
By: Senator Dorman

Introduced and read first time: February 1, 1996

Assigned to: Finance

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.