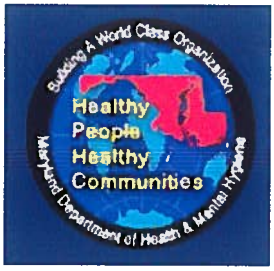

MARYLAND
BOARD OF PHARMACY
WHOLESALE DISTRIBUTOR PERMITTING AND PRESCRIPTION DRUG INTEGRITY ACT

EIGHTH ANNUAL REPORT TO THE GOVERNOR AND THE GENERAL ASSEMBLY

January 1, 2015

MARYLAND BOARD OF PHARMACY WHOLESALE DISTRIBUTOR PERMITTING AND PRESCRIPTION DRUG INTEGRITY ACT

EIGHTH ANNUAL REPORT

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EXECUTIVE SUMMARY

This is the eighth annual report on the implementation of the Wholesale Distributor Permitting and Prescription Drug Integrity Act (the "Act") as required by Health Occupations Article, 10-6C-13, Annotated Code of Maryland. The Act, Senate Bill 759/House Bill 1030, Chapters 352 and 353, was passed in the 2007 Legislative Session. The Act provides requirements for persons applying to be licensed to distribute prescription drugs or devices into, out of, or within Maryland. The Act further requires a pedigree, or history of the distribution chain, for prescription drugs that are distributed in Maryland outside of the normal distribution chain. As revised in 2007, it is one of the more stringent wholesale distributor acts in the country and is in the forefront of protecting the prescription drug supply chain nationwide.

The Board faced a number of challenges with the first, second and third renewals after the passage of the new law. Those challenges, and how they were resolved, were described in detail in the 2009 through 2014 Annual Reports and described briefly in the next section of this report.

The present major change, and challenge, for the Board will be the effects of the U.S. Drug Supply Chain Security Act (DSCSA) which passed in November 2013. This federal legislation provides national uniformity regarding pedigrees, the national implementation timeline for electronic track and trace of pedigrees, and the licensure of third party logistics providers. Maryland, and other states, will need to re-evaluate their laws and regulations to comply with the new federal standards. At this time the U.S. Food and Drug Administration (FDA) has issued a guidance on the implementation of the DSCSA, but has not, as the writing of this report, published proposed regulations in the Federal Register. Those regulations will determine the revisions the Board will have to make to the Wholesale Distributor Permitting and Prescription Drug Integrity Act during the 2016 Legislative Session and the corresponding regulations.

MEETING REGULATORY REQUIREMENTS

In 2009 and 2010, the Board sought legislation to remedy specific implementation challenges with the Act. In 2009, House Bill 1195 Prescription Drugs – Wholesale Drug Distribution – Surety Bond Requirements, Chapter 170, reduced the surety bond requirement to $50,000 for wholesale distributors that distribute less than $10,000,000 of their gross receipts from sales of prescription drugs and devices in Maryland. This legislation provided relief for those smaller wholesale distributors that found it difficult to obtain a $100,000 surety bond. Regulations were promptly promulgated with an emergency effective date of June 18, 2009 and a final effective date of October 5, 2009.

In 2010, Senate Bill 163/House Bill 868 State Board of Pharmacy - Wholesale Distributor Permitting and Prescription Drug Integrity Act revisions, provided "deemed status" only for those wholesale distributors accredited by a Board-approved accreditation program or those wholesale distributors located in states with wholesale distribution laws substantially equivalent to Maryland's laws. The Board may waive

requirements, such as inspections, for distributors granted deemed status. The legislation relieved Board inspectors from inspecting out-of-state wholesale distributors. Prior to enactment of the bill, the Board contracted with the National Association of Boards of Pharmacy to act as the Board's agent to inspect out-of-state distributor facilities. No regulations were required to implement this revision to the law.

In 2012, SB 133/HB 316 State Board of Pharmacy – Wholesale Distributor Permits – Permit and Application Requirements, Chapters 462 and 463, proposed three amendments to the Act. The first amendment removed the requirements for a physical inspection of a wholesale distributor location that does not hold product. The second amendment substituted a new requirement that criminal background checks be submitted for designated representatives and their supervisors from the state where the wholesale distributor is located, for the previous requirement that these out-of-state individuals submit to a Maryland criminal background check. The third amendment allowed applicants to submit their fingerprints and fees for a criminal background check directly to the Criminal Justice Information System Central Repository of the Department of Public Safety and Correctional Services. All three amendments were passed.

