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CHAPTER

### 1 AN ACT concerning

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

- FOR the purpose of requiring the Department of Health and Mental Hygiene, on or 3
- before a certain date, to seek approval of a certain waiver from the federal Food 4
- and Drug Administration to operate a program to purchase and import 5
- prescription drugs from Canada and to certify the safety and efficacy of the 6
- 7 imported prescription drugs; requiring the Department, on or before a certain
- date, to seek approval from the Centers for Medicare and Medicaid Services to 8
- 9 allow the State to use certain funds to operate a certain program; requiring, on
- or before a certain date, the Secretary of Health and Mental Hygiene, in 10
- coordination with the Secretary of Budget and Management, the Department, 11
- 12 on or before a certain date, to develop a plan to implement a Canadian Mail
- 13 Order Plan for the purchase and importation of prescription drugs; requiring the
- 14 Canadian Mail Order Plan to provide prescription drugs to certain participants
- individuals; authorizing the Secretary of Health and Mental Hygiene to include 15
- enrollees and recipients of other State prescription drug programs in the 16
- Canadian Mail Order Plan; requiring the Secretary of Health and Mental 17
- Hygiene to contract with a pharmacy benefits manager to operate the Canadian 18
- 19 Mail Order Plan, under the Secretary's direction; requiring the pharmacy
- benefits manager to incorporate certain patient safety features in the Canadian 20
- 21 Mail Order Plan; specifying certain cost requirements for a prescription drug
- 22 provided through the Canadian Mail Order Plan; requiring the Secretary of
- 23 Health and Mental Hygiene to provide certain financial incentives to
- participants to purchase prescription drugs through the Canadian Mail Order 24
- Plan; requiring the Department to submit a certain annual report to the 25
- Governor and the General Assembly; requiring the Department to implement a 26

- 1 certain plan within a certain number of days after the approval of certain
- 2 requests; providing for the termination of this Act contingent on certain
- 3 <u>circumstances</u>; and generally relating to <del>provision of prescription drugs through</del>
- 4 a Canadian Mail Order Plan for the purchase and importation of prescription
- 5 <u>drugs from Canada</u>.
- 6 BY adding to
- 7 Article Health General
- 8 Section 15 141
- 9 Annotated Code of Maryland
- 10 (2000 Replacement Volume and 2003 Supplement)
- 11 Preamble
- WHEREAS, Like many states, Maryland has experienced double-digit growth
- 13 in pharmacy costs in recent years, averaging 18 percent per year over the past three
- 14 years; and
- 15 WHEREAS, Growth in prescription drug costs has resulted from escalating
- 16 enrollment in State assistance programs, increased drug utilization per beneficiary,
- 17 rising drug costs, and new high-cost drugs replacing less costly drugs; and
- 18 WHEREAS, The State has used various mechanisms, such as tiered
- 19 co-payments and restricted formularies, to rein in rising prescription drug costs; and
- 20 WHEREAS, Canadian pharmaceutical pricing, distribution practices, and
- 21 favorable exchange rates can make medications needed by Maryland State
- 22 employees, Maryland Medical Assistance recipients, and Maryland Pharmacy
- 23 Assistance recipients available at far less cost to the State than current policy and
- 24 practice allows;
- 25 WHEREAS, Other states and localities, including Illinois, Iowa, Minnesota, and
- 26 Springfield, Massachusetts, are promoting access to Canadian pharmacies for their
- 27 citizens; and
- 28 WHEREAS, The pharmaceutical manufacturing, storage, distribution, and
- 29 dispensing requirements under Canadian law are substantially equivalent to United
- 30 States federal requirements; now, therefore,
- 31 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF
- 32 MARYLAND, That, on or before November 1, 2004, the Department of Health and
- 33 Mental Hygiene, in consultation with the Attorney General's Office, shall seek
- 34 approval of a waiver from the federal Food and Drug Administration that would allow
- 35 the State to operate a program to purchase and import prescription drugs from
- 36 Canada and certify the safety and efficacy of any prescription drugs imported from
- 37 Canada.
- 38 SECTION 2. AND BE IT FURTHER ENACTED, That, on or before November 1,
- 39 2004, the Department of Health and Mental Hygiene shall seek approval from the

