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By: **Delegate Rudolph**

Introduced and read first time: January 24, 2005

Assigned to: Health and Government Operations

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A BILL ENTITLED

1 AN ACT concerning

2 **Prescription Drugs - Canadian Mail Order Plan**

3 FOR the purpose of requiring the Department of Health and Mental Hygiene, on or  
4 before a certain date, to seek approval of a certain waiver from the federal Food  
5 and Drug Administration to operate a program to purchase and import  
6 prescription drugs from Canada and to certify the safety and efficacy of the  
7 imported prescription drugs; requiring the Department, on or before a certain  
8 date, to seek approval from the Centers for Medicare and Medicaid Services to  
9 allow the State to use certain funds to operate a certain program; requiring the  
10 Department, on or before a certain date, to develop a plan to implement a  
11 Canadian Mail Order Plan for the purchase and importation of prescription  
12 drugs; requiring the Canadian Mail Order Plan to provide prescription drugs to  
13 certain individuals; requiring the Secretary of Health and Mental Hygiene to  
14 contract with a pharmacy benefits manager to operate the Canadian Mail Order  
15 Plan, under the Secretary's direction; requiring the pharmacy benefits manager  
16 to incorporate certain patient safety features in the Canadian Mail Order Plan;  
17 specifying certain cost requirements for a prescription drug provided through  
18 the Canadian Mail Order Plan; requiring the Secretary to provide certain  
19 financial incentives to participants to purchase prescription drugs through the  
20 Canadian Mail Order Plan; requiring the Department to submit a certain  
21 annual report to the Governor and the General Assembly; requiring the  
22 Department to implement a certain plan within a certain number of days after  
23 the approval of certain requests; requiring the Office of the Attorney General to  
24 file suit under certain circumstances; making certain provisions of this Act  
25 subject to a certain contingency; and generally relating to a Canadian Mail  
26 Order Plan for the purchase and importation of prescription drugs from Canada.

27 **Preamble**

28 WHEREAS, Like many states, Maryland has experienced double-digit growth  
29 in pharmacy costs in recent years, averaging 16.2 percent per year in the State  
30 Employee Health Benefit Program and 17.2 percent per year in the Medical  
31 Assistance Program over the past 5 years; and

1 WHEREAS, Growth in prescription drug costs has resulted from escalating  
2 enrollment in State assistance programs, increased drug utilization per beneficiary,  
3 rising drug costs, and new high-cost drugs replacing less costly drugs; and

4 WHEREAS, The State has used various mechanisms, such as tiered  
5 co-payments and restricted formularies, to rein in rising prescription drug costs; and

6 WHEREAS, Canadian pharmaceutical pricing, distribution practices, and  
7 favorable exchange rates can make medications needed by Maryland State  
8 employees, Maryland Medical Assistance recipients, and Maryland Pharmacy  
9 Assistance recipients available at far less cost to the State than current policy and  
10 practice allows; and

11 WHEREAS, Other states, including Illinois, Iowa, Minnesota, Wisconsin,  
12 Oregon, Vermont, North Dakota, New Hampshire, Rhode Island, Connecticut,  
13 Michigan, and Massachusetts, and localities, including Montgomery County,  
14 Maryland and Springfield, Massachusetts, are promoting access to Canadian  
15 pharmacies for their citizens; and

16 WHEREAS, The pharmaceutical manufacturing, storage, distribution, and  
17 dispensing requirements under Canadian law are substantially equivalent to United  
18 States federal requirements; now, therefore,

19 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF  
20 MARYLAND, That, on or before November 1, 2005, the Department of Health and  
21 Mental Hygiene, in consultation with the Attorney General's Office, shall seek  
22 approval of a waiver from the federal Food and Drug Administration that would allow  
23 the State to operate a program to purchase and import prescription drugs from  
24 Canada and certify the safety and efficacy of any prescription drugs imported from  
25 Canada.

26 SECTION 2. AND BE IT FURTHER ENACTED, That, on or before November 1,  
27 2005, the Department of Health and Mental Hygiene shall seek approval from the  
28 Centers for Medicare and Medicaid Services to allow the State to use matching funds  
29 to operate a program that purchases and imports prescription drugs from Canada on  
30 the approval of the waiver from the federal Food and Drug Administration sought by  
31 the Department under Section 1 of this Act.

32 SECTION 3. AND BE IT FURTHER ENACTED, That:

33 (a) On or before January 1, 2006, the Department of Health and Mental  
34 Hygiene shall complete a plan to implement a Canadian Mail Order Plan for the  
35 purchase and importation of prescription drugs in accordance with subsection (b) of  
36 this section.