In 2013, SB 595/HB 591 State Board of Pharmacy – Wholesale Distribution – Pharmacies, Chapters 298 and 621, limited the authority of a pharmacy permit holder to distribute prescription drugs and prescription devices to another pharmacy permit holder. Pharmacies holding a waiver permit under COMAR 10.34.17.01 - .04 would only be able to wholesale distributor to other pharmacies. Full service pharmacies would be able to wholesale distribute to a wholesale distributor with proper record keeping and reporting to the Board. This legislation also struck the word "retail" from the section of the law that allows pharmacies to wholesale distribute, if the percentage of wholesale distribution is 5% or less of the pharmacy's annual sales. This change requires all pharmacies, no matter if retail or waiver, to comply with the 5% restriction.

These revisions to the law were made because over the past few years drug shortages have become a major issue in the drug supply nationwide and in Maryland. There exists a "gray market" where wholesale distributors and pharmacies buy and sell to each other drugs in short supply increasing the prices significantly before the drugs are dispensed to the patient. Oftentimes it is a pharmacy that sells "upstream" increasing the price to a wholesale distributor when drugs are in short supply. The wholesale distributor then increases the price again when the product is sold. The Board has worked closely with federal authorities over the past year or two to end this practice, and identified ways to restrict the sale of prescription drugs and prescription devices by a pharmacy to any entity besides another pharmacy. SB 595/HB 591 proposed one method to thwart price gouging that has impacted the supply of critically needed prescription drugs.

There are exceptions in the Act which allow a pharmacy to continue to buy and sell prescription drugs under certain circumstances and accommodating traditional pharmacy practices. The Act includes a definition of wholesale distribution which sets out a number of transactions that are not considered "wholesale distribution." These transactions allow pharmacies to buy and sell prescription drugs and prescription devices in their usual

course of business so that they may return overstock of drugs, sell to a reverse distributor for disposal, conduct intracompany sales, sell their inventory when closing a pharmacy, and other limited activities.

Some wholesale distributors objected to this legislation as too stringent, preventing them from assisting hospital pharmacies in finding drugs in short supply at a moment's notice. Passage of the legislation, however; does not prevent anyone from providing information to a pharmacy as to where they may obtain a drug that a patient desperately needs. It does eliminate the possibility that a wholesale distributor, acting as a middleman, could overcharge for a desperately needed prescription because it has limited availability.

Since the passage of 2012 and 2013 legislation, the Board worked diligently to revise COMAR 10.34.22.01 - .11 Licensing of Wholesale Prescription Drug or Device Distributors, to implement the new laws. In the 2012 regulatory proposal, the Board addressed the revisions from SB 133 and also addressed closing requirements, reinstatement requirements and licensure requirements for the distribution by "virtual" manufacturers. New legislation was introduced and passed during the 2013 Legislative Session, so the Board withdrew the April 2013 proposal and approved a revised version at the September 20, 2013 Public Board Meeting to accommodate all the new laws. A new chapter COMAR 10.34.37 Pharmacy Permit Holder – Wholesale Distribution, was included in the same proposal with the revisions to COMAR 10.34.22 to address pharmacy wholesale distribution and pharmacy reporting requirements. Both chapters became effective on July 1, 2014 and are included as Appendices I and II.

Drug Supply Chain Security Act (DSCSA)

On November 17, 2013, the U.S. Congress passed the Drug Supply Chain Security Act (DSCSA). This act

> establishes a Federal system for tracing prescription drug products through the pharmaceutical distribution supply chain and requires trading partners to pass, receive, and maintain certain product and distribution information. The DSCSA also requires FDA to establish Federal standards for licensing of wholesale drug distributors and third party logistics providers;[1]

The federal legislation is important because it establishes uniform legislation throughout the country. States will no longer be allowed to establish or continue in effect any laws or regulations for tracing products through the distribution system which are inconsistent with, more stringent than, or in addition to, any requirements applicable under the new federal law.

