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By: Delegates Pitkin, Benson, R. Baker, Boutin, Bronrott, Burns, Cadden, Conroy, Conway, Cryor, D'Amato, DeCarlo, Dypski, Frush, Gladden, Glassman, Heller, Hubers, James, V. Jones, Malone, Nathan-Pulliam, Parrott, Patterson, Pitkin, Riley, Rosso, Snodgrass, Turner, and Valderrama

Introduced and read first time: February 7, 2001

Assigned to: Economic Matters

#### A BILL ENTITLED

#### 1 AN ACT concerning

## 2 Maryland Prescription Drug Fair Pricing Act

- 3 FOR the purpose of altering income eligibility levels for the Maryland Pharmacy
- 4 Assistance Program; altering the scope of benefits available under the Program;
- 5 creating the Maryland Prescription Drug Fair Pricing Board and the Maryland
- 6 Prescription Drug Fair Pricing Fund; providing for the membership of the
- 7 Board, the appointment of the members, their terms, the chairmanship of the
- 8 Board, its meetings, its staff, and the compensation of its members; requiring
  - board, its inectings, its starr, and the compensation of its inemocrs, requiring
- 9 the Board to annually set certain maximum manufacturer prices for
- 10 prescription drugs sold in the State by manufacturers located in the State after
- 11 considering certain factors; providing for the setting of certain other prescription
- drug prices; requiring that the prices set by the Board be implemented unless
- 13 the Board makes certain determinations; providing for the factors to be
- considered by the Board; providing that a manufacturer, wholesaler, or retailer
- of prescription drugs located in the State who sells prescription drugs in the
- State and who charges more than the maximum price allowable under this Act
- is guilty of an unfair or deceptive trade practice and subject to certain remedies
- and penalties; providing for the appeal of a maximum price set by the Board and
- the factors to be considered by the Board in any appeal; providing for the effect
- of an appeal and the burden of proof; providing for subsequent appeals;
- 21 requiring the Board to conduct certain semi-annual surveys and requiring that
- 22 the survey include certain information; requiring that the Board draft a plan of
- emergency measures and providing for the implementation of that plan;
- providing for certain other duties of the Board, requiring an annual report, and
- 25 requiring the Board to work cooperatively with certain State agencies; requiring
- 26 health care providers in the State to provide certain information to their
- 27 patients; providing for the source of the moneys in the Fund, the administration
- of the Fund, and the use of the moneys in the Fund; requiring that
- appointments to the Board be made by a certain date; requiring that the
- 30 Secretary of Health and Mental Hygiene call the first meeting of the Board by a
- 31 certain date; requiring that the Board forward its initial regulations to a certain

1	committee of the Gene	ral Assembly by a	certain date: red	uiring the Secretary to

- 2 conduct a certain investigation; providing for the application of certain
- 3 provisions of this Act; and generally relating to the maximum prices of
- 4 prescription drugs manufactured and sold in Maryland by certain
- 5 manufacturers, wholesalers, and retailers, and to the Maryland Prescription
- 6 Drug Fair Pricing Board, and the Maryland Prescription Drug Fair Pricing
- Fund.
- 8 BY repealing and reenacting, with amendments,
- 9 Article Commercial Law
- 10 Section 13-301(14)
- 11 Annotated Code of Maryland
- 12 (2000 Replacement Volume and 2000 Supplement)
- 13 BY repealing and reenacting, with amendments,
- 14 Article Health General
- 15 Section 15-124(a) and (b)
- 16 Annotated Code of Maryland
- 17 (2000 Replacement Volume)
- 18 BY adding to
- 19 Article Health General
- Section 15-1A-01 through 15-1A-12 to be under the new subtitle "Subtitle 1A.
- 21 Maryland Prescription Drug Fair Pricing Act"
- 22 Annotated Code of Maryland
- 23 (2000 Replacement Volume)
- 24 Preamble
- 25 WHEREAS, Pharmaceutical companies are charging the citizens of Maryland
- 26 excessive prices for prescription drugs, denying Marylanders access to medically
- 27 necessary health care and thereby threatening their health and safety; and
- WHEREAS, Marylanders and other Americans pay the highest prices in the
- 29 world for prescription drugs, prices that result in extremely high profits for
- 30 pharmaceutical companies; and
- WHEREAS, The lack of affordable access to medically necessary prescription
- 32 drugs results in the denial of health care, the likelihood of serious illness and death,
- 33 and the inability to lead a life of good health for many Marylanders; and
- 34 WHEREAS, All Maryland residents are threatened by the possibility that when
- 35 they need medically necessary prescription drugs most, they will be unable to afford
- 36 their doctor's recommended treatment; and
- 37 WHEREAS, Many Maryland residents are admitted to or treated at hospitals
- 38 each year because they cannot afford the drugs prescribed for them; and

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### **HOUSE BILL 587**

			HOUSE BILL 307		
	WHEREAS, Many other Maryland residents are forced into expensive institutional care settings because they cannot afford their necessary prescription drugs; and				
	WHEREAS, Prescription drug costs represent the fastest growing item in health care and are a driving force in rapidly increasing hospital costs and insurance rates; and				
9 10 11	WHEREAS, Excessive pricing for prescription drugs threatens the ability of the State government to assist with the health care costs of Maryland's citizens, undermines the financial capacity of Maryland's communities to meet the educational needs of Maryland's children, hurts the ability of the Maryland business community to provide health insurance coverage to its workforce, and has a negative effect on the Maryland economy; now, therefore,				
13 14	SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:				
15			Article - Commercial Law		
16	13-301.				
17	7 Unfair or deceptive trade practices include any:				
18	(14)	Violatio	n of a provision of:		
19		(i)	This title;		
20 21	relating to unit pricin	(ii) g under T	An order of the Attorney General or agreement of a party Fitle 14, Subtitle 1 of this article;		
22 23	Collection Act;	(iii)	Title 14, Subtitle 2 of this article, the Maryland Consumer Debt		
24 25	Sales Act;	(iv)	Title 14, Subtitle 3 of this article, the Maryland Door-to-Door		
26		(v)	Title 14, Subtitle 9 of this article, Kosher Products;		
27		(vi)	Title 14, Subtitle 10 of this article, Automotive Repair Facilities;		
28		(vii)	Section 14-1302 of this article;		
29 30	Act;	(viii)	Title 14, Subtitle 11 of this article, Maryland Layaway Sales		
31		(ix)	Section 22-415 of the Transportation Article;		

