

HOUSE BILL 591

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3lr2041
CF SB 595

By: **Delegate Morhaim**

Introduced and read first time: January 31, 2013

Assigned to: Health and Government Operations

Committee Report: Favorable with amendments

House action: Adopted

Read second time: March 13, 2013

CHAPTER _____

1 AN ACT concerning

2 **State Board of Pharmacy – Wholesale Distribution – Pharmacies**

3 FOR the purpose of authorizing certain pharmacy permit holders to conduct wholesale
4 distribution under certain circumstances; limiting the authority of a ~~pharmacy~~
5 ~~permit holder~~ certain pharmacy permit holders to engage in wholesale
6 distribution; ~~altering certain definitions~~ altering the definition of “intracompany
7 sales” to exclude from the definition a transaction or transfer of prescription
8 drugs from a pharmacy to a wholesale distributor; altering the definition of
9 “wholesale distribution” to exempt from the requirement to obtain a wholesale
10 distribution permit the sale or transfer from a pharmacy or pharmacy
11 warehouse of certain prescription drugs to the original wholesale distributor;
12 conforming the definition of “wholesale distributor” to certain provisions of this
13 Act; and generally relating to wholesale distribution and pharmacies.

14 BY repealing and reenacting, with amendments,

15 Article – Health Occupations

16 Section 12-406 and ~~12-6C-01(i) and (v)~~ 12-6C-01(i), (u), and (v)

17 Annotated Code of Maryland

18 (2009 Replacement Volume and 2012 Supplement)

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

21 **Article – Health Occupations**

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 12-406.

2 (A) A pharmacy permit authorizes the pharmacy permit holder to establish
3 and operate the pharmacy while the pharmacy permit is effective.

4 ~~(B) A PHARMACY PERMIT HOLDER MAY ENGAGE IN WHOLESALE~~
5 ~~DISTRIBUTION ONLY WITH ANOTHER PHARMACY PERMIT HOLDER.~~

6 (B) (1) SUBJECT TO PARAGRAPHS (2) AND (3) OF THIS SUBSECTION,
7 A PHARMACY PERMIT HOLDER MAY CONDUCT WHOLESALE DISTRIBUTION, IF:

8 (I) THE WHOLESALE DISTRIBUTION BUSINESS DOES NOT
9 EXCEED 5% OF THE PHARMACY PERMIT HOLDER'S ANNUAL SALES; AND

10 (II) THE PHARMACY PERMIT HOLDER:

11 1. MAINTAINS RECORDS OF WHOLESALE
12 DISTRIBUTION SEPARATELY FROM ITS OTHER RECORDS; AND

13 2. MAKES THE RECORDS OF WHOLESALE
14 DISTRIBUTION AVAILABLE FOR INSPECTION BY THE BOARD.

15 (2) A PHARMACY PERMIT HOLDER THAT OBTAINS A WAIVER
16 FROM THE BOARD UNDER § 12-403(C) OF THIS SUBTITLE MAY CONDUCT
17 WHOLESALE DISTRIBUTION ONLY WITH ANOTHER PHARMACY PERMIT HOLDER.

18 (3) A RETAIL PHARMACY THAT HOLDS A PHARMACY PERMIT MAY
19 CONDUCT WHOLESALE DISTRIBUTION ONLY WITH:

20 (I) ANOTHER PHARMACY PERMIT HOLDER; AND

21 (II) A WHOLESALE DISTRIBUTOR IF THE RETAIL PHARMACY:

22 1. REPORTS TO THE BOARD THAT THE RETAIL
23 PHARMACY IS CONDUCTING WHOLESALE DISTRIBUTION WITH A WHOLESALE
24 DISTRIBUTOR; AND

25 2. A. MAINTAINS RECORDS OF WHOLESALE
26 DISTRIBUTION WITH WHOLESALE DISTRIBUTORS SEPARATELY FROM ITS
27 RECORDS OF WHOLESALE DISTRIBUTION WITH PHARMACY PERMIT HOLDERS;
28 AND

29 B. MAKES THE RECORDS OF WHOLESALE
30 DISTRIBUTION AVAILABLE FOR INSPECTION BY THE BOARD.

1 12-6C-01.