The federal law will significantly impact the recommendations made by the

[1] The Effect of Section 585 of the FD&C Act on Drug Product Tracing and Wholesale Drug Distributor and Third-Party Logistics Provider Licensing Standards and Requirements: Questions and Answers; Guidance for Industry. October 2014

Wholesale Distributor SB 759 Workgroup (Workgroup), which was convened under the 2007 legislation. Its tasks included:

- Determine when electronic track and trace pedigree technology will be universally available across the entire prescription pharmaceutical supply chain; and
- Based on its determination of the universal availability of electronic track and trace pedigree technology, make recommendations to the Board for a target date, no sooner than July 1, 2010, for implementation of electronic track and trace pedigree technology across the entire prescription pharmaceutical supply chain.

At the November 19, 2008 Public Board Meeting, the Board, with the Workgroup's recommendation before it, set the target date for implementation for electronic track and trace pedigree technology to be the same dates as set by the State of California's legislature, plus one year. Those dates are summarized as follows:

- January 1, 2016: Manufacturers (generic and brand) must pedigree:
  - 50 percent of their products by 2016;
  - The remaining 50 percent by 2017;

- July 1, 2017: Wholesalers and repackagers must accept and pass pedigrees.

- July 1, 2018: Pharmacies and pharmacy warehouses must accept pedigrees.

These dates now conflict with the DSCSA which has set unit level traceability of product for 9 years in the future – 2023.

Additionally in the DSCSA, no State may establish or continue any laws or regulations with respect to wholesale prescription drug distributor or third-party logistics provider licensure that are inconsistent with, less stringent than, directly related to, or covered by the standards and requirements of the federal law. No State shall regulate third-party logistics providers as wholesale distributors. At the present time, the Maryland Pharmacy Act requires third-party logistics providers to be licensed as wholesale distributors, so the Board anticipates revising Subtitle 6C. Wholesale Distributor Permitting and Prescription Drug Integrity Act, in either the 2016 or 2017 Legislative Sessions depending on the release of the draft federal regulations.

As of October 2014, the FDA has issued "Guidance for the Industry" and anticipates that draft regulations will be forthcoming with two years of the enactment of the DSCSA. See the FDA website for additional information: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM417564.pdf.

CONCLUSION

The Board, legislators and stakeholders were aware in 2007 that the Wholesale Distributor Permitting and Prescription Drug Integrity Act would be a challenge to implement and would be revised as the industry changes. The Act has changed how wholesale distributors in Maryland do business. Distributor personnel are strictly scrutinized. Distributor facilities are inspected and may not be operated in a residence, and distributors are required to maintain pedigrees for prescription drugs which leave the normal distribution channel. Since the Board first implemented the Act, legislative changes have ensured greater compliance by the wholesale distributor industry, greater monitoring by the Board and ultimately greater protection of the prescription drug and prescription device supply in Maryland.

With the enactment of the DSCSA, Maryland's Wholesale Distributor Permitting and Prescription Drug Integrity Act will require revisions to comply with the new federal law. Perhaps the Board's recommendation for setting the target date for implementation for electronic track and trace pedigree technology was too ambitious with respect to the technology available in the industry. The emphasis for the Board was then, and continues to be, protecting the public by imposing additional requirements for persons applying to be licensed to distribute prescription drugs or devices into Maryland; thereby protecting the supply chain of prescription drugs and devices in this State. Look for the Board to introduce legislation amending the Wholesale Distributor Permitting and Prescription Drug Integrity Act in the 2016 or 2017 Legislative Sessions.

APPENDIX I

Title 10 DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 34 BOARD OF PHARMACY

Chapter 22 Licensing of Wholesale Prescription Drug or Device Distributors

Authority: Health Occupations Article, §§12-205, 12-601, and 12-6C-01—12-6C-13, Annotated Code of Maryland

.02 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "ANDA" means an Abbreviated New Drug Application number and contains data that, when submitted to the U.S. Food and Drug Administration's (FDA) Center for Drug Evaluation and Research, Office of Generic Drugs, provides for the review and ultimate approval of a generic drug product.

(1-1) "Authenticate" means to affirmatively verify, before any wholesale distribution of a prescription drug occurs, that each transaction listed on the pedigree for the prescription drug has occurred.

(2) "Authorized distributor of record" means a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drug.

