
By: **Senators Pinsky, Britt, Brochin, Conway, Currie, Della, Dyson, Exum, Frosh, Gladden, Green, Grosfeld, Hollinger, Hooper, Hughes, Jones, Kasemeyer, Kelley, Klausmeier, Lawlah, McFadden, Miller, Pipkin, Stone, and Teitelbaum**

Introduced and read first time: February 4, 2005

Assigned to: Finance

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.