Title 14, Subtitle 20 of this article;

(x)

1 2	Enforcement Act;	(xi)	Title 14,	Subtitle 15 of this article, the Automotive Warranty
3		(xii)	Title 14,	Subtitle 21 of this article;
4		(xiii)	Section	18-107 of the Transportation Article;
5 6	Solicitations Act;	(xiv)	Title 14,	Subtitle 22 of this article, the Maryland Telephone
7 8	Act;	(xv)	Title 14,	Subtitle 23 of this article, the Automotive Crash Parts
9		(xvi)	Title 10	Subtitle 6 of the Real Property Article;
10		(xvii)	Title 10,	Subtitle 8 of the Real Property Article;
11 12	[or]	(xviii)	Title 1	4, Subtitle 25 of this article, the Hearing Aid Sales Act;
13 14	Solicitations Act; or	(xix)	Title 14,	Subtitle 26 of this article, the Maryland Door-to-Door
15 16	THE MARYLAND	(XX) PRESCR		15, SUBTITLE 1A OF THE HEALTH - GENERAL ARTICLE, DRUG FAIR PRICING ACT; OR
17				Article - Health - General
	15-124.			Article - Health - General
18 19	15-124.  (a) (1) Program for low income			shall maintain a Maryland Pharmacy Assistance
18 19 20 21 22	(a) (1) Program for low inco	ome indiv	riduals wh Assets a	shall maintain a Maryland Pharmacy Assistance
18 19 20 21 22	(a) (1) Program for low inco	ome indiv	Assets a et schedu	shall maintain a Maryland Pharmacy Assistance nose: re not more than 1.5 times the amount of accountable
18 19 20 21 22 23 24 25	(a) (1) Program for low inco	ome indiv (i) to the ass	Assets a et schedu	shall maintain a Maryland Pharmacy Assistance nose:  re not more than 1.5 times the amount of accountable le of the Maryland Medical Assistance
18 19 20 21 22 23 24 25 26 27	(a) (1) Program for low incorresources according to Program; and unit; and	(i) to the ass (ii)	Assets a et schedu  [Gross]  1.	shall maintain a Maryland Pharmacy Assistance nose:  re not more than 1.5 times the amount of accountable le of the Maryland Medical Assistance  FAMILY UNIT'S GROSS annual income does not exceed[:
18 19 20 21 22 23 24 25 26 27 28 29	(a) (1) Program for low incorresources according to Program; and unit; and	(i) to the ass (ii)	Assets a et schedu  [Gross]  1.	shall maintain a Maryland Pharmacy Assistance nose:  re not more than 1.5 times the amount of accountable le of the Maryland Medical Assistance  FAMILY UNIT'S GROSS annual income does not exceed[: \$4,600 plus \$500 for each individual over 1 in a family  An annual increase set by the Secretary under paragraph

1 2	3. "Sheltered workshop" means a workshop licensed by the Developmental Disabilities Administration under Title 7, Subtitle 9 of this article.
3 4	(ii) For the purpose of paragraph (1) of this subsection, the Secretary shall:
	1. In order to determine eligibility for the Maryland Pharmacy Assistance Program, deduct any income disregards from the countable gross income of a FAMILY unit that contains a disabled individual;
8	2. Define excluded assets; AND
9	3. Establish a family unit structure[; and
12	4. Beginning July 1, 1985, increase annually at the time Social Security benefits are increased, rounded to the next highest even \$50 level, the income level within which an individual is eligible for benefits under the Maryland Pharmacy Assistance Program by the larger of:
16	A. The percentage by which benefits under Title II of the Social Security Act (42 U.S.C. 401-433) are increased by the federal government due to cost-of-living changes as that percentage is reported in the Federal Register pursuant to 42 U.S.C. 415(I)(2)(D) but not to exceed 8 percent; or
18 19	B. The dollar amount by which the medical assistance income schedules are increased by the State].
22 23	(b) (1) (i) [Reimbursement] EXCEPT AS PROVIDED UNDER PARAGRAPH (3) OF THIS SUBSECTION, REIMBURSEMENT under the Maryland Pharmacy Assistance Program shall be limited to maintenance drugs, anti-infectives, and AZT as specified in regulations to be issued by the Secretary after consultation with the Maryland Pharmacists Association.
27 28	(ii) 1. For any drug on the Program's interchangeable drug list, the Program shall reimburse providers in an amount not more than it would reimburse for the drug's generic equivalent, unless the individual's physician states, in his or her own handwriting, on the face of the prescription, that a specific brand is "medically necessary" for the particular patient.
	2. If an appropriate generic drug is not generally available,
	the Department may waive the reimbursement requirement under sub-subparagraph 1 of this subparagraph.

