HOUSE BILL 1056

J2, J5 4lr2443
CF SB 986

By: **Delegates Guzzone, Bagnall, Hill, Kaiser, R. Lewis, White Holland, ~~and Woods~~ Woods, Alston, Bhandari, Chisholm, Cullison, Hutchinson, S. Johnson, Kerr, Kipke, Lopez, Martinez, M. Morgan, Pena–Melnyk, Reilly, Rosenberg, Szeliga, and Taveras**

Introduced and read first time: February 7, 2024
Assigned to: Health and Government Operations

Committee Report: Favorable with amendments
House action: Adopted
Read second time: March 7, 2024

CHAPTER _____

AN ACT concerning

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

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

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

BY repealing and reenacting, without amendments,
Article – Commercial Law
Section 13–301(14)(xli)
Annotated Code of Maryland

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.

(2013 Replacement Volume and 2023 Supplement)

BY adding to
Article – Commercial Law
Section 13–301(14)(xlii)
Annotated Code of Maryland
(2013 Replacement Volume and 2023 Supplement)

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

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

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

Article – Commercial Law

13–301.

Unfair, abusive, or deceptive trade practices include any:

(14) Violation of a provision of:

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

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

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

Article – Health Occupations

12–101.

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

(d) "Board" means the State Board of Pharmacy.

12–6C–09.1.

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

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

(3) "PACKAGE" HAS THE MEANING STATED IN 21 U.S.C. § 360EEE(11).

(4) (I) "340B DRUG" MEANS A DRUG THAT:

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

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

3. IS PURCHASED BY A COVERED ENTITY.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

SECTION 2. AND BE IT FURTHER ENACTED, That:

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

(1) shall conduct a study on:

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

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

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

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

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

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