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THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 2084 Session of 2024

INTRODUCED BY BRIGGS, SANCHEZ, HILL-EVANS, MALAGARI, DALEY, KINSEY AND GREEN, MARCH 6, 2024

AS REPORTED FROM COMMITTEE ON HEALTH, HOUSE OF REPRESENTATIVES, AS AMENDED, MARCH 27, 2024

AN ACT

Amending the act of December 14, 1992 (P.L.1116, No.145), entitled "An act providing minimum standards, terms and conditions for the licensing of persons who engage in wholesale distributions in interstate commerce of prescription drugs; and making a repeal," further providing for definitions~~.~~, FOR LICENSE APPLICATION AND FOR STORAGE, HANDLING AND RECORDKEEPING. <--

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

Section 1. The definition of "wholesale distributor of prescription drugs" in section 3 of the act of December 14, 1992 (P.L.1116, No.145), known as the Wholesale Prescription Drug Distributors License Act, is amended and the section is amended by adding a definition to read:

Section 3. Definitions.

The following words and phrases when used in this act shall have the meanings given to them in this section unless the context clearly indicates otherwise:

* * *

~~"Virtual manufacturer." A person in the business of~~ <--

~~manufacturing or distributing a controlled substance, other drug or device and who has a principal place of business located in this Commonwealth, but at no time takes physical possession of any controlled substance in this Commonwealth.~~

"VIRTUAL MANUFACTURER." A PERSON WITH A PLACE OF BUSINESS LOCATED IN THIS COMMONWEALTH IN THE BUSINESS OF MANUFACTURING AND DISTRIBUTING A DRUG OR MEDICAL DEVICE THAT: <--

(1) HOLDS THE DRUG OR DEVICE APPROVAL AND LABEL CODE OR IS OTHERWISE IDENTIFIED ON THE PRODUCT LABEL FROM THE UNITED STATES FOOD AND DRUG ADMINISTRATION.

(2) AT NO TIME TAKES PHYSICAL POSSESSION OF ANY DRUG OR DEVICE IN THIS COMMONWEALTH.

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"Wholesale distributor of prescription drugs." A person who operates a facility from which a person engages in the wholesale distribution of prescription drugs, including, but not limited to, manufacturers, virtual manufacturers, repackers, own-label distributors, private-label distributors or jobbers, warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses and wholesale drug warehouses, independent wholesale drug traders and retail pharmacies that conduct wholesale distributions.

~~Section 2. This act shall take effect in 60 days.~~ <--

SECTION 2. SECTION 5(A) OF THE ACT IS AMENDED BY ADDING <-- PARAGRAPHS AND THE SECTION IS AMENDED BY ADDING A SUBSECTION TO READ:

SECTION 5. LICENSE APPLICATION.

(A) INFORMATION ON APPLICATION.--AN APPLICANT FOR A LICENSE SHALL PROVIDE THE FOLLOWING INFORMATION ON A LICENSE APPLICATION FORM APPROVED BY THE DEPARTMENT:

* * *

(1.1) DOCUMENTATION SHOWING COMPLIANCE WITH ALL FEDERAL, STATE AND LOCAL BUSINESS REGISTRATION REQUIREMENTS.

* * *

(6.1) A SURETY BOND IN ACCORDANCE WITH SUBSECTION (A.1).

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(A.1) BOND REQUIREMENT.--THE APPLICANT OR OWNER SHALL SUBMIT A SURETY BOND OF $100,000 TO THE DEPARTMENT WITH AN APPLICATION. THE DEPARTMENT MAY REDUCE THE AMOUNT OF THE SURETY BOND IF THE ANNUAL GROSS RECEIPTS IS EXPECTED TO BE UNDER $10,000,000 AT THE FACILITY LOCATION. THE SURETY BOND MAY NOT BE REDUCED TO LESS THAN $25,000.

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SECTION 3. SECTION 6(A) OF THE ACT IS AMENDED AND THE SECTION IS AMENDED BY ADDING A SUBSECTION TO READ:

SECTION 6. STORAGE, HANDLING AND RECORDKEEPING.

(A) MINIMUM REQUIREMENTS.--[LICENSEES] EXCEPT AS PROVIDED UNDER SUBSECTION (A.1), LICENSEES AND [THEIR] THE LICENSEES' OFFICERS, AGENTS, REPRESENTATIVES AND EMPLOYEES SHALL SATISFY THE MINIMUM REQUIREMENTS OF THIS SECTION FOR THE STORAGE AND HANDLING OF PRESCRIPTION DRUGS AND FOR THE ESTABLISHMENT AND MAINTENANCE OF PRESCRIPTION DRUG DISTRIBUTION RECORDS.

(A.1) VIRTUAL MANUFACTURERS.--THE FOLLOWING REQUIREMENTS APPLY TO VIRTUAL MANUFACTURERS:

(1) A VIRTUAL MANUFACTURER SHALL BE EXEMPT FROM THE MINIMUM REQUIREMENTS UNDER SUBSECTIONS (B), (C), (D), (E), (F) AND (J) AT THE VIRTUAL MANUFACTURER'S PRINCIPAL PLACE OF BUSINESS LISTED ON AN APPLICATION THAT WAS SUBMITTED TO THE DEPARTMENT UNDER SECTION 5(A)(1) WHERE NO DRUG OR DEVICES ARE PHYSICALLY STORED OR HANDLED.

(2) A VIRTUAL MANUFACTURER SHALL ENSURE THAT THE MINIMUM REQUIREMENTS UNDER SUBSECTIONS (B), (C), (D), (E), (F) AND (J) ARE MET AT ANY LOCATIONS OR CONTRACT FACILITIES WHERE ANY DRUG OR MEDICAL DEVICES ARE PHYSICALLY STORED OR HANDLED ON THE VIRTUAL MANUFACTURER'S BEHALF.

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SECTION 4. THIS ACT SHALL TAKE EFFECT IN 180 DAYS.