37 (b) (1) The Canadian Mail Order Plan shall provide prescription drugs, as  
38 specified in this subsection, to the following individuals:

39 (i) State Employee and Retiree Health and Welfare Benefits  
40 Program enrollees;

- 1 (ii) Maryland Medical Assistance Program recipients;
- 2 (iii) Maryland Pharmacy Assistance Program recipients;
- 3 (iv) enrollees and recipients of any other State prescription drug  
4 program as the Secretary of Health and Mental Hygiene considers appropriate;
- 5 (v) upon the request of a local jurisdiction and the execution by the  
6 local jurisdiction and the Department of Health and Mental Hygiene of a  
7 memorandum of understanding, local government employees and retirees; and
- 8 (vi) any individual in the State without health insurance or  
9 prescription drug coverage.

10 (2) The Secretary of Health and Mental Hygiene shall contract with a  
11 pharmacy benefits manager to operate the Canadian Mail Order Plan, under the  
12 direction of the Secretary.

13 (3) The pharmacy benefits manager shall incorporate patient safety  
14 features in the Canadian Mail Order Plan, including:

15 (i) requiring a participant, prior to filling a drug prescription  
16 through the Canadian Mail Order Plan, to:

17 1. use and tolerate the prescription drug for a minimum of 1  
18 month through retail purchase; and

19 2. submit to the pharmacy benefits manager a brief medical  
20 history, including allergies, medication history, and diagnoses;

21 (ii) developing a restricted list of prescription drugs appropriate for  
22 purchase through mail order;

23 (iii) using only licensed pharmacists to dispense prescription drugs;  
24 and

25 (iv) requiring prescription drugs to be provided through "unit of  
26 use" packaging, sealed and shipped directly from the manufacturer to the pharmacy  
27 and then to the participant, in order to reduce medication errors and the possibility of  
28 counterfeit drugs.

29 (4) The cost to both the State and the participant for a prescription drug  
30 provided through the Canadian Mail Order Plan shall be less than the cost to both the  
31 State and the participant through retail purchase.

32 (5) The Secretary of Health and Mental Hygiene shall provide a  
33 financial incentive, such as the elimination or reduction of the co-payment, to  
34 participants to purchase prescription drugs through the Canadian Mail Order Plan.

35 SECTION 4. AND BE IT FURTHER ENACTED, That, on or before January 1 of  
36 each year, the Department of Health and Mental Hygiene shall submit a report for

1 the prior fiscal year to the Governor and, in accordance with § 2-1246 of the State  
2 Government Article, to the General Assembly:

3 (1) comparing the approximate costs to the State of purchasing and  
4 importing prescription drugs from Canada under the Canadian Mail Order Plan and  
5 the approximate costs to the State of purchasing prescription drugs in the United  
6 States;

7 (2) if the waiver and the request specified in Section 5 of this Act are  
8 approved, specifying the savings, if any, realized as a result of participation in the  
9 Canadian Mail Order Plan; and

10 (3) if either the waiver or the request specified in Section 5 of this Act is  
11 denied, specifying the potential savings that could be realized as a result of  
12 participation in the Canadian Mail Order Plan.

13 SECTION 5. AND BE IT FURTHER ENACTED, That, the Department of  
14 Health and Mental Hygiene shall implement the Canadian Mail Order Plan in  
15 accordance with the implementation plan required under Section 3 of this Act within  
16 30 days after the later occurs:

17 (1) approval by the federal Food and Drug Administration of the waiver  
18 applied for under Section 1 of this Act; and

19 (2) approval by the Centers for Medicare and Medicaid Services of the  
20 request applied for under Section 2 of this Act.

21 SECTION 6. AND BE IT FURTHER ENACTED, That if the waiver requested  
22 in Section 1 of this Act is denied, the Office of the Attorney General shall file suit in  
23 the appropriate court to seek appropriate relief to address the refusal to authorize the  
24 purchase and importation of prescription drugs from Canada.

25 SECTION 7. AND BE IT FURTHER ENACTED, That Sections 3 and 5 of this  
26 Act shall take effect, contingent on the approval by the federal Food and Drug  
27 Administration of the waiver applied for under Section 1 of this Act and the approval  
28 by the Centers for Medicare and Medicaid Services of the request applied for under  
29 Section 2 of this Act. If on or before December 31, 2006, the approvals of the waiver  
30 and the request have not been granted, Sections 3 and 5 of this Act, with no further  
31 action required by the General Assembly, shall be null and void and of no further force  
32 and effect. The Department of Health and Mental Hygiene, within 5 days after  
33 receiving notice of approval or denial of a waiver applied for under Section 1 of this  
34 Act or a request applied for under Section 2 of this Act, shall forward a copy of the  
35 notice to the Department of Legislative Services, 90 State Circle, Annapolis,  
36 Maryland 21401.

37 SECTION 8. AND BE IT FURTHER ENACTED, That, subject to Section 7 of  
38 this Act, this Act shall take effect July 1, 2005.