

SENATE BILL 163

J2

0lr1337
CF 0lr1871

By: **Senator Conway**

Introduced and read first time: January 19, 2010

Assigned to: Education, Health, and Environmental Affairs

A BILL ENTITLED

1 AN ACT concerning

2 **State Board of Pharmacy – Wholesale Distributors – Accreditation and**
3 **Reciprocity**

4 FOR the purpose of altering certain circumstances when the State Board of Pharmacy
5 may grant “deemed status” to wholesale distributors; requiring wholesale
6 distributors that receive a permit by reciprocity to comply with certain
7 requirements; requiring wholesale distributors that are not eligible for
8 reciprocity to be accredited; requiring the Board to grant “deemed status” to
9 certain wholesale distributors under certain circumstances; altering the
10 definition of “deemed status” and defining certain other terms; and generally
11 relating to the accreditation of and granting of reciprocity to wholesale
12 distributors of prescription drugs.

13 BY repealing and reenacting, without amendments,
14 Article – Health Occupations
15 Section 12–6C–01(a), (h), (n), (v), and (w)
16 Annotated Code of Maryland
17 (2009 Replacement Volume)

18 BY repealing and reenacting, with amendments,
19 Article – Health Occupations
20 Section 12–6C–04
21 Annotated Code of Maryland
22 (2009 Replacement Volume)

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

25 **Article – Health Occupations**

26 12–6C–01.

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



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

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

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

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

8 (2) “Wholesale distributor” includes:

9 (i) A manufacturer;

10 (ii) A repackager;

11 (iii) An own-label distributor;

12 (iv) A private-label distributor;

13 (v) A jobber;

14 (vi) A broker;

15 (vii) A warehouse, including a manufacturer’s or distributor’s
16 warehouse;

17 (viii) A manufacturer’s exclusive distributor or an authorized
18 distributor of record;

19 (ix) A drug wholesaler or distributor;

20 (x) An independent wholesale drug trader;

21 (xi) A third party logistics provider;

22 (xii) A retail pharmacy that conducts wholesale distribution, if
23 the wholesale distribution business accounts for more than 5% of the retail
24 pharmacy’s annual sales; and

25 (xiii) A pharmacy warehouse that conducts wholesale
26 distribution.

27 (w) “Wholesale distributor permit” means a permit issued by the Board
28 under this subtitle to distribute prescription drugs or prescription devices into, out of,
29 or within the State as a wholesale distributor.

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
6 wholesale 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
17 Board 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 **SUBSTANTIALLY EQUIVALENT TO THE REQUIREMENTS OF THIS STATE.**

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

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

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

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

10 **(I) IS CURRENTLY ACCREDITED BY AN ACCREDITATION**
11 **ORGANIZATION; OR**

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

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

15 (1) Determine compliance with any permit requirement under this
16 subtitle; or

17 (2) Investigate a complaint.

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