Department of Legislative Services

Maryland General Assembly
2005 Session

FISCAL AND POLICY NOTE

House Bill 65 (Delegate Franchot)
Appropriations and Health and Government Operations

State Employees - Prescription Drugs - Canadian Mail Order Plan

This bill establishes the Canadian Mail Order Plan for State Employee and Retiree Health and Welfare Benefit Program (State plan) enrollees. It requires that any savings realized under the mail order plan be allocated to a dedicated purpose account for breast cancer research and prevention for low-income women at the University of Maryland Medical System (UMMS).

The bill takes effect July 1, 2005, subject to federal waiver approval.

Fiscal Summary

State Effect: Assuming federal waiver approval, State plan prescription drug expenditures could decrease by as much as $4.21 million in FY 2007 and UMMS special fund revenues would increase by the same amount as the Department of Budget and Management (DBM) transfers the savings to a dedicated purpose account for breast cancer research and screening. 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
SF Revenue	$0	$4.21	$4.86	$5.61	$6.47
SF Expenditure	0	-	-	-	-
GF/SF/FF Exp.	0	(4.21)	(4.86)	(5.61)	(6.47)
Net Effect	$0	$8.43	$9.72	$11.22	$12.95

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

Local Effect: None.

Small Business Effect: Potential minimal.

Analysis

Bill Summary: DBM, in consultation with the Office of the Attorney General (OAG), must seek waiver approval by November 1, 2005 from the federal Food and Drug Administration (FDA) that would permit the State to operate a purchase and importation program for prescription drugs from Canada.

By January 1, 2006, DBM must develop a Canadian Mail Order Plan that provides prescription drugs to State plan enrollees. The pharmacy benefits manager (PBM) that administers the plan must: (1) incorporate certain patient safety features in the plan; (2) develop a restricted list of prescription drugs appropriate for mail order purchase; (3) use only licensed pharmacists to dispense drugs; and (4) require drugs to be provided through "unit of use" packaging, shipped directly from the manufacturer to the pharmacy and then to the enrollee.

The cost to both the State and the enrollee for a prescription drug provided through the plan must be less than the cost to both the State and the participant through retail purchase. DBM must provide a financial incentive, such as the elimination or reduction of a copayment to enrollees, to purchase drugs through the Canadian Mail Order Plan.

DBM must report by January 1 annually to the Governor and the General Assembly: (1) comparing approximate costs to the State of purchasing drugs under the Canadian Mail Order Plan and the costs of purchasing prescription drugs in the U.S.; and (2) specifying the savings, if any, realized as a result of participation in the Canadian Mail Order Plan.

Any savings achieved during the current fiscal year must be allocated to a dedicated purpose account for breast cancer research and prevention for low-income women at UMMS.

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 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.

The Board of Pharmacy regulates pharmacies located within the State, as well as nonresident pharmacies that conduct business within the State. A nonresident pharmacy

must apply for a pharmacy permit and conform with Maryland law as it relates to pharmacy operation. A nonresident pharmacy is subject to inspection by the State Board of Pharmacy.

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. FDA 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 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 (HHS) 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 to 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.

In September 2004, the Montgomery County Council passed a resolution to permit prescription drug reimportation from Canada for approximately 85,000 county employees, retirees, and eligible dependents. Montgomery County spends about $70 million on prescription drug coverage annually for its employees, and county officials initially estimated the county could save $15-$20 million annually through an importation program. The county released a new study in December 2004, questioning those findings. Several factors would potentially reduce these estimates, such as the

declining value of the U.S. dollar, an estimated $15 shipping cost for each prescription drug (for which original estimates failed to account), and new incentives from the county's pharmacy benefits manager, Caremark, making domestic drugs cheaper.

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.

University of Maryland Medical System (UMMS): Chapter 18 of 2000 created the Cancer Prevention, Education, Screening, and Treatment Program within the Department of Health and Mental Hygiene. This program is funded with Cigarette Restitution Fund (CRF) funds. The program distributes Statewide Academic Health Center Cancer Research Grants to UMMS and the Johns Hopkins Institutions for the purpose of enhancing cancer research activities.

UMMS has focused its efforts on breast, cervical, and oral cancers. As of September 22, 2004, UMMS has performed 8,169 free screenings with CRF funds. These screenings have identified 31 patients with cancer. The specific cancer screening totals are:

- 3,036 oral cancer screenings;
- 1,433 cervical cancer screenings;
- 1,727 clinical breast exams; and
- 1,973 mammograms.

In fiscal 2004, UMMS received $1.4 million (CRF funds) for this cancer program.

State Fiscal Effect:

State Plan: State plan expenditures could decrease by about $4.21 million, beginning in fiscal 2007. Assuming waiver approval by FDA, DBM would implement a Canadian mail order drug plan that covers 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 State plan prescription

drugs are $316 million. It is assumed the earliest the State plan could implement a mail order plan would be fiscal 2007. Assuming 15.4% annual inflation for prescription drugs, State plan prescription drug expenditures could be as much as $421 million in fiscal 2007. Accordingly, State plan expenditures could decrease by $4.21 million in fiscal 2007 from savings achieved under the mail order plan.

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.

UMMS: UMMS special fund revenues could increase by $4.21 million in fiscal 2007. DBM must transfer to UMMS an amount equal to any savings realized under the Canadian Mail Order Plan. Future year estimates reflect savings increases under the mail order plan.

Board of Pharmacy: Board 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.

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

Additional Information

Prior Introductions: A similar bill, SB 167, was introduced in 2004. It was passed by both chambers with amendments. No conference committee was appointed and no further action was taken.

Cross File: None.

Information Source(s): *HHS Task Force Report on Drug Importation (December 2004)*, U.S. Department of Health and Human Services; Department of Health and Mental Hygiene (Medicaid, Board of Pharmacy); Department of Budget and Management (Employee Benefits Division); Office of the Attorney General; Department of Legislative Services

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