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**By: Delegates Barve, Boston, Goldwater, Harrison, Krysiak, and Kirk**

Introduced and read first time: February 22, 1996

Assigned to: Economic Matters

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A BILL ENTITLED

1 AN ACT concerning

2 **Commercial Law - Trade Regulation - Fairness in Drug Pricing Practices**

3 FOR the purpose of requiring manufacturers of drugs to offer and sell drugs to certain  
4 purchasers in the State on the same terms and conditions; authorizing  
5 manufacturers of drugs to offer price reductions or programs under certain  
6 circumstances; prohibiting a unit of the State or a unit of any political subdivision of  
7 the State from purchasing any drugs from a manufacturer that engages in certain  
8 price discrimination activities; providing an exception for necessary and unique  
9 drugs; requiring manufacturers of drugs in this State to file a certain affidavit with  
10 the Department of Health and Mental Hygiene each year on or before a certain  
11 date; providing that drugs sold by manufacturers will be declared ineligible for sale  
12 in the State's medicaid program under certain circumstances; requiring the  
13 Attorney General to bring an action in the circuit court to restrain violations of this  
14 Act; providing certain penalties for violations of this Act; authorizing a civil action  
15 by a purchaser injured by a violation of this Act; providing for the applicability of  
16 this Act; providing that this Act may not be deemed to supersede, restrict, or  
17 otherwise limit the antitrust laws of this State; defining certain terms; and generally  
18 relating to the regulation of drug pricing in this State.

19 BY adding to

20 Article - Commercial Law  
21 Section 11-1501 through 11-1507, inclusive, to be under the new subtitle "Subtitle  
22 15. Fairness in Drug Pricing Practices"  
23 Annotated Code of Maryland  
24 (1990 Replacement Volume and 1995 Supplement)

25 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF  
26 MARYLAND, That the Laws of Maryland read as follows:

27 **Article - Commercial Law**

28 **SUBTITLE 15. FAIRNESS IN DRUG PRICING PRACTICES.**

29 11-1501.

30 (A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS  
31 INDICATED.

1 (B) "ADMINISTERING" MEANS THE DIRECT INTRODUCTION OF A DRUG AT A  
2 GIVEN TIME OR TIMES, WHETHER BY INJECTION OR OTHER MEANS, AND WHETHER  
3 IN LIQUID, TABLET, CAPSULE, OR OTHER FORM.

4 (C) "CHARITABLE HEALTH CARE PROVIDER" MEANS ANY HEALTH CARE  
5 PROVIDER EXEMPTED FROM FEDERAL TAXATION BY § 501(C)(3) OF THE INTERNAL  
6 REVENUE CODE AND WHICH PROVIDES HEALTH CARE SERVICES TO THE PUBLIC, A  
7 SUBSTANTIAL PORTION OF WHICH ARE PROVIDED FREE OR AT A REDUCED FEE  
8 BASED ON THE PATIENT'S ABILITY TO PAY.

9 (D) "COVERED TRANSACTION" MEANS ANY SALE OR OFFER TO SELL A DRUG  
10 TO A PURCHASER IN THIS STATE IN WHICH A MANUFACTURER NEGOTIATES,  
11 ESTABLISHES, DETERMINES, OR OTHERWISE CONTROLS THE PRICE, TERMS, OR  
12 CONDITIONS OF SALE, WHETHER BY DIRECT SALE TO A PURCHASER OR THROUGH A  
13 CONTRACTUAL ARRANGEMENT IMPLEMENTED BY ONE OR MORE WHOLESALERS.

14 (E) "DRUG" MEANS ANY SUBSTANCE THAT IS SUBJECT TO THE PROVISIONS  
15 OF § 503(B)(1) OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.

16 (F) "MANUFACTURER" MEANS ANY PERSON, OTHER THAN A WHOLESALER,  
17 THAT SELLS DRUGS EITHER DIRECTLY TO PURCHASERS OR THROUGH A  
18 WHOLESALER FOR RESALE.

19 (G) (1) "PURCHASER" MEANS ANY PERSON DOING BUSINESS IN THIS STATE  
20 WHO SELLS OR DISPENSES DRUGS DIRECTLY TO CONSUMERS IN THIS STATE.

21 (2) "PURCHASER" DOES NOT INCLUDE:

22 (I) THE DEPARTMENT OF VETERANS' AFFAIRS, THE DEPARTMENT  
23 OF DEFENSE, COVERED ENTITIES UNDER § 340(B) OF THE PUBLIC HEALTH SERVICE  
24 ACT, AND ANY OTHER FEDERAL, STATE, OR LOCAL GOVERNMENT AGENCY THAT  
25 DIRECTLY PURCHASES DRUGS;

26 (II) NURSING HOMES AND OTHER LONG-TERM CARE  
27 INSTITUTIONS WHICH HAVE PHARMACY SERVICES PROVIDED FOR THEIR  
28 INPATIENTS' OWN USE, BUT NOT FOR RESALE OR OUTPATIENT USE;

