

Chapter 239

(Senate Bill 163)

AN ACT concerning

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

FOR the purpose of authorizing the State Department of Health and Mental Hygiene to purchase and distribute certain drugs and devices for certain purposes; requiring the Department to adopt certain regulations, in consultation with the State Board of Pharmacy, for certain purposes; altering ~~certain circumstances when~~ *the circumstances under which* the ~~State Board of Pharmacy~~ Board may grant “deemed status” to wholesale distributors; requiring wholesale distributors that receive a permit by reciprocity to comply with certain requirements; requiring wholesale distributors that are not eligible for reciprocity to be accredited; requiring the Board to grant “deemed status” to certain wholesale distributors under certain circumstances; altering ~~the definition of “deemed status” and certain definitions and defining certain other terms;~~ and generally relating to the ~~accreditation of and granting of reciprocity to wholesale distributors of prescription drugs~~ *Wholesale Distributor Permitting and Prescription Drug Integrity Act.*

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

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

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

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

Article – Health Occupations

12–6C–01.

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

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

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

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

(2) “Wholesale distribution” does not include:

(i) Intracompany sales;

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

(iii) THE SALE, PURCHASE, DISTRIBUTION, TRADE, OR TRANSFER OF A PRESCRIPTION DRUG OR PRESCRIPTION DEVICE BY THE DEPARTMENT FOR PUBLIC HEALTH PURPOSES;

[(iii)] (IV) The distribution of samples of a prescription drug by a manufacturer’s representative;

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

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

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

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

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

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

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

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

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

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

(2) "Wholesale distributor" includes:

- (i) A manufacturer;
- (ii) A repackager;
- (iii) An own-label distributor;
- (iv) A private-label distributor;
- (v) A jobber;
- (vi) A broker;
- (vii) A warehouse, including a manufacturer's or distributor's warehouse;
- (viii) A manufacturer's exclusive distributor or an authorized distributor of record;
- (ix) A drug wholesaler or distributor;

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

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

12-6C-03.1.

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

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

12-6C-04.

- (a) (1) In this section the following words have the meanings indicated.
- (2) "Accreditation organization" means a private entity that:
 - (I) **IS RECOGNIZED BY THE BOARD; AND**
 - (II) **[conducts] CONDUCTS** inspections and surveys of wholesale distributors based on nationally recognized and developed standards.
- (3) "Deemed status" means a status under which a wholesale distributor may be exempt from **INITIAL AND** routine [inspections and other permit] **INSPECTION** requirements [of the Board] **UNDER THIS SUBTITLE.**
- ~~(4) "SUBSTANTIALLY EQUIVALENT" MEANS THAT THE LAWS OF ANOTHER STATE ARE EQUAL TO OR MORE STRINGENT THAN THE LAWS OF THIS STATE AND REQUIRE, AT MINIMUM, PEDIGREES, ROUTINE INSPECTIONS OF WHOLESALE DISTRIBUTORS, OPERATION OF WHOLESALE DISTRIBUTORS IN A COMMERCIAL NONRESIDENTIAL FACILITY, AND SECURITY MEASURES.~~

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

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

(2) Grant the wholesale distributor deemed status.]

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

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

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

(I) ARE SUBSTANTIALLY EQUIVALENT TO THE REQUIREMENTS OF THIS STATE; AND

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

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

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

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

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

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

(II) HAS BEEN GRANTED RECIPROCITY BY THE BOARD.

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

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

(2) Investigate a complaint.

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

Approved by the Governor, May 4, 2010.