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2 3	to operate a program ti	hat purch iver fron	icaid Services to allow the State to use matching funds hases and imports prescription drugs from Canada on the federal Food and Drug Administration sought by 1 of this Act.
5	SECTION 3. AN	D BE IT	FURTHER ENACTED, That:
8	Hygiene shall develop	a plan to	uary 1, 2005, the Department of Health and Mental o implement a Canadian Mail Order Plan for the escription drugs in accordance with subsection (b) of
10 11			nadian Mail Order Plan shall provide prescription drugs, as the following individuals:
12 13	Program enrollees;	<u>(i)</u>	State Employee and Retiree Health and Welfare Benefits
14		<u>(ii)</u>	Maryland Medical Assistance Program recipients;
15		<u>(iii)</u>	Maryland Pharmacy Assistance Program recipients;
16 17	program as the Secret	(iv) ary of H	enrollees and recipients of any other State prescription drug ealth and Mental Hygiene deems appropriate; and
18 19	prescription drug cove	(v) erage.	any individual in the State without health insurance or
		nager to	retary of Health and Mental Hygiene shall contract with a operate the Canadian Mail Order Plan, under the
23 24	(3) features in the Canadi		rmacy benefits manager shall incorporate patient safety Order Plan, including:
25 26	through the Canadian	(i) Mail Or	requiring a participant, prior to filling a drug prescription der Plan, to:
27 28	month through retail 1	purchase	1. use and tolerate the prescription drug for a minimum of 1 ; and
29 30	history, including alle	ergies, m	2. submit to the pharmacy benefits manager a brief medical edication history, and diagnoses;
31 32	purchase through mai	(ii) l order;	developing a restricted list of prescription drugs appropriate for
33 34	and	(iii)	using only licensed pharmacists to dispense prescription drugs;

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3	(iv) requiring prescription drugs to be provided through "unit of use" packaging, sealed and shipped directly from the manufacturer to the pharmacy and then to the participant, in order to reduce medication errors and the possibility of counterfeit drugs.
	(4) The cost to both the State and the participant for a prescription drug provided through the Canadian Mail Order Plan shall be less than the cost to both the State and the participant through retail purchase.
	(5) The Secretary of Health and Mental Hygiene shall provide a financial incentive, such as the elimination or reduction of the co-payment, to participants to purchase prescription drugs through the Canadian Mail Order Plan.
	(6) On or before January 1 of each year, the Department of Health and Mental Hygiene shall submit a report for the prior fiscal year to the Governor and, in accordance with § 2-1246 of the State Government Article, to the General Assembly:
16	(i) comparing the approximate costs to the State of purchasing and importing prescription drugs from Canada under the Canadian Mail Order Plan and the approximate costs to the State of purchasing prescription drugs in the United States; and
18 19	(ii) specifying the savings, if any, realized as a result of participation in the Canadian Mail Order Plan.
20	SECTION 4. AND BE IT FURTHER ENACTED, That:
	(a) The Department of Health and Mental Hygiene shall implement the Canadian Mail Order Plan in accordance with the implementation plan required under Section 3 of this Act within 30 days after the later to occur of the following:
24 25	(1) approval by the federal Food and Drug Administration of the waiver applied for under Section 1 of this Act; and
26 27	(2) approval by the Centers for Medicare and Medicaid Services of the request applied for under Section 2 of this Act.
	(b) If the waiver or the request specified in subsection (a) of this section is denied, this Act shall be null and void without the necessity of any further action by the General Assembly.
33	(c) The Department of Health and Mental Hygiene, within 5 days after receiving notice of approval or denial of a waiver or request specified in subsection (a) of this section, shall forward a copy of the notice to the Department of Legislative Services, 90 State Circle, Annapolis, Maryland 21401.
35 36	SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

