

SENATE BILL 163

J2

(0lr1337)

ENROLLED BILL

— Education, Health, and Environmental Affairs / Health and Government Operations —

Introduced by **Senator Conway**

Read and Examined by Proofreaders:

Proofreader.

Proofreader.

Sealed with the Great Seal and presented to the Governor, for his approval this

_____ day of _____ at _____ o'clock, _____ M.

President.

CHAPTER _____

1 AN ACT concerning

2 **State Board of Pharmacy – ~~Wholesale Distributors – Accreditation and~~**
3 **~~Reciprocity~~ Wholesale Distributor Permitting and Prescription Drug**
4 **Integrity Act – Revisions**

5 FOR the purpose of authorizing the State Department of Health and Mental Hygiene
6 to purchase and distribute certain drugs and devices for certain purposes;
7 requiring the Department to adopt certain regulations, in consultation with the
8 State Board of Pharmacy, for certain purposes; altering ~~certain circumstances~~
9 ~~when the circumstances under which~~ the ~~State Board of Pharmacy~~ Board may
10 grant “deemed status” to wholesale distributors; requiring wholesale
11 distributors that receive a permit by reciprocity to comply with certain
12 requirements; requiring wholesale distributors that are not eligible for
13 reciprocity to be accredited; requiring the Board to grant “deemed status” to
14 certain wholesale distributors under certain circumstances; altering ~~the~~
15 ~~definition of “deemed status” and certain definitions and defining certain other~~

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.

Italics indicate opposite chamber / conference committee amendments.



1 ~~terms; and generally relating to the accreditation of and granting of reciprocity~~
 2 ~~to wholesale distributors of prescription drugs~~ Wholesale Distributor Permitting
 3 and Prescription Drug Integrity Act.

4 BY repealing and reenacting, without amendments,
 5 Article – Health Occupations
 6 Section 12–6C–01(a), (h), (n), (v), and (w)
 7 Annotated Code of Maryland
 8 (2009 Replacement Volume)

9 BY repealing and reenacting, with amendments,
 10 Article – Health Occupations
 11 Section 12–6C–01(u) and 12–6C–04
 12 Annotated Code of Maryland
 13 (2009 Replacement Volume)

14 BY adding to
 15 Article – Health Occupations
 16 Section 12–6C–03.1
 17 Annotated Code of Maryland
 18 (2009 Replacement Volume)

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**

22 12–6C–01.

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

24 (h) “Facility” means a facility of a wholesale distributor where prescription
 25 drugs are stored, handled, repackaged, or offered for sale.

26 (n) “Pedigree” means a document or electronic file containing information
 27 that records each wholesale distribution of a prescription drug.

28 (u) (1) “Wholesale distribution” means the distribution of prescription
 29 drugs or prescription devices to persons other than a consumer or patient.

30 (2) “Wholesale distribution” does not include:

31 (i) Intracompany sales;

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

1 **(III) THE SALE, PURCHASE, DISTRIBUTION, TRADE, OR**
2 **TRANSFER OF A PRESCRIPTION DRUG OR PRESCRIPTION DEVICE BY THE**
3 **DEPARTMENT FOR PUBLIC HEALTH PURPOSES;**

4 ~~[(iii)] (IV)~~ **The distribution of samples of a prescription drug by a**
5 **manufacturer's representative;**

6 ~~[(iv)] (V)~~ **Prescription drug returns conducted by a hospital,**
7 **health care entity, or charitable institution in accordance with 21 C.F.R. § 203.23;**

8 ~~[(v)] (VI)~~ **The sale of minimal quantities of prescription drugs**
9 **by retail pharmacies to licensed health care practitioners for office use;**

10 ~~[(vi)] (VII)~~ **The sale, purchase, or trade of a prescription drug, an**
11 **offer to sell, purchase, or trade a prescription drug, or the dispensing of a prescription**
12 **drug in accordance with a prescription;**

13 ~~[(vii)] (VIII)~~ **The sale, transfer, merger, or consolidation of all or**
14 **part of the business of a pharmacy to or with another pharmacy, whether**
15 **accomplished as a purchase and sale of stock or business assets;**

16 ~~[(viii)] (IX)~~ **The sale, purchase, distribution, trade, or transfer of a**
17 **prescription drug from one authorized distributor of record to one additional**
18 **authorized distributor of record if:**

19 1. **The manufacturer has stated in writing to the**
20 **receiving authorized distributor of record that the manufacturer is unable to supply**
21 **the prescription drug; and**

22 2. **The supplying authorized distributor of record states**
23 **in writing that the prescription drug being supplied had until that time been**
24 **exclusively in the normal distribution channel;**

25 ~~[(ix)] (X)~~ **The delivery of, or offer to deliver, a prescription drug**
26 **by a common carrier solely in the common carrier's usual course of business of**
27 **transporting prescription drugs, if the common carrier does not store, warehouse, or**
28 **take legal ownership of the prescription drug; or**

29 ~~[(x)] (XI)~~ **The sale or transfer from a retail pharmacy or**
30 **pharmacy warehouse of expired, damaged, returned, or recalled prescription drugs to**
31 **the original manufacturer or to a third party returns processor.**

32 (v) (1) "Wholesale distributor" means a person that is engaged in the
33 wholesale distribution of prescription drugs or prescription devices.