2 (i) "Intracompany sales" means a:

3 (1) Transaction or transfer of prescription drugs between a division,
4 subsidiary, parent, or affiliated or related company under common ownership and
5 control of a corporate entity, **OTHER THAN A TRANSACTION OR TRANSFER OF**
6 **PRESCRIPTION DRUGS FROM A PHARMACY TO A WHOLESALE DISTRIBUTOR;** or

7 (2) Transaction or transfer of a co-licensed product between
8 co-licensed partners.

9 (u) (1) "Wholesale distribution" means the distribution of prescription
10 drugs or prescription devices to persons other than a consumer or patient.

11 (2) "Wholesale distribution" does not include:

12 (i) Intracompany sales;

13 (ii) The sale, purchase, distribution, trade, or transfer of a
14 prescription drug or an offer to sell, purchase, distribute, trade, or transfer a
15 prescription drug for emergency medical reasons;

16 (iii) The sale, purchase, distribution, trade, or transfer of a
17 prescription drug or prescription device by the Department for public health purposes;

18 (iv) The distribution of samples of a prescription drug by a
19 manufacturer's representative;

20 (v) Prescription drug returns conducted by a hospital, health
21 care entity, or charitable institution in accordance with 21 C.F.R. § 203.23;

22 (vi) The sale of minimal quantities of prescription drugs by retail
23 pharmacies to licensed health care practitioners for office use;

24 (vii) The sale, purchase, or trade of a prescription drug, an offer
25 to sell, purchase, or trade a prescription drug, or the dispensing of a prescription drug
26 in accordance with a prescription;

27 (viii) The sale, transfer, merger, or consolidation of all or part of
28 the business of a pharmacy to or with another pharmacy, whether accomplished as a
29 purchase and sale of stock or business assets;

30 (ix) The sale, purchase, distribution, trade, or transfer of a
31 prescription drug from one authorized distributor of record to one additional
32 authorized distributor of record if:

1 1. The manufacturer has stated in writing to the
 2 receiving authorized distributor of record that the manufacturer is unable to supply
 3 the prescription drug; and

4 2. The supplying authorized distributor of record states
 5 in writing that the prescription drug being supplied had until that time been
 6 exclusively in the normal distribution channel;

7 (x) The delivery of, or offer to deliver, a prescription drug by a
 8 common carrier solely in the common carrier's usual course of business of transporting
 9 prescription drugs, if the common carrier does not store, warehouse, or take legal
 10 ownership of the prescription drug; or

11 (xi) The sale or transfer from a [retail] pharmacy or pharmacy
 12 warehouse of expired, damaged, returned, or recalled prescription drugs to:

13 1. **THE ORIGINAL WHOLESALE DISTRIBUTOR;**

14 2. [the] **THE** original manufacturer; or

15 3. [to a] **A** third party returns processor.

16 (v) (1) “Wholesale distributor” means a person that is engaged in the
 17 wholesale distribution of prescription drugs or prescription devices.

18 (2) “Wholesale distributor” includes:

19 (i) A manufacturer;

20 (ii) A repackager;

21 (iii) An own-label distributor;

22 (iv) A private-label distributor;

23 (v) A jobber;

24 (vi) A broker;

25 (vii) A warehouse, including a manufacturer's or distributor's
 26 warehouse;

27 (viii) A manufacturer's exclusive distributor or an authorized
 28 distributor of record;

29 (ix) A drug wholesaler or distributor;

- 1 (x) An independent wholesale drug trader;
- 2 (xi) A third party logistics provider;
- 3 (xii) A [retail] pharmacy that conducts wholesale distribution, if
- 4 the wholesale distribution business accounts for more than 5% of the [retail]
- 5 pharmacy's annual sales; and
- 6 (xiii) A pharmacy warehouse that conducts wholesale
- 7 distribution.

8 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect

9 October 1, 2013.

Approved:

Governor.

Speaker of the House of Delegates.

President of the Senate.