6 **HOUSE BILL 587** IF SUFFICIENT FUNDS ARE PROVIDED IN THE STATE BUDGET. THE (3) 2 PROGRAM MAY PROVIDE DRUGS AND MEDICATIONS FOR ADDITIONAL MEDICAL 3 CONDITIONS. 4 SUBTITLE 1A. MARYLAND PRESCRIPTION DRUG FAIR PRICING ACT. 5 15-1A-01. IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS (A) 6 7 INDICATED. "BOARD" MEANS THE MARYLAND PRESCRIPTION DRUG FAIR PRICING (B) 8 9 BOARD CREATED UNDER § 15-1A-03 OF THIS SUBTITLE. "FUND" MEANS THE MARYLAND PRESCRIPTION DRUG FAIR PRICING FUND 11 CREATED UNDER § 15-1A-11 OF THIS SUBTITLE. 12 15-1A-02. 13 THE PURPOSES OF THIS SUBTITLE ARE: TO IMPLEMENT A PACKAGE OF NONREGULATORY PROGRAMS TO 14 15 ACHIEVE THE LEGISLATIVE PURPOSE OF PROVIDING AFFORDABLE ACCESS TO 16 MEDICALLY NECESSARY PRESCRIPTION DRUGS FOR ALL RESIDENTS OF MARYLAND; **17 AND** 18 IF THESE NONREGULATORY PROGRAMS DO NOT SUCCEED IN 19 ENSURING THAT PRESCRIPTION DRUGS ARE SOLD IN MARYLAND AT FAIR AND 20 NONDISCRIMINATORY PRICES, TO IMPLEMENT A FAIR PRICING PROGRAM THAT: 21 PROHIBITS EXCESSIVE AND DISCRIMINATORY PRICING IN (I) 22 TRANSACTIONS THAT TAKE PLACE IN MARYLAND; IS THE MOST EFFECTIVE AND TIMELY ALTERNATIVE IN 23 (II)24 PROVIDING LOWER DRUG PRICES FOR ALL MARYLAND RESIDENTS; AND THEREBY PROTECTS THE HEALTH AND SAFETY OF ALL 25 (III)26 MARYLAND RESIDENTS. 27 15-1A-03. 28 (A) THERE IS A MARYLAND PRESCRIPTION DRUG FAIR PRICING BOARD. 29 (B) THE BOARD IS IN THE DEPARTMENT.

THE BOARD IS COMPOSED OF 11 MEMBERS AS FOLLOWS:

ONE MEMBER OF THE SENATE OF MARYLAND, APPOINTED BY THE

30 15-1A-04.

(A)

(1) 33 PRESIDENT OF THE SENATE;

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32

1 2	SPEAKER C			EMBER OF THE HOUSE OF DELEGATES, APPOINTED BY THE
	PRESIDENT OF THE FOI	OF THE	E SENAT	MEMBERS OF THE PUBLIC, APPOINTED JOINTLY BY THE CE AND THE SPEAKER OF THE HOUSE, TO REPRESENT EACH RESTS:
6			(I)	SENIOR RESIDENTS OF THE STATE;
7			(II)	RESIDENTS WITH DISABILITIES OF THE STATE; AND
8			(III)	LOW-INCOME RESIDENTS OF THE STATE;
11		ST REPI Γ OF TH	RESENT E SENA	EMBERS OF THE MEDICAL COMMUNITY IN THE STATE, ONE OF THE NURSING INDUSTRY, APPOINTED JOINTLY BY THE TE AND THE SPEAKER OF THE HOUSE, TO REPRESENT THE SIDENTS;
13 14	WHOM:	(5)	TWO PI	HARMACISTS, APPOINTED BY THE GOVERNOR, EACH OF
15			(I)	IS LICENSED TO PRACTICE PHARMACY IN THE STATE;
16			(II)	IS ENGAGED IN THE PRACTICE OF PHARMACY IN THE STATE;
17 18	LICENSED	PHARM	(III) ACIST;	HAS AT LEAST 5 YEARS OF EXPERIENCE IN THE STATE AS A
19			(IV)	IS A RESIDENT OF THE STATE; AND
20			(V)	IS NOT A MEMBER OF THE STATE BOARD OF PHARMACY;
21 22	SERVE AS			CRETARY OR THE SECRETARY'S DESIGNEE, WHO SHALL, NONVOTING MEMBER; AND
	THE CHAIR MEMBER.	` /		HAIRMAN OF THE MARYLAND HEALTH CARE COMMISSION OR IEE, WHO SHALL SERVE AS AN EX OFFICIO, NONVOTING
26	(B)	(1)	THE TE	RM OF AN APPOINTED MEMBER OF THE BOARD IS 3 YEARS.
	REQUIRED 2001.			RMS OF APPOINTED MEMBERS ARE STAGGERED AS PROVIDED FOR MEMBERS OF THE BOARD ON OCTOBER 1,
30 31	TERM.	(3)	A MEM	BER OF THE BOARD MAY BE REAPPOINTED TO A SECOND
32 33	QUALIFICA			T FOR THE PHARMACIST MEMBERS, IF THE PROFESSION OR APPOINTED BOARD MEMBER CHANGES DURING THE