- 1 (2) “Wholesale distributor” includes:
- 2 (i) A manufacturer;
- 3 (ii) A repackager;
- 4 (iii) An own-label distributor;
- 5 (iv) A private-label distributor;
- 6 (v) A jobber;
- 7 (vi) A broker;
- 8 (vii) A warehouse, including a manufacturer’s or distributor’s
9 warehouse;
- 10 (viii) A manufacturer’s exclusive distributor or an authorized
11 distributor of record;
- 12 (ix) A drug wholesaler or distributor;
- 13 (x) An independent wholesale drug trader;
- 14 (xi) A third party logistics provider;
- 15 (xii) A retail pharmacy that conducts wholesale distribution, if
16 the wholesale distribution business accounts for more than 5% of the retail pharmacy’s
17 annual sales; and
- 18 (xiii) A pharmacy warehouse that conducts wholesale
19 distribution.
- 20 (w) “Wholesale distributor permit” means a permit issued by the Board under
21 this subtitle to distribute prescription drugs or prescription devices into, out of, or
22 within the State as a wholesale distributor.

23 **12-6C-03.1.**

24 **(A) THE DEPARTMENT ~~IS AUTHORIZED TO~~ MAY PURCHASE AND**
25 **DISTRIBUTE PRESCRIPTION DRUGS AND PRESCRIPTION DEVICES FOR PUBLIC**
26 **HEALTH PURPOSES.**

27 **(B) THE DEPARTMENT SHALL ADOPT REGULATIONS, IN CONSULTATION**
28 **WITH THE BOARD, TO IMPLEMENT THIS SECTION.**

1 12-6C-04.

2 (a) (1) In this section the following words have the meanings indicated.

3 (2) “Accreditation organization” means a private entity that:

4 (I) **IS RECOGNIZED BY THE BOARD; AND**

5 (II) **[conducts] CONDUCTS** inspections and surveys of wholesale
6 distributors based on nationally recognized and developed standards.

7 (3) “Deemed status” means a status under which a wholesale
8 distributor may be exempt from **INITIAL AND** routine [inspections and other permit]
9 **INSPECTION** requirements [of the Board] **UNDER THIS SUBTITLE.**

10 ~~(4) “SUBSTANTIALLY EQUIVALENT” MEANS THAT THE LAWS OF~~
11 ~~ANOTHER STATE ARE EQUAL TO OR MORE STRINGENT THAN THE LAWS OF THIS~~
12 ~~STATE AND REQUIRE, AT MINIMUM, PEDIGREES, ROUTINE INSPECTIONS OF~~
13 ~~WHOLESALE DISTRIBUTORS, OPERATION OF WHOLESALE DISTRIBUTORS IN A~~
14 ~~COMMERCIAL NONRESIDENTIAL FACILITY, AND SECURITY MEASURES.~~

15 [(b) If the Board determines that the standards of an accreditation
16 organization are equal to or more stringent than State permit requirements, the Board
17 may:

18 (1) Accept the accreditation of a wholesale distributor by an
19 accreditation organization as evidence that the wholesale distributor has met State
20 permit requirements; and

21 (2) Grant the wholesale distributor deemed status.]

22 **(B) THE BOARD MAY ONLY GRANT DEEMED STATUS TO A WHOLESALE**
23 **DISTRIBUTOR THAT IS:**

24 **(1) CURRENTLY ACCREDITED BY AN ACCREDITATION**
25 **ORGANIZATION, WHEREVER THE WHOLESALE DISTRIBUTOR IS LOCATED; OR**

26 **(2) LOCATED IN A STATE THAT HAS REQUIREMENTS ~~THAT ARE~~**
27 **THAT:**

28 **(1) ARE SUBSTANTIALLY EQUIVALENT TO THE**
29 **REQUIREMENTS OF THIS STATE; AND**

1 **(II) INCLUDE PEDIGREES, ROUTINE INSPECTIONS OF**
2 **WHOLESALE DISTRIBUTORS, OPERATION OF WHOLESALE DISTRIBUTORS IN A**
3 **COMMERCIAL NONRESIDENTIAL FACILITY, AND SECURITY MEASURES.**

4 (c) **(1)** The Board may issue a **WHOLESALE DISTRIBUTOR** permit by
5 reciprocity to a wholesale distributor who holds a license or permit under the laws of
6 another state if the Board determines that the requirements of that state are
7 substantially equivalent to the requirements of this State.

8 **(2)** **A WHOLESALE DISTRIBUTOR THAT RECEIVES A PERMIT BY**
9 **RECIPROCITY SHALL COMPLY WITH THE REQUIREMENTS OF § 12-6C-05(E) AND**
10 **(F) OF THIS SUBTITLE.**

11 **(3)** **IN ADDITION TO MEETING THE REQUIREMENTS UNDER THIS**
12 **SUBTITLE, A WHOLESALE DISTRIBUTOR LOCATED OUT-OF-STATE THAT IS NOT**
13 **ELIGIBLE FOR RECIPROCITY SHALL BE ACCREDITED BY AN ACCREDITATION**
14 **ORGANIZATION.**

15 **(4)** **THE BOARD SHALL GRANT DEEMED STATUS TO A WHOLESALE**
16 **DISTRIBUTOR THAT:**

17 **(I)** **IS CURRENTLY ACCREDITED BY AN ACCREDITATION**
18 **ORGANIZATION; OR**

19 **(II)** **HAS BEEN GRANTED RECIPROCITY BY THE BOARD.**

20 (d) The Board or its designee may inspect a wholesale distributor who is
21 accredited or has been issued a permit by reciprocity to:

22 (1) Determine compliance with any permit requirement under this
23 subtitle; or

24 (2) Investigate a complaint.

25 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
26 October 1, 2010.