(3) "Blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

(4) "Blood component" means that part of blood separated by physical or mechanical means.

(5) "Board" means the State Board of Pharmacy.

(5-1) “Cease to operate” means the date on which the last prescription drug or prescription device is distributed by the permit holder.

(5-2) “Central repository” means the Criminal Justice Information System Central Repository of the Department of Public Safety and Correctional Services.

(6) "Co-licensed partner" means a person in a relationship in which two or more persons have the right to engage in the manufacturing or marketing of a prescription drug, consistent with the U.S. Food and Drug Administration's implementation of the Federal Prescription Drug Marketing Act.

(7) "DEA" means the U. S. Drug Enforcement Administration.

(8) "Designated representative" means an individual who:

(a) Is designated by the wholesale distributor;

(b) Serves as the primary contact of the wholesale distributor with the Board; and

(c) Is actively involved in, and aware of, the daily operation of the wholesale distributor.

(8-1) “Designee” means a Board contracted or Board recognized entity.

(9) "Drop shipment" means the sale of a prescription drug:

(a) To a wholesale distributor by:

(i) The manufacturer of the prescription drug; or

(ii) The manufacturer's co-licensed partner, third-party logistics provider, or manufacturer's exclusive distributor; and

(b) Through which:

(i) The wholesale distributor or a pharmacy warehouse takes title to, but not physical possession of, the prescription drug;

(ii) The wholesale distributor invoices the pharmacy, pharmacy warehouse, or other person authorized by law to dispense or administer the prescription drug to a patient; and

(iii) The pharmacy, pharmacy warehouse, or other authorized person receives delivery of the prescription drug directly from the manufacturer, the manufacturer's third-party logistics provider, or the manufacturer's exclusive distributor.

(10) "FDA" means the U. S. Food and Drug Administration.

(11) "Gross receipts" means gross receipts from sales of prescription drugs and devices in the State.

(12) Health Care Entity.

(a) "Health care entity" means a person that provides diagnostic, medical, surgical, or dental treatment, or chronic or rehabilitative care.

(b) "Health care entity" does not include a community pharmacy or a wholesale distributor.

(c) "Health care entity" may not simultaneously be a health care entity and a community pharmacy or wholesale distributor.

(12-1) "Intracompany sales" means a:

(a) 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

(b) Transaction or transfer of a co–licensed product between co–licensed partners.

(13) "Manufacturer" means a person licensed or approved by the U.S. Food and Drug Administration to engage in the manufacture of prescription drugs or prescription devices, consistent with the definition of "Manufacturer" under the U.S. Food and Drug Administration's regulations and guidelines implementing the Prescription Drug Marketing Act.

(14) "Manufacturer's exclusive distributor" means a person who:

(a) Contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of the manufacturer; and

(b) Takes title to the manufacturer's prescription drug, but does not have general responsibility to direct the sale or disposition of the manufacturer's prescription drug.

(14-1) "NDA" means a New Drug Application number assigned by the FDA for drugs formally proposed to the FDA as a new pharmaceutical for sale and marketing in the U.S.

(15) "Normal distribution channel" means a chain of custody for a prescription drug that, directly or by drop shipment, goes:

(a) From:

(i) A manufacturer of the prescription drug; or

(ii) The manufacturer's co-licensed partner, third-party logistics provider, or manufacturer's exclusive distributor; and

(b) To:

(i) A pharmacy or other designated person authorized by law to dispense or administer the prescription drug to a patient;

(ii) A wholesale distributor to a pharmacy or other designated person authorized by law to dispense or administer the prescription drug to a patient;

(iii) A wholesale distributor to a pharmacy warehouse to the pharmacy warehouse's intracompany pharmacy or other designated person authorized by law to dispense or administer the prescription drug to a patient;

(iv) A pharmacy warehouse to the pharmacy warehouse's intracompany pharmacy, or other designated person authorized by law to dispense or administer the prescription drug to a patient; or

(v) An authorized distributor of record to another authorized distributor of record solely for distribution to an office-based health care practitioner authorized by law to dispense or administer the prescription drug to a patient.

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

(16-1) "Pharmacy" means a pharmacy that has been issued a:

(a) Waiver pharmacy permit in accordance with COMAR 10.34.17; or

(b) Full service pharmacy permit.