- 1 MEMBER'S TERM, THE MEMBER MAY CONTINUE TO SERVE UNTIL THE END OF THAT 2 TERM.
- 3 (5) AT THE END OF A TERM, A MEMBER CONTINUES TO SERVE UNTIL A 4 SUCCESSOR IS APPOINTED AND QUALIFIES.
- 5 (6) A MEMBER WHO IS APPOINTED AFTER A TERM HAS BEGUN SERVES 6 ONLY FOR THE REMAINDER OF THAT TERM AND UNTIL A SUCCESSOR IS APPOINTED 7 AND QUALIFIES.
- 8 (C) THE MEMBERS OF THE BOARD SHALL ANNUALLY ELECT A CHAIRMAN.
- 9 (D) THE BOARD SHALL MEET AT LEAST ONCE EACH MONTH AT A PLACE TO BE 10 DETERMINED BY THE BOARD.
- 11 (E) A MEMBER OF THE BOARD:
- 12 (1) MAY NOT RECEIVE COMPENSATION; BUT
- 13 (2) IS ENTITLED TO REIMBURSEMENT FOR EXPENSES UNDER THE 14 STANDARD STATE TRAVEL REGULATIONS AS PROVIDED IN THE STATE BUDGET.
- 15 (F) (1) THE BOARD SHALL APPOINT A DIRECTOR WHO SHALL PERFORM THE 16 DUTIES DELEGATED BY THE BOARD.
- 17 (2) IF THE BOARD DETERMINES THAT ADDITIONAL STAFF IS NEEDED,
- 18 THE BOARD MAY HIRE THE NECESSARY STAFF AFTER RECEIVING THE APPROVAL OF
- 19 AND APPROPRIATE FUNDING AS PROVIDED IN THE STATE BUDGET.
- 20 15-1A-05.
- 21 (A) (1) BEGINNING JANUARY 10, 2003, AND ANNUALLY ON THE SAME DATE
- 22 THEREAFTER, THE BOARD SHALL ADOPT REGULATIONS ESTABLISHING THE
- 23 MAXIMUM MANUFACTURER PRICE FOR PRESCRIPTION DRUGS SOLD IN THE STATE
- 24 BY MANUFACTURERS LOCATED IN THE STATE.
- 25 (2) THE BOARD SHALL ESTABLISH THE PRICE SCHEDULE OF MAXIMUM
- 26 MANUFACTURER PRICES FOR PRESCRIPTION DRUGS SOLD IN THE STATE BY
- 27 MANUFACTURERS LOCATED IN THE STATE AFTER CONSIDERING:
- 28 (I) THE PRICES CHARGED FOR PRESCRIPTION DRUGS IN CANADA;
- 29 (II) THE PRICES LISTED ON THE FEDERAL SUPPLY SCHEDULE FOR
- 30 PHARMACEUTICALS AND DRUGS MAINTAINED BY THE UNITED STATES DEPARTMENT
- 31 OF VETERANS AFFAIRS; AND
- 32 (III) ANY OTHER RELEVANT INFORMATION.
- 33 (3) (I) THE MAXIMUM MANUFACTURER PRICE OF A PRESCRIPTION
- 34 DRUG SOLD BY A MANUFACTURER LOCATED IN THE STATE MAY NOT EXCEED THE
- 35 MANUFACTURER PRICE IN CANADA FOR THAT DRUG.

- **HOUSE BILL 587** (II)IF A PRESCRIPTION DRUG IS NOT SOLD IN CANADA, THE 2 MAXIMUM MANUFACTURER PRICE OF A PRESCRIPTION DRUG SOLD BY A 3 MANUFACTURER LOCATED IN THE STATE MAY NOT EXCEED THE MAXIMUM PRICE IN 4 CANADA FOR ALL OTHER PRESCRIPTION DRUGS WITHIN THE SAME CLASSIFICATION 5 OF DRUGS. THE MAXIMUM WHOLESALE PRICE FOR A PRESCRIPTION DRUG SOLD (B) (1) 7 IN THE STATE BY A WHOLESALER LOCATED IN THE STATE IS THE MAXIMUM 8 MANUFACTURER PRICE ESTABLISHED UNDER SUBSECTION (A) OF THIS SECTION, 9 PLUS: 10 THE REASONABLE AND CUSTOMARY COST OF DOING BUSINESS. (I)11 AS DETERMINED BY THE WHOLESALER: AND 12 (II)THE REASONABLE AND CUSTOMARY PROFIT MARKUP BY THE 13 WHOLESALER, AS DETERMINED BY THE WHOLESALER. A WHOLESALE PRICE ESTABLISHED UNDER THIS SUBSECTION (I)15 MAY NOT BE SET AT A LEVEL THAT CONSTITUTES AN UNFAIR OR DECEPTIVE ACT OR 16 PRACTICE. THE ATTORNEY GENERAL SHALL DETERMINE WHETHER A 17 (II)18 WHOLESALE PRICE IS SET AT A LEVEL THAT CONSTITUTES AN UNFAIR OR 19 DECEPTIVE ACT OR PRACTICE, ON A CASE BY CASE BASIS, AFTER REVIEW OF A 20 COMPLAINT. (C) THE MAXIMUM RETAIL PRICE FOR A PRESCRIPTION DRUG SOLD IN 22 THE STATE BY A RETAILER LOCATED IN THE STATE IS THE MAXIMUM WHOLESALE 23 PRICE ESTABLISHED UNDER SUBSECTION (B) OF THIS SECTION, PLUS: 24 THE REASONABLE AND CUSTOMARY COST OF DOING BUSINESS, (I) 25 AS DETERMINED BY THE RETAILER; AND THE REASONABLE AND CUSTOMARY PROFIT MARKUP BY THE 26 (II)27 WHOLESALER, AS DETERMINED BY THE RETAILER. A RETAIL PRICE ESTABLISHED UNDER THIS SUBSECTION MAY 28 (I) 29 NOT BE SET AT A LEVEL THAT CONSTITUTES AN UNFAIR OR DECEPTIVE ACT OR 30 PRACTICE.
- 31 (II) THE ATTORNEY GENERAL SHALL DETERMINE WHETHER A
- 32 RETAIL PRICE IS SET AT A LEVEL THAT CONSTITUTES AN UNFAIR OR DECEPTIVE ACT
- 33 OR PRACTICE, ON A CASE BY CASE BASIS, AFTER REVIEW OF A COMPLAINT.
- 34 (D) (1) THE MAXIMUM PRICES FOR PRESCRIPTION DRUGS ESTABLISHED
- 35 UNDER THIS SECTION SHALL TAKE EFFECT ON OCTOBER 1 OF THE SAME YEAR IN
- 36 WHICH THE PRICES ARE ADOPTED BY THE BOARD, UNLESS BY SEPTEMBER 1 OF THAT
- 37 SAME YEAR THE BOARD DETERMINES, AFTER A PUBLIC HEARING AND A PUBLIC
- 38 VOTE, NOTICE OF THE RESULTS OF WHICH IS PUBLISHED IN THE MARYLAND
- 39 REGISTER, THAT:

- 1 (I) PRESCRIPTION DRUG PRICES ARE LESS THAN OR EQUAL TO 2 THE MAXIMUM PRICES SET UNDER THIS SECTION; OR
- 3 (II) ALTERNATIVE, NONREGULATORY MECHANISMS HAVE BEEN
- 4 IMPLEMENTED TO ENSURE THAT PRESCRIPTION DRUGS ARE SOLD IN THIS STATE AT
- 5 PRICES THAT DO NOT EXCEED THE MAXIMUM PRICES ESTABLISHED UNDER THIS
- 6 SECTION.
- 7 (2) IN MAKING A DETERMINATION UNDER THIS SUBSECTION, THE
- 8 BOARD SHALL CONSIDER THE EFFECT OF NONREGULATORY INITIATIVES
- 9 UNDERTAKEN BY THE STATE AND OTHER FACTORS, INCLUDING:
- 10 (I) THE EFFECT ON PRESCRIPTION DRUG PRICES OF THE
- 11 SHORT-TERM PRESCRIPTION DRUG SUBSIDY PLAN FOR MEDICARE PLUS CHOICE
- 12 ELIGIBLE INDIVIDUALS LIVING IN MEDICALLY UNDERSERVED COUNTIES AND
- 13 PORTIONS OF COUNTIES OPERATED UNDER SUBTITLE 6 OF THIS TITLE;
- 14 (II) THE EFFECT ON PRESCRIPTION DRUG PRICES OF THE
- 15 IMPLEMENTATION OF THE INFORMATION ASSISTANCE PROGRAM FOR INELIGIBLE
- 16 MARYLAND PHARMACY ASSISTANCE PROGRAM APPLICANTS DEVELOPED BY THE
- 17 SECRETARY UNDER § 15-124(E) OF THIS TITLE;
- 18 (III) THE EFFECT ON PRESCRIPTION DRUG PRICES OF THE
- 19 PHARMACY BENEFITS OFFERED UNDER THE MARYLAND COMPREHENSIVE
- 20 STANDARD HEALTH BENEFIT PLAN ADOPTED BY THE MARYLAND HEALTH CARE
- 21 COMMISSION AND OFFERED TO SMALL EMPLOYERS UNDER TITLE 15, SUBTITLE 12 OF
- 22 THE INSURANCE ARTICLE;
- 23 (IV) THE EFFECT ON PRESCRIPTION DRUG PRICES OF PATIENT
- 24 ACCESS TO PHARMACEUTICAL MANUFACTURER PATIENT ASSISTANCE PROGRAMS;
- 25 (V) THE EFFECT ON PRESCRIPTION DRUG PRICES OF ANY
- 26 REGIONAL STRATEGIES AND REGIONAL PURCHASING ALLIANCES IMPLEMENTED IN
- 27 THE STATE:
- 28 (VI) THE FINDINGS OF ANY RELEVANT STUDIES BY THE MARYLAND
- 29 HEALTH CARE COMMISSION OR THE DEPARTMENT ON THE COST AND AVAILABILITY
- 30 TO MARYLAND RESIDENTS OF PRESCRIPTION DRUGS; AND
- 31 (VII) THE FINDINGS OF ANY RELEVANT STUDIES BY THE MARYLAND
- 32 INSURANCE ADMINISTRATION OR ANY PRIVATE INSURER OR INSURANCE GROUP ON
- 33 THE COST AND AVAILABILITY TO MARYLAND RESIDENTS OF INSURANCE COVERAGE
- 34 FOR PRESCRIPTION DRUGS.
- 35 (E) A MANUFACTURER, WHOLESALER, OR RETAILER LOCATED IN THE STATE
- 36 THAT SELLS PRESCRIPTION DRUGS IN THE STATE THAT CHARGES MORE THAN THE
- 37 MAXIMUM PRICE SET UNDER THIS SECTION HAS ENGAGED IN AN UNFAIR OR
- 38 DECEPTIVE TRADE PRACTICE UNDER TITLE 13, SUBTITLE 3 OF THE COMMERCIAL
- 39 LAW ARTICLE AND, ON CONVICTION, IS SUBJECT TO THE REMEDIES AND PENALTIES
- 40 PROVIDED UNDER TITLE 13, SUBTITLE 4 OF THE COMMERCIAL LAW ARTICLE.

