

SB0163/274430/1

BY: Education, Health, and Environmental Affairs Committee

AMENDMENTS TO SENATE BILL 163

(First Reading File Bill)

AMENDMENT NO. 1

On page 1, strike beginning with “Wholesale” in line 2 down through “Reciprocity” in line 3 and substitute “Wholesale Distributor Permitting and Prescription Drug Integrity Act – Revisions”; in line 4, after the first “of” insert “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;”; in the same line, strike “State Board of Pharmacy” and substitute “Board”; strike beginning with “the” in line 9 down through the first “and” in line 10 and substitute “certain definitions and”; in line 20, after “Section” insert “12-6C-01(u) and”; and after line 22, insert:

“BY adding to

Article - Health Occupations

Section 12-6C-03.1

Annotated Code of Maryland

(2009 Replacement Volume)”.

AMENDMENT NO. 2

On page 2, after line 5, insert:

“(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;

(Over)

(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.”;

and after line 29, insert:

“12-6C-03.1.

(A) THE DEPARTMENT IS AUTHORIZED TO 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.”.