(17) "Prescription device" means any device required by federal law or regulation to be dispensed only by a prescription.

(18) Prescription Drug.

(a) "Prescription drug" means any drug required by federal law or regulation to be dispensed only by a prescription.

(b) "Prescription drug" includes:

(i) A biological product; and

(ii) Finished dosage forms and bulk drug substances subject to §503(b) of the Federal Food, Drug and Cosmetic Act.

(c) "Prescription drug" does not include blood and blood components intended for transfusion or biological products that are also medical devices.

(18-1) "Reinstatement" means renewal of a wholesale distributor permit after the permit has expired.

(18-2) "Renewal" means renewing a wholesale distributor permit before the date of expiration.

(19) Repackage.

(a) "Repackage" means to repackage or otherwise change the container, wrapper, or labeling of a prescription drug to further the distribution of the prescription drug.

(b) "Repackage" does not include changes to a container, wrapper, or labeling of a prescription drug completed by the pharmacist responsible for dispensing the prescription drug to a patient.

(20) "Repackager" means a person who repackages prescription drugs.

(21) "Third-party logistics provider" means a person who:

(a) Contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of the manufacturer; and

(b) Does not take title to the prescription drug, or have general responsibility to direct the prescription drug's sale or disposition.

(21-1) "UDI" means a Unique Device Identification number that is created through a globally accepted device identification and coding standard that allows the unambiguous identification of a specific medical device.

(21-2) Virtual Manufacturer.

(a) "Virtual Manufacturer" means an entity that engages in the manufacture of drug or device products for which it:

(i) Owns the NDA or ANDA number, if a prescription drug;

(ii) Owns the UDI number, as available, for a prescription device;

(iii) Contracts with a contract manufacturing organization for the physical manufacture of the drug or device product;

(iv) Is not involved in the physical manufacture of the drug or device product; and

(v) At no time takes physical possession of, or stores, the drug or device product.

(b) "Virtual Manufacturer" may include entities that are identified as a broker, own-label distributor, sponsor manufacturer, private-label manufacturer, or contract manufacturer.

(22) Wholesale Distribution.

(a) "Wholesale distribution" means the distribution of prescription drugs or prescription devices to persons other than a consumer or patient.

(b) "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 which include transfers of prescription drugs or devices by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage;

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

(iv) Prescription drug returns conducted by a hospital, health care entity, or charitable institution in accordance with 21 CFR §203.23, as amended;

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

(vi) 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) 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) 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 the manufacturer has stated in writing to the receiving authorized distributor of record that the manufacturer is unable to supply the prescription drug, and 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) 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) The sale or transfer from a pharmacy or pharmacy warehouse of expired, damaged, returned, or recalled prescription drugs to the original wholesale distributor, the original manufacturer, or a third-party returns processor.

(23) Wholesale Distributor.

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

(b) "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 pharmacy that conducts wholesale distribution, if the wholesale distribution business accounts for more than 5 percent of the pharmacy's annual sales; and

(xiii) A pharmacy warehouse that conducts wholesale distribution.

.03 Minimum Application Requirements for Applicants Holding Product.

A. The Board shall require the following minimum information from a wholesale distributor as part of an application for a permit and as part of a renewal of a permit:

(1) The type of business form under which the applicant operates, such as partnership, corporation, or sole proprietorship;

(2) The full name or names of the owner and the operator of the wholesale distributor applying for or renewing a permit, including:

(a) For an individual, the:

(i) Full name of the individual;

(ii) Telephone number of the individual;

(iii) Business address of the individual; and

(iv) Date of birth of the individual;

(b) For a partnership, the:

(i) Full name of each partner;

(ii) Telephone number of the partnership;

(iii) Address of each partner;

(iv) Date of birth of each partner;

(v) Business address of the partnership; and

(vi) Federal employer identification number of the partnership;

(c) For a publicly traded corporation, the:

(i) Full name and title of each corporate officer and director;

(ii) Telephone number of the publicly traded corporation;

(iii) Business address of the corporation;

(iv) Federal employer identification number of the corporation;

(v) Name of parent company or companies if applicable;

(vi) Corporate names;