29 (III) HOSPITALS, INCLUDING ANY FACILITIES OWNED BY A  
30 HOSPITAL, WHICH PROVIDE PHARMACY SERVICES FOR THEIR PATIENTS' OWN USE  
31 ON AN INPATIENT OR OUTPATIENT BASIS, PROVIDED:

32 1. THAT THE SERVICES ARE FOR ADMINISTERING AT THE  
33 HOSPITAL OR HOSPITAL FACILITY AND ARE NOT FOR RESALE;

34 2. NOT MORE THAN A 72-HOUR SUPPLY OF PRESCRIPTION  
35 DRUGS IS PROVIDED FOR A PATIENT AT THE TIME OF DISCHARGE FOR A PATIENT'S  
36 OWN USE AND NOT FOR RESALE; OR

37 3. AN EMPLOYEE OF THE HOSPITAL MAY BE SUPPLIED  
38 PHARMACY SERVICES FOR THE EMPLOYEE'S OWN USE AND NOT FOR RESALE;

39 (IV) A GROUP PURCHASING ENTITY OR SERVICE THAT PURCHASES  
40 DRUGS OR PHARMACY SERVICES ON BEHALF OF HOSPITALS, PROVIDED THAT THE

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1 DRUGS OR PHARMACY SERVICES ARE FOR ADMINISTERING AT THE HOSPITAL OR  
2 HOSPITAL FACILITY AND ARE NOT FOR RESALE; OR

3 (V) CHARITABLE HEALTH CARE PROVIDERS, EXCEPT THOSE  
4 WHICH ISSUE, OFFER, OR ADMINISTER A HEALTH INSURANCE POLICY OR AN  
5 EMPLOYEE BENEFIT PLAN FOR OTHER THAN THE EMPLOYEES OF THE CHARITABLE  
6 HEALTH CARE PROVIDER.

7 (H) "WHOLESALER" MEANS ANY PERSON, OTHER THAN A MANUFACTURER,  
8 THAT SELLS DRUGS TO PURCHASERS FOR RESALE.

9 11-1502.

10 (A) THIS SUBTITLE IS INTENDED TO ENCOURAGE MANUFACTURERS TO  
11 DEVELOP A VARIETY OF MARKETING PROGRAMS. NOTHING IN THIS SUBTITLE IS  
12 INTENDED TO CREATE A SINGLE PRICE FOR PRESCRIPTION DRUGS OR TO  
13 ELIMINATE EXISTING PRICE REDUCTION PROGRAMS, AS LONG AS THOSE  
14 PROGRAMS COMPLY WITH THIS SUBTITLE.

15 (B) THIS SUBTITLE MAY NOT BE DEEMED TO SUPERSEDE, RESTRICT, OR  
16 OTHERWISE LIMIT THE ANTITRUST LAWS OF THIS STATE.

17 11-1503.

18 THIS SUBTITLE APPLIES TO ANY PURCHASE OF DRUGS TO BE DELIVERED TO A  
19 PURCHASER OR A PURCHASER'S FACILITY, WHETHER OR NOT LOCATED IN THIS  
20 STATE, FOR RESALE TO CONSUMERS FROM A FACILITY LOCATED IN THIS STATE.

21 11-1504.

22 (A) A MANUFACTURER SHALL OFFER TO SELL AND SHALL SELL DRUGS IN A  
23 COVERED TRANSACTION, DURING THE SAME TIME PERIOD, TO ALL PURCHASERS  
24 ON THE SAME TERMS AND CONDITIONS, WHETHER THE SALE IS A DIRECT  
25 TRANSACTION BETWEEN A MANUFACTURER AND A PURCHASER OR ONE IN WHICH  
26 A MANUFACTURER SELLS TO A PURCHASER THROUGH A CONTRACTUAL  
27 ARRANGEMENT IMPLEMENTED BY ONE OR MORE WHOLESALERS.

28 (B) (1) THIS SECTION DOES NOT PROHIBIT A MANUFACTURER FROM  
29 OFFERING ANY PRICE REDUCTION OR PROGRAM, AS LONG AS THE PRICE  
30 REDUCTION OR PROGRAM IS MADE AVAILABLE TO ALL PURCHASERS ON THE SAME  
31 TERMS AND CONDITIONS, INCLUDING BUT NOT LIMITED TO:

32 (I) REDUCTIONS JUSTIFIED BY THE ECONOMIES OR EFFICIENCIES  
33 REALIZED THROUGH VOLUME PURCHASES;

34 (II) REDUCTIONS AVAILABLE THROUGH MARKET SHARE  
35 MOVEMENT AGREEMENTS;

36 (III) REDUCTIONS FOR PLACING DRUGS ON A FORMULARY;

37 (IV) REDUCTIONS FOR PROMPT PAYMENT;

38 (V) REDUCTIONS FOR LIMITED SITE DELIVERY; AND

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1 (VI) OPPORTUNITIES INVOLVING FREE MERCHANDISE, SAMPLES,  
2 AND SIMILAR TRADE CONCESSIONS.

