

Chapter 298

(Senate Bill 595)

AN ACT concerning

State Board of Pharmacy – Wholesale Distribution – Pharmacies

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

BY repealing and reenacting, with amendments,

Article – Health Occupations

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

Annotated Code of Maryland

(2009 Replacement Volume and 2012 Supplement)

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

Article – Health Occupations

12-406.

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

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

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

(1) THE WHOLESALE DISTRIBUTION BUSINESS DOES NOT EXCEED 5% OF THE PHARMACY PERMIT HOLDER’S ANNUAL SALES; AND

(II) THE PHARMACY PERMIT HOLDER:

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

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

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

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

(I) ANOTHER PHARMACY PERMIT HOLDER; AND

(II) A WHOLESALE DISTRIBUTOR IF THE RETAIL PHARMACY:

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

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

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

12-6C-01.

(i) “Intracompany sales” means a:

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

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

(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;

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

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

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

(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;

(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;

(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;

(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

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

1. THE ORIGINAL WHOLESALE DISTRIBUTOR;
2. [the] THE original manufacturer; or
3. [to a] 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.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2013.

Approved by the Governor, May 2, 2013.