(vii) Name of the state of incorporation; and

(viii) Name and address of the resident agent of the corporation;

(d) For a nonpublicly traded corporation, the:

(i) Full name and title of each corporate officer and director;

(ii) The telephone number of the nonpublicly traded corporation;

(iii) Business address of the corporation;

(iv) Federal employer identification number of the corporation;

(v) Name of parent company or companies if applicable;

(vi) Corporate names;

(vii) Full name and business address of shareholders of more than 10 percent of the corporation, including over-the-counter stock, unless the stock is traded on a major stock exchange;

(viii) Name of the state of incorporation; and

(ix) Name and address of the resident agent of the corporation;

(e) For a sole proprietorship, the:

(i) Full name of the sole proprietor;

(ii) The telephone number of the sole proprietor;

(iii) Full name of the business entity;

(iv) Business address; and

(v) Date of birth of the sole proprietor;

(f) For a limited liability company, the:

(i) Full name and business address of the limited liability company;

(ii) Telephone number of the limited liability company;

(iii) Full name of each member;

(iv) Full name of each manager;

(v) Federal employer identification number of the limited liability company;

(vi) Name of the state in which the limited liability company was organized; and

(vii) Name and address of the resident agent of the company;

(3) Addresses, telephone numbers, and the names of contact persons for the facility used by the applicant for the storage, handling, and distribution of prescription drugs;

(4) All trade or business names used by the permit holder which may not be identical to the name used by another unrelated applicant in the State;

(5) A list of federal and state licenses, registrations, or permits, including the license, registration, or permit numbers issued to the wholesale distributor by federal authority or another state that authorizes the wholesale distributor to purchase, possess, and distribute prescription drugs or devices;

(6) A list of disciplinary actions by federal or state agencies against the wholesale distributor as well as any such actions against principals, owners, directors, or officers;

(7) For the designated representative and the immediate supervisor of the designated representative at the applicant's place of business the following information:

(a) Names;

(b) Places of residence for the past 7 years;

(c) Dates and places of birth;

(d) The name and address of each business where the individual was employed during the past 7 years, and the individual's job title or office held at each business;

(e) A statement of whether, during the past 7 years, the individual has been the subject of any proceeding for the revocation of any professional or business license or any criminal violation and, if so, the nature and disposition of the proceeding;

(f) A statement of whether, during the past 7 years, the individual has been enjoined, either temporarily or permanently, by a court of competent jurisdiction from violating any federal or state law regulating the possession, control, or distribution of prescription drugs, together with details concerning the event;

(g) A description of any involvement, including any investments other than the ownership of stock in a publicly traded company or mutual fund, by the individual during the past 7 years, with any business that manufactures, administers, prescribes, distributes, or stores prescription drugs, and any lawsuits in which the business was named as a party;

(h) A description of any misdemeanor or felony offense of which the individual, as an adult, was found guilty, regardless of whether adjudication of the guilt was withheld or whether the individual pled guilty or nolo contendere;

(i) If the individual indicates that a criminal conviction is under appeal and submits a copy of the notice of appeal, within 15 days after the disposition of the appeal, a copy of the final written order of disposition; and

(j) A photograph of the individual taken in the previous 180 days;

(8) A full description of the facility and warehouse including:

(a) Square footage;

(b) Security and alarm system descriptions;

(c) Terms of lease or ownership;

(d) Address; and

(e) Description of temperature and humidity controls;

(9) Written evidence that the wholesale distributor has obtained general and product liability insurance;

(10) A description of the wholesale distributor's import and export activities; and

(11) Other relevant information that the Board may require.

B. Criminal Background Check Requirements for an Applicant Located in this State. The Board shall require the designated representative and the immediate supervisor of the designated representative at the applicant's place of business as part of the application for a permit to submit to the Central Repository and the Federal Bureau of Investigation:

(1) Electronically or digitally captured fingerprints at approved electronic fingerprint locations approved by the Director of the Central Repository;

(2) The fee authorized under the Criminal Procedure Article, §10-221(b)(7), Annotated Code of Maryland, for access to State criminal history records; and

(3) The processing fee required by the Federal Bureau of Investigation for a national criminal history records check.

B-1. Criminal Background Check Requirements for an Applicant Located Outside this State.