3 (2) A MANUFACTURER MAY NOT PROVIDE PRICE REDUCTIONS TO ANY  
4 PURCHASER BASED SOLELY ON THE CLASS OF TRADE TO WHICH THE PURCHASER  
5 BELONGS.

6 11-1505.

7 (A) A UNIT OF THE STATE OR A UNIT OF ANY POLITICAL SUBDIVISION OF THE  
8 STATE MAY NOT PURCHASE ANY DRUGS OF A MANUFACTURER THAT ENGAGES IN  
9 PRICE DISCRIMINATION PROHIBITED BY THIS SUBTITLE, INCLUDING A COVERED  
10 TRANSACTION IN WHICH A MANUFACTURER SELLS TO A UNIT OF THE STATE OR A  
11 UNIT OF ANY POLITICAL SUBDIVISION OF THE STATE THROUGH A CONTRACTUAL  
12 ARRANGEMENT IMPLEMENTED BY ONE OR MORE WHOLESALERS.

13 (B) EXCEPTIONS MAY BE PERMITTED UNDER THIS SUBTITLE BY THE  
14 SECRETARY OF THE DEPARTMENT OF HEALTH AND MENTAL HYGIENE IN THE CASE  
15 OF A NECESSARY AND UNIQUE DRUG NOT OTHERWISE AVAILABLE WHICH IS  
16 PRODUCED OR DISTRIBUTED BY A MANUFACTURER WHO HAS VIOLATED THIS  
17 SUBTITLE.

18 11-1506.

19 EACH MANUFACTURER SELLING DRUGS IN THIS STATE SHALL SUBMIT TO THE  
20 SECRETARY OF THE DEPARTMENT OF HEALTH AND MENTAL HYGIENE BEFORE  
21 JANUARY 1 OF 1996 AND OF EACH YEAR THEREAFTER AN AFFIDAVIT STATING THAT  
22 IT WILL NOT ENGAGE IN CONDUCT PROHIBITED BY THIS SUBTITLE.

23 11-1507.

24 (A) (1) THE ATTORNEY GENERAL SHALL BRING AN ACTION IN THE CIRCUIT  
25 COURT OF ANY COUNTY IN WHICH A VIOLATION OCCURRED TO RESTRAIN  
26 VIOLATIONS OF THIS SUBTITLE.

27 (2) THE COURT MAY EXERCISE ALL EQUITABLE POWERS NECESSARY  
28 TO REMOVE THE EFFECTS OF ANY VIOLATION IT FINDS AND TO PREVENT THE  
29 CONTINUATION OR RENEWAL OF THE VIOLATION.

30 (3) IN ADDITION TO EQUITABLE REMEDIES OR OTHER RELIEF, THE  
31 COURT MAY ASSESS AGAINST ANY PERSON WHO VIOLATES THIS SUBTITLE OR ANY  
32 REGULATION ADOPTED UNDER THIS SUBTITLE A CIVIL PENALTY OF NOT LESS THAN  
33 \$1,000 NOR MORE THAN \$50,000 FOR EACH VIOLATION TO BE PAID TO THE GENERAL  
34 FUND OF THE STATE.

35 (4) IN EXERCISING THE AUTHORITY UNDER THIS SUBSECTION, THE  
36 ATTORNEY GENERAL SHALL HAVE THE SAME POWERS GRANTED TO THE  
37 ATTORNEY GENERAL UNDER § 11-205 OF THIS TITLE.

38 (B) (1) A PURCHASER INJURED BY A VIOLATION OF THIS SUBTITLE MAY  
39 BRING A CIVIL ACTION FOR DAMAGES OR FOR AN INJUNCTION OR BOTH AGAINST  
40 ANY MANUFACTURER WHO HAS VIOLATED THIS SUBTITLE.

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1                   (2) AN INJURED PURCHASER SHALL BE AWARDED THREE TIMES THE  
2 AMOUNT OF ACTUAL DAMAGES RESULTING FROM THE VIOLATION, WITH COSTS  
3 AND REASONABLE ATTORNEY'S FEES.

4                   (C) (1) ANY MANUFACTURER WHO VIOLATES THIS SUBTITLE SHALL HAVE  
5 ALL OF ITS DRUGS DECLARED INELIGIBLE FOR SALE UNDER THIS STATE'S  
6 MEDICAID PROGRAM.

7                   (2) EXCEPTIONS MAY BE PERMITTED UNDER THIS SUBTITLE BY THE  
8 SECRETARY OF THE DEPARTMENT OF HEALTH AND MENTAL HYGIENE IN THE CASE  
9 OF A NECESSARY AND UNIQUE DRUG NOT OTHERWISE AVAILABLE WHICH IS  
10 PRODUCED OR DISTRIBUTED BY A MANUFACTURER WHO HAS VIOLATED THIS  
11 SUBTITLE.

12                  SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect  
13 October 1, 1996.