

SENATE BILL 986

J2, J5

4lr3300
CF HB 1056

By: **Senator Lam**

Introduced and read first time: February 2, 2024

Assigned to: Finance

Committee Report: Favorable with amendments

Senate action: Adopted

Read second time: March 21, 2024

CHAPTER _____

1 AN ACT concerning

2 **State Board of Pharmacy – Prohibition on Discrimination Against 340B Drug**
3 **Distribution**

4 FOR the purpose of prohibiting a 340B manufacturer, ~~wholesale drug distributor, or~~
5 ~~third party logistics provider, or an agent or affiliate of a 340B manufacturer,~~
6 ~~wholesale drug distributor, or third party logistics provider,~~ from taking certain
7 direct or indirect actions to limit or restrict the acquisition or delivery of a 340B drug;
8 making a violation of this Act an unfair, abusive, or deceptive trade practice within
9 the meaning of the Consumer Protection Act; requiring the Maryland Prescription
10 Drug Affordability Board to conduct a study of the 340B Program; and generally
11 relating to 340B drugs.

12 BY repealing and reenacting, with amendments,
13 Article – Commercial Law
14 Section 13–301(14)(xl)
15 Annotated Code of Maryland
16 (2013 Replacement Volume and 2023 Supplement)

17 BY repealing and reenacting, without amendments,
18 Article – Commercial Law
19 Section 13–301(14)(xli)
20 Annotated Code of Maryland
21 (2013 Replacement Volume and 2023 Supplement)

22 BY adding to

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.

Underlining indicates amendments to bill.

~~Strike out~~ indicates matter stricken from the bill by amendment or deleted from the law by amendment.



1 Article – Commercial Law
2 Section 13–301(14)(xlii)
3 Annotated Code of Maryland
4 (2013 Replacement Volume and 2023 Supplement)

5 BY repealing and reenacting, without amendments,
6 Article – Health Occupations
7 Section 12–101(a) and (d)
8 Annotated Code of Maryland
9 (2021 Replacement Volume and 2023 Supplement)

10 BY adding to
11 Article – Health Occupations
12 Section 12–6C–09.1
13 Annotated Code of Maryland
14 (2021 Replacement Volume and 2023 Supplement)

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

17 **Article – Commercial Law**

18 13–301.

19 Unfair, abusive, or deceptive trade practices include any:

20 (14) Violation of a provision of:

21 (xl) Title 14, Subtitle 13 of the Public Safety Article; [or]

22 (xli) Title 14, Subtitle 45 of this article; or

23 **(XLII) SECTION 12–6C–09.1 OF THE HEALTH OCCUPATIONS**
24 **ARTICLE; OR**

25 **Article – Health Occupations**

26 12–101.

27 (a) In this title the following words have the meanings indicated.

28 (d) “Board” means the State Board of Pharmacy.

29 **12–6C–09.1.**

1 (A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE MEANINGS
2 INDICATED.

3 (2) “COVERED ENTITY” HAS THE MEANING STATED IN 42 U.S.C. §
4 256B(A)(4).

5 (3) “PACKAGE” HAS THE MEANING STATED IN 21 U.S.C. §
6 360EEE(11).

7 (4) (I) “340B DRUG” MEANS A DRUG THAT:

8 1. IS A COVERED OUTPATIENT DRUG UNDER 42 U.S.C. §
9 256B;

10 2. HAS BEEN SUBJECT TO AN OFFER FOR REDUCED
11 PRICES BY A 340B MANUFACTURER UNDER 42 U.S.C. § 256B(A)(1); AND

12 3. IS PURCHASED BY A COVERED ENTITY.

13 (II) “340B DRUG” INCLUDES A DRUG THAT WOULD HAVE BEEN
14 PURCHASED BUT FOR THE LIMITATION UNDER SUBSECTION ~~(D)~~ (C) OF THIS
15 SECTION.

16 (5) “340B MANUFACTURER” MEANS A MANUFACTURER, AS DEFINED
17 IN 42 U.S.C. § 1396R-8(K)(5), OF COVERED OUTPATIENT DRUGS THAT HAS SIGNED
18 A PHARMACEUTICAL PRICING AGREEMENT UNDER 42 U.S.C. § 256B(A)(1).

19 (B) ~~THIS SECTION APPLIES TO:~~

20 ~~(1) A 340B MANUFACTURER;~~

21 ~~(2) A WHOLESALE DRUG DISTRIBUTOR;~~

22 ~~(3) A THIRD PARTY LOGISTICS PROVIDER; AND~~

23 ~~(4) AN AGENT OR AFFILIATE OF A 340B MANUFACTURER,~~
24 ~~WHOLESALE DRUG DISTRIBUTOR, OR THIRD PARTY LOGISTICS PROVIDER.~~

25 ~~(C)~~ THIS SECTION MAY NOT BE CONSTRUED TO BE:

26 (1) LESS RESTRICTIVE THAN ANY FEDERAL LAW THAT IS APPLICABLE
27 TO A PERSON REGULATED BY THIS SECTION; OR

28 (2) IN CONFLICT WITH APPLICABLE FEDERAL AND STATE LAWS AND
29 REGULATIONS.

