt)
Finance

Prescription Drugs - Canadian Mail Order Plan

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, 2007.

Fiscal Summary

State Effect: Total State expenditures on drugs could increase or decrease by a significant amount, beginning in FY 2009, 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.

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 enrollees; (3) Maryland Rx Program participants; (4) Maryland Primary Adult Care Program enrollees; (5) any other State prescription drug program that DHMH considers

appropriate; and (6) any individual in the State without health insurance or prescription drug coverage. Local jurisdictions and county boards of education may request their employees and retirees to participate.

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 it by July 1, 2008. The Secretary must submit the report to the Legislative Policy Committee for review and comment by December 1, 2007. After receiving the comments of the Legislative Policy Committee, the Secretary must implement the Canadian Mail Order Plan by July 1, 2008.

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, various 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 required 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 to 2%. A 2003 Congressional Budget Office estimate also found that importation of prescription drugs could reduce total prescription drug expenditures in the United States by about 1%.

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 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, State expenditures could decrease by at least $8,957,430 (all funds) in fiscal 2009. The information and assumptions used in calculating the estimate are stated below:

- State plan prescription drug expenditures are about $354,723,000 in fiscal 2009;
- Medicaid drug expenditures are $541,020,000; 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.

Additional Information

Prior Introductions: An identical bill was introduced in 2006 as SB 568. No action was taken on the bill.

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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