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1	Article - Health - General
2	<del>15 141.</del>
	(A) ON OR BEFORE JULY 1, 2005, THE SECRETARY, IN COORDINATION WITH THE SECRETARY OF BUDGET AND MANAGEMENT, SHALL IMPLEMENT A CANADIAN MAIL ORDER PLAN FOR PRESCRIPTION DRUGS.
6 7	(B) THE CANADIAN MAIL ORDER PLAN SHALL PROVIDE PRESCRIPTION DRUGS, AS SPECIFIED IN THIS SECTION, TO THE FOLLOWING PARTICIPANTS:
8 9	(1) STATE EMPLOYEE AND RETIREE HEALTH AND WELFARE BENEFITS PROGRAM ENROLLEES;
10	(2) MARYLAND MEDICAL ASSISTANCE PROGRAM RECIPIENTS;
11	(3) MARYLAND PHARMACY ASSISTANCE PROGRAM RECIPIENTS; AND
12 13	(4) ENROLLEES AND RECIPIENTS OF ANY OTHER STATE PRESCRIPTION DRUG PROGRAM AS THE SECRETARY DEEMS APPROPRIATE.
	(C) THE SECRETARY SHALL CONTRACT WITH A PHARMACY BENEFITS MANAGER TO OPERATE THE CANADIAN MAIL ORDER PLAN, UNDER THE DIRECTION OF THE SECRETARY.
17 18	(D) THE PHARMACY BENEFITS MANAGER SHALL INCORPORATE PATIENT SAFETY FEATURES IN THE CANADIAN MAIL ORDER PLAN, INCLUDING:
19 20	(1) REQUIRING A PARTICIPANT, PRIOR TO FILLING A DRUG PRESCRIPTION THROUGH THE CANADIAN MAIL ORDER PLAN, TO:
21 22	(I) HAVE TOLERATED THE PRESCRIPTION DRUG FOR A MINIMUM OF 1 MONTH THROUGH RETAIL PURCHASE; AND
23 24	(II) SUBMIT TO THE PHARMACY BENEFITS MANAGER A BRIEF MEDICAL HISTORY, INCLUDING ALLERGIES, MEDICATION HISTORY, AND DIAGNOSES;
25 26	(2) DEVELOPING A RESTRICTED LIST OF PRESCRIPTION DRUGS APPROPRIATE FOR MAIL ORDER;
27 28	(3) USING ONLY LICENSED PHARMACISTS TO DISPENSE PRESCRIPTION DRUGS; AND
31	(4) REQUIRING PRESCRIPTION DRUGS TO BE PROVIDED THROUGH "UNIT OF USE" PACKAGING SEALED AND SHIPPED DIRECTLY FROM THE MANUFACTURER TO THE PHARMACY AND THEN TO THE PARTICIPANT, IN ORDER TO REDUCE MEDICATION ERRORS AND THE POSSIBILITY OF COUNTERFEIT DRUGS.
33 34	(E) THE COST TO BOTH THE STATE AND THE PARTICIPANT FOR A PRESCRIPTION DRUG PROVIDED THROUGH THE CANADIAN MAIL ORDER PLAN SHALL

- 1 BE LESS THAN THE COST TO BOTH THE STATE AND THE PARTICIPANT THROUGH
- 2 RETAIL PURCHASE.
- 3 (F) THE SECRETARY SHALL PROVIDE A FINANCIAL INCENTIVE, SUCH AS THE
- 4 ELIMINATION OR REDUCTION OF THE CO PAYMENT, TO PARTICIPANTS TO
- 5 PURCHASE PRESCRIPTION DRUGS THROUGH THE CANADIAN MAIL ORDER PLAN.
- 6 SECTION 2. 5. AND BE IT FURTHER ENACTED, That this Act shall take
- 7 effect October July 1, 2004.