1 ~~(D)~~ (C) (1) EXCEPT AS PROVIDED IN PARAGRAPH (2) OF THIS
 2 SUBSECTION, ~~AN ENTITY SUBJECT TO THIS SECTION~~ A 340B MANUFACTURER MAY
 3 NOT DIRECTLY OR INDIRECTLY DENY, RESTRICT, PROHIBIT, DISCRIMINATE
 4 AGAINST, OR OTHERWISE LIMIT THE ACQUISITION OF A 340B DRUG BY, OR
 5 DELIVERY OF A 340B DRUG TO, A PHARMACY THAT IS UNDER CONTRACT WITH OR
 6 OTHERWISE AUTHORIZED BY A COVERED ENTITY TO RECEIVE 340B DRUGS ON
 7 BEHALF OF THE COVERED ENTITY UNLESS THE RECEIPT OF 340B DRUGS IS
 8 PROHIBITED BY THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES.

9 (2) ~~AN ENTITY SUBJECT TO THIS SECTION~~ A 340B MANUFACTURER
 10 MAY LIMIT THE DISTRIBUTION OF A 340B DRUG IF THE LIMITATION IS REQUIRED
 11 UNDER 21 U.S.C. § 355-1.

12 ~~(E)~~ (D) (1) (I) A VIOLATION OF SUBSECTION ~~(D)~~ (C) OF THIS
 13 SECTION:

14 ~~(H)~~ 1. SUBJECT TO PARAGRAPH (2) OF THIS SUBSECTION, IS
 15 AN UNFAIR, ABUSIVE, OR DECEPTIVE TRADE PRACTICE WITHIN THE MEANING OF
 16 TITLE 13 OF THE COMMERCIAL LAW ARTICLE AND IS SUBJECT TO THE
 17 ENFORCEMENT AND PENALTY PROVISIONS CONTAINED IN TITLE 13 OF THE
 18 COMMERCIAL LAW ARTICLE; AND

19 ~~(H)~~ 2. A. SHALL IF THE ALLEGED VIOLATION WAS
 20 COMMITTED BY A PERSON THAT IS LICENSED OR PERMITTED BY THE BOARD, SHALL
 21 BE JOINTLY OR SEPARATELY INVESTIGATED BY THE BOARD OR THE CONSUMER
 22 PROTECTION DIVISION OF THE OFFICE OF THE ATTORNEY GENERAL; OR

23 B. IF THE ALLEGED VIOLATION WAS COMMITTED BY A
 24 PERSON THAT IS NOT LICENSED OR PERMITTED BY THE BOARD, SHALL BE
 25 INVESTIGATED BY THE CONSUMER PROTECTION DIVISION OF THE OFFICE OF THE
 26 ATTORNEY GENERAL.

27 (II) AS PART OF AN INVESTIGATION CONDUCTED UNDER
 28 PARAGRAPH (1)(I)2 OF THIS SUBSECTION, THE BOARD OR THE CONSUMER
 29 PROTECTION DIVISION OF THE OFFICE OF THE ATTORNEY GENERAL MAY
 30 INVESTIGATE AN AFFILIATE OR A CONTRACTOR OF THE 340B MANUFACTURER,
 31 INCLUDING A WHOLESALER OR THIRD-PARTY LOGISTICS PROVIDER.

32 (2) (I) IN ADDITION TO THE PENALTIES UNDER TITLE 13 OF THE
 33 COMMERCIAL LAW ARTICLE, A CIVIL FINE MAY BE ASSESSED IN THE AMOUNT OF
 34 ~~\$50,000~~ \$5,000 PER VIOLATION OF SUBSECTION ~~(D)~~ (C) OF THIS SECTION.

1 **(II) A VIOLATION OF THIS SECTION DOES NOT CREATE A**
2 **PRIVATE RIGHT OF ACTION UNDER § 13-408 OF THE COMMERCIAL LAW ARTICLE.**

3 **(3) IF A VIOLATION OF SUBSECTION ~~(D)~~ (C) OF THIS SECTION IS**
4 **COMMITTED BY A PERSON LICENSED OR PERMITTED BY THE BOARD, THE BOARD**
5 **MAY IMPOSE DISCIPLINE, SUSPENSION, OR REVOCATION OF THE PERSON'S LICENSE**
6 **OR PERMIT.**

7 **(4) EACH PACKAGE OF 340B DRUGS SUBJECT TO A VIOLATION OF**
8 **SUBSECTION ~~(D)~~ (C) OF THIS SECTION SHALL CONSTITUTE A SEPARATE VIOLATION.**

9 SECTION 2. AND BE IT FURTHER ENACTED, That:

10 (a) The Maryland Prescription Drug Affordability Board, in consultation with the
11 Maryland Department of Health:

12 (1) shall conduct a study on:

13 (i) the current implementation and scope of the 340B Program in
14 the State;

15 (ii) the implementation and impact of the implementation of Section
16 1 of this Act; and

17 (iii) the finances of the Program in the State, including how covered
18 entities reinvest savings realized from the Program; and

19 (2) may require covered entities and 340B manufacturers to report
20 information as necessary to complete the study.

21 (b) On or before July 1, 2026, the Maryland Prescription Drug Affordability Board
22 shall report its findings and recommendations from the study to the Senate Finance
23 Committee and the House Health and Government Operations Committee, in accordance
24 with § 2-1257 of the State Government Article.

25 SECTION ~~2~~ 3. AND BE IT FURTHER ENACTED, That this Act shall take effect
26 July 1, 2024.