- 1 15-1A-06.
- 2 (A) (1) A MANUFACTURER OF PRESCRIPTION DRUGS LOCATED IN THE
- 3 STATE THAT SELLS PRESCRIPTION DRUGS IN THE STATE MAY APPEAL THE MAXIMUM
- 4 PRICE OF A PRESCRIPTION DRUG ESTABLISHED UNDER § 15-1A-05 OF THIS SUBTITLE
- 5 TO THE BOARD.
- 6 (2) A MANUFACTURER THAT APPEALS THE MAXIMUM PRICE BEARS THE 7 BURDEN OF PROOF IN DEMONSTRATING THE NEED FOR AN EXEMPTION.
- 8 (3) THE FILING OF AN APPEAL DOES NOT DELAY THE IMPLEMENTATION 9 OR EFFECTIVE DATES OF MAXIMUM PRICES IMPOSED BY THE BOARD.
- 10 (B) NOTWITHSTANDING ANY LAW PROTECTING THE MANUFACTURER FROM
- 11 HAVING TO DISCLOSE THE INFORMATION, A MANUFACTURER OF PRESCRIPTION
- 12 DRUGS THAT APPEALS A PRICE SET BY THE BOARD SHALL FULLY DISCLOSE TO THE
- 13 BOARD ANY INFORMATION REGARDING THE PRODUCTION COSTS OF THE DRUG OR
- 14 OTHER INFORMATION REQUESTED BY THE BOARD THAT IS RELEVANT TO THE
- 15 APPEAL.
- 16 (C) THE FACTORS THAT THE BOARD MAY CONSIDER IN AN APPEAL INCLUDE:
- 17 (1) CIRCUMSTANCES WHICH HAVE CHANGED SINCE THE PRICE
- 18 SCHEDULE WAS ADOPTED BY THE BOARD;
- 19 (2) THE REASONABLE COSTS OF PRODUCTION, DISTRIBUTION,
- 20 MARKETING, AND RESEARCH:
- 21 (3) THE PROFIT THROUGH SALE AND THE PRICE CHARGED IN OTHER
- 22 MARKETS FOR THE PRESCRIPTION DRUG:
- 23 (4) THE AVAILABILITY OF THE PRESCRIPTION DRUG, HOW ESSENTIAL
- 24 THE DRUG IS TO THE HEALTH OF THE STATE'S CITIZENS, OR ANY OTHER FACTOR
- 25 RELATED TO THE HEALTH AND SAFETY OF THE STATE'S RESIDENTS; AND
- 26 (5) ANY OTHER RELEVANT INFORMATION.
- 27 (D) IN ADDITION TO GRANTING AN EXEMPTION FROM THE PRICE SCHEDULE
- 28 ON APPEAL BY A MANUFACTURER, THE BOARD MAY GRANT AN EXEMPTION ON ITS
- 29 OWN INITIATIVE.
- 30 (E) A RULING BY THE BOARD ON AN APPEAL MAY BE APPEALED IN
- 31 ACCORDANCE WITH TITLE 10, SUBTITLE 2 OF THE STATE GOVERNMENT ARTICLE.
- 32 15-1A-07.
- 33 (A) TO ASSIST IN THE DEVELOPMENT OF MAXIMUM DRUG PRICES AND THE
- 34 DETERMINATIONS REQUIRED UNDER § 15-1A-05 OF THIS SUBTITLE, THE BOARD
- 35 SHALL CONDUCT A SURVEY OF PRESCRIPTION DRUG PRICES ON OR BEFORE
- 36 JANUARY 1 AND JULY 1 OF EACH YEAR.

- 1 (B) THE SURVEY SHALL INCLUDE THE FOLLOWING INFORMATION:
- 2 (1) CURRENT MANUFACTURER MAXIMUM PRICES OF PRESCRIPTION 3 DRUGS SOLD IN THE STATE, AS SET BY THE BOARD UNDER THIS SUBTITLE;
- 4 (2) CURRENT WHOLESALE AND RETAIL MAXIMUM PRICES OF
- 5 PRESCRIPTION DRUGS SOLD IN THE STATE, AS DETERMINED BY WHOLESALER AND
- 6 RETAILER MARKUP:
- 7 (3) MANUFACTURER, WHOLESALE, AND RETAIL MAXIMUM PRICES FOR
- 8 PRESCRIPTION DRUGS SOLD IN THE STATE FOR THE PREVIOUS 5 YEARS AT 6-MONTH
- 9 INTERVALS:
- 10 (4) THE FEDERAL SUPPLY SCHEDULE FOR PHARMACEUTICALS AND
- 11 DRUGS MAINTAINED BY THE UNITED STATES DEPARTMENT OF VETERANS AFFAIRS;
- 12 (5) ANY DRUG FORMULARY MAINTAINED BY THE CANADIAN
- 13 GOVERNMENT OR ANY OF IT PROVINCES;
- 14 (6) CURRENT DATA REGARDING THE PRICES OF DRUGS OFFERED
- 15 UNDER THE SHORT-TERM PRESCRIPTION DRUG SUBSIDY PLAN FOR MEDICARE PLUS
- 16 CHOICE ELIGIBLE INDIVIDUALS LIVING IN MEDICALLY UNDERSERVED COUNTIES
- 17 AND PORTIONS OF COUNTIES OPERATED UNDER SUBTITLE 6 OF THIS TITLE:
- 18 (7) CURRENT DATA REGARDING THE PRICES OF PRESCRIPTION DRUGS
- 19 OFFERED UNDER THE MARYLAND COMPREHENSIVE STANDARD HEALTH BENEFIT
- 20 PLAN ADOPTED BY THE MARYLAND HEALTH CARE COMMISSION AND OFFERED TO
- 21 SMALL EMPLOYERS UNDER TITLE 15, SUBTITLE 12 OF THE INSURANCE ARTICLE; AND
- 22 (8) ANY OTHER INFORMATION CONCERNING PRESCRIPTION DRUG
- 23 PRICES IN THE STATE OR NATION THAT THE BOARD CONSIDERS APPROPRIATE TO
- 24 SURVEY.
- 25 (C) (1) WITHIN ONE MONTH OF COMPILING THE RESULTS OF A SURVEY
- 26 PERFORMED UNDER THIS SECTION, THE BOARD SHALL REPORT THE RESULTS TO
- 27 THE GOVERNOR, THE SECRETARY, THE MARYLAND HEALTH CARE COMMISSION, AND,
- 28 SUBJECT TO § 2-1246 OF THE STATE GOVERNMENT ARTICLE, TO THE APPROPRIATE
- 29 STANDING COMMITTEES OF THE GENERAL ASSEMBLY.
- 30 (2) THE BOARD SHALL MAINTAIN A PUBLICLY ACCESSIBLE SITE ON THE
- 31 INTERNET AND SHALL POST THE RESULTS OF EACH SURVEY CONDUCTED UNDER
- 32 THIS SECTION WITHIN ONE MONTH OF REPORTING THE RESULTS TO THE GOVERNOR
- 33 AND THE GENERAL ASSEMBLY.
- 34 (D) THE BOARD SHALL ADOPT REGULATIONS TO IMPLEMENT THIS SECTION.
- 35 15-1A-08.
- 36 (A) THE BOARD SHALL DRAFT A PLAN THAT INCLUDES EMERGENCY
- 37 MEASURES TO BE IMPLEMENTED BY THE GOVERNOR IF THE BOARD DETERMINES

- 1 THAT THERE IS A SEVERE SHORTAGE OF, OR LOSS OF ACCESS TO, PRESCRIPTION
- 2 DRUGS IN THE STATE THAT THREATENS OR ENDANGERS THE HEALTH OR WELFARE
- 3 OF THE PUBLIC.
- 4 (B) IF, AFTER A SURVEY CONDUCTED UNDER § 10-1A-07 OF THIS SUBTITLE,
- 5 THE BOARD DETERMINES THAT EMERGENCY MEASURES MUST BE IMPLEMENTED,
- 6 THE BOARD SHALL PROVIDE THE GOVERNOR WITH THE PLAN AND PETITION THE
- 7 GOVERNOR TO IMPLEMENT THE EMERGENCY MEASURES.
- 8 15-1A-09.
- 9 (A) IN CARRYING OUT ITS DUTIES UNDER THIS SUBTITLE, THE BOARD MAY:
- 10 (1) COLLECT FROM ANY MANUFACTURER, WHOLESALER, OR RETAILER
- 11 OF PRESCRIPTION DRUGS LOCATED IN THIS STATE, FOR DRUGS SOLD IN THIS STATE,
- 12 ANY INFORMATION NECESSARY TO CARRY OUT THE BOARD'S DUTIES UNDER THIS
- 13 SUBTITLE, INCLUDING ANY DATA, STATISTICS, SCHEDULES, OR INFORMATION;
- 14 (2) EXAMINE ANY BOOKS, ACCOUNTS, AND DOCUMENTS OF ANY
- 15 MANUFACTURER, WHOLESALER, OR RETAILER OF PRESCRIPTION DRUGS LOCATED IN
- 16 THIS STATE FOR DRUGS SOLD IN THIS STATE;
- 17 (3) SUBPOENA WITNESSES AND DOCUMENTS AND EXAMINE THOSE
- 18 SUBPOENAED WITNESSES AND DOCUMENTS ON ALL MATTERS OVER WHICH THE
- 19 BOARD HAS JURISDICTION:
- 20 (4) ADOPT REGULATIONS IN ADDITION TO THOSE REQUIRED UNDER §
- 21 15-1A-07(D) OF THIS SUBTITLE, INCLUDING REGULATIONS DESIGNATING
- 22 INFORMATION COLLECTED BY THE BOARD AS PUBLIC INFORMATION OR AS
- 23 PROPRIETARY INFORMATION THAT MAY NOT BE DISCLOSED TO ANY PERSON OTHER
- 24 THAN THE BOARD OR ITS STAFF, OR TO THE ATTORNEY GENERAL FOR LAW
- 25 ENFORCEMENT PURPOSES;
- 26 (5) ENTER INTO AGREEMENTS WITH OTHER STATES AND WITH THE
- 27 CANADIAN GOVERNMENT OR ANY OF ITS PROVINCES FOR THE PURPOSE OF
- 28 MAINTAINING FAIR AND UNIFORM PRESCRIPTION DRUG PRICES AND ENSURING
- 29 MAXIMUM ACCESS TO AFFORDABLE PRESCRIPTION DRUGS; AND
- 30 (6) EXPLORE REGIONAL STRATEGIES AND PURCHASING ALLIANCES TO
- 31 BENEFIT THE PEOPLE OF THE STATE.
- 32 (B) THE BOARD SHALL REPORT ANNUALLY TO THE GOVERNOR, THE
- 33 DEPARTMENT, THE MARYLAND HEALTH CARE COMMISSION, AND, SUBJECT TO §
- 34 2-1246 OF THE STATE GOVERNMENT ARTICLE. TO THE APPROPRIATE STANDING
- 35 COMMITTEES OF THE GENERAL ASSEMBLY ON:
- 36 (1) THE RESULTS OF ANY EFFORTS TO DEVELOP REGIONAL STRATEGIES
- 37 AND PURCHASING ALLIANCES; AND

- 1 (2) ANY RECOMMENDATIONS FOR ENTERING INTO REGIONAL 2 STRATEGIES AND PURCHASING ALLIANCES.
- 3 (C) IN PERFORMING ITS DUTIES UNDER THIS SUBTITLE, THE BOARD SHALL
- 4 WORK COOPERATIVELY WITH THE DEPARTMENT, THE STATE BOARD OF PHARMACY,
- 5 THE MARYLAND HEALTH CARE COMMISSION, AND THE MARYLAND INSURANCE
- 6 ADMINISTRATION.
- 7 15-1A-10.
- 8 EACH HEALTH CARE PROVIDER LICENSED BY THE STATE SHALL EXAMINE THE
- 9 APPLICABILITY OF PHARMACEUTICAL MANUFACTURER PATIENT ASSISTANCE
- 10 PROGRAMS AND PRESCRIPTION DRUG ASSISTANCE PROGRAMS PROVIDED BY THE
- 11 STATE TO EACH PATIENT OF THE HEALTH CARE PROVIDER AND, IF THOSE
- 12 PROGRAMS WOULD BE OF ASSISTANCE TO THE PATIENT, PROVIDE THE APPROPRIATE
- 13 INFORMATION TO THE PATIENT TO INCREASE THE PATIENT'S ACCESS TO
- 14 REASONABLY PRICED PRESCRIPTION DRUGS AND LOWER THE COST OF THE
- 15 PATIENT'S PRESCRIBED DRUGS.
- 16 15-1A-11.
- 17 (A) (1) THERE IS A MARYLAND PRESCRIPTION DRUG FAIR PRICING FUND IN 18 THE DEPARTMENT.
- 19 (2) THE MONEYS IN THE FUND ARE USED TO SUPPLEMENT THE
- 20 FUNDING LEVELS OF:
- 21 (I) THE MARYLAND PHARMACY ASSISTANCE PROGRAM; AND
- 22 (II) THE SHORT-TERM PRESCRIPTION DRUG SUBSIDY PLAN FOR
- 23 MEDICARE PLUS CHOICE ELIGIBLE INDIVIDUALS LIVING IN MEDICALLY
- 24 UNDERSERVED COUNTIES AND PORTIONS OF COUNTIES OPERATED UNDER
- 25 SUBTITLE 6 OF THIS TITLE.
- 26 (B) THE FUND IS A NONLAPSING, REVOLVING FUND.
- 27 (C) ON OR BEFORE FEBRUARY 1 OF EACH YEAR, THE DEPARTMENT OF
- 28 MANAGEMENT AND BUDGET SHALL FORWARD TO THE SECRETARY, FOR PLACEMENT
- 29 IN THE FUND, AN AMOUNT EQUAL TO ANY SAVINGS THAT ARE REALIZED AS A
- 30 RESULT OF THE IMPLEMENTATION OF THIS SUBTITLE DUE TO A DECREASE IN THE
- 31 COSTS OF THE PRESCRIPTION DRUG INSURANCE PLAN PROVIDED TO STATE
- 32 EMPLOYEES AND RETIREES.
- 33 (D) ON OR BEFORE MAY 1 OF EACH YEAR, THE SECRETARY SHALL DISTRIBUTE
- 34 THE MONEYS IN THE FUND TO THE MARYLAND PHARMACY ASSISTANCE PROGRAM
- 35 AND THE SHORT-TERM PRESCRIPTION DRUG SUBSIDY PLAN AS THE GOVERNOR AND
- 36 THE SECRETARY DETERMINES THOSE MONEYS ARE NEEDED.

- 1 15-1A-12.
- THIS SUBTITLE SHALL BE KNOWN AS THE MARYLAND PRESCRIPTION DRUG FAIR PRICING ACT.
- 4 SECTION 2. AND BE IT FURTHER ENACTED, That the initial appointments
- 5 to the Maryland Prescription Drug Fair Pricing Board under § 15-1A-04 of the
- 6 Health General Article, as enacted by this Act, shall be made not later than October
- 7 15, 2001. The Secretary of Health and Mental Hygiene shall call the first meeting of
- 8 the Board not later than November 1, 2001.
- 9 SECTION 3. AND BE IT FURTHER ENACTED, That the terms of the initial
- 10 appointed members of the Maryland Prescription Drug Fair Pricing Board who are
- 11 not members of the General Assembly shall expire as follows:
- 12 (1) two members in 2002;
- 13 (2) two members in 2003; and
- 14 (3) three members in 2004.
- 15 SECTION 4. AND BE IT FURTHER ENACTED, That the Maryland
- 16 Prescription Drug Fair Pricing Board shall submit its initial proposed regulations to
- 17 the Joint Committee on Administrative, Executive, and Legislative Review, including
- 18 its regulations establishing the initial schedule of prices for prescription drugs, by the
- 19 emergency process provided under § 10-111(b) of the State Government Article, not
- 20 later than September 1, 2002.
- 21 SECTION 5. AND BE IT FURTHER ENACTED, That the Secretary of Health
- 22 and Mental Hygiene shall:
- 23 (1) investigate the ability of the federally qualified health centers
- 24 authorized under 42 U.S.C. § 1395x(aa) to obtain lower priced prescription drugs
- 25 under § 340B of the federal Public Health Service Act;
- 26 (2) investigate any barriers under State or federal law to obtaining lower
- 27 cost drugs through that act; and
- 28 (3) report its findings by January 1, 2002 to the Maryland Prescription
- 29 Drug Fair Pricing Board, the Governor, and, subject to § 2-1246 of the State
- 30 Government Article, to the General Assembly.
- 31 SECTION 6. AND BE IT FURTHER ENACTED, That the provisions of this Act
- 32 establishing maximum prices for prescription drugs do not apply to prices set under
- 33 legally binding contracts entered into before October 1, 2001.
- 34 SECTION 7. AND BE IT FURTHER ENACTED, That this Act shall take effect
- 35 October 1, 2001.