(1) The Board shall require the designated representative and the immediate supervisor of the designated representative at the applicant's place of business as part of the application for a permit to submit to a criminal history records check by the applicant's state of residence, in accordance with the laws of the applicant's state of residence.

(2) The criminal history records check shall consist of:

(a) A state criminal history records check for the applicant's state of residence; and

(b) A national criminal history records check.

(3) The designated representative and the immediate supervisor of the designated representative of an applicant shall request the appropriate entity in the applicant's state of residence to forward the results of the criminal history records check to the Board and the applicant.

(4) If the appropriate entity in the applicant's state of residence is unable to forward the results of the criminal history records check, then the designated representative and the immediate supervisor of the designated representative of an applicant shall ensure that the results of the criminal history records check are forwarded to the Board in a manner approved by the Board.

C. The information required under §A of this regulation shall be provided under oath.

D. The Board may not issue an initial or renewal wholesale distributor permit to an applicant unless the Board or its designee:

(1) If the applicant holds prescription drugs or devices, conducts a physical inspection of the applicant's place of business, including any facility of the applicant;

(2) Finds that the place of business and facility, if any, meets the Board's requirements;

(3) Determines that the designated representative of the applicant meets the following qualifications:

(a) Is 21 years old or older;

(b) Has been employed full time for at least 3 years in a pharmacy or with a wholesale distributor in a capacity related to the dispensing and distribution of, and record keeping relating to, prescription drugs;

(c) Is employed by the applicant full time in a managerial level position;

(d) Is actively involved in, and aware of, the daily operation of the wholesale distributor;

(e) Is physically present, except for an authorized absence such as sick leave or vacation leave, at the facility of the applicant during regular business hours;

(f) Is serving as a designated representative for only one applicant at a time, or for two or more wholesale distributors who are located in the same facility and are members of an affiliated group, as defined in §1504 of the Internal Revenue Code;

(g) Does not have any convictions for a violation of any federal, State, or local laws relating to wholesale or retail prescription drug distribution or distribution of controlled substances; and

(h) Does not have any convictions for a felony under federal, State, or local laws; and

(4) Determines that the immediate supervisor of the designated representative of the applicant meets the following qualifications:

(a) Is 21 years old or older;

(b) Has been employed full time for at least 3 years in a pharmacy or with a wholesale distributor in a capacity related to the dispensing and distribution of, and record keeping relating to, prescription drugs;

(c) Is employed by the applicant full time in a managerial level position;

(d) Is actively involved in, and aware of, the daily operation of the wholesale distributor;

(e) Does not have any convictions for a violation of any federal, state, or local laws relating to wholesale or retail prescription drug distribution, or distribution of controlled substances; and

(f) Does not have any convictions for a felony under federal, state, or local laws.

E. Surety Bond.

(1) An applicant for a wholesale distributor permit shall submit a surety bond or other equivalent means of security acceptable to the State such as an irrevocable letter of credit, or a deposit in a trust account or financial institution, payable to the State Board of Pharmacy to be deposited into an account established by the State under Health Occupations Article, §12-6C-05(f)(7), Annotated Code of Maryland.

(2) The surety bond, or other security, shall be in the amount of:

(a) $100,000, if the annual gross receipts of the applicant for the previous tax year are $10,000,000 or more; or

(b) $50,000, if the annual gross receipts of the applicant for the previous tax year are less than $10,000,000.

(3) An applicant shall submit the following documentation to verify the applicant's annual gross receipts in the State are less than $10,000,000 for the previous tax year:

(a) A federal tax return; or

(b) An annual sales report specifying the sales of prescription drugs and devices in the State audited by a certified public accountant.

(4) A surety bond is not required for a pharmacy warehouse that is not engaged in wholesale distribution.

(5) An applicant shall obtain a surety bond for each facility.

(6) A single surety bond may cover all facilities operated by the applicant within this State.

F. If a wholesale distributor distributes prescription drugs or prescription devices from more than one facility, the wholesale distributor shall obtain a permit for each facility.

G. The Board shall notify the applicant of the Board's acceptance or rejection of the application within 30 days after the date the Board receives a completed application, including the results of all required criminal history records checks.

H. The applicant shall pay to the Board an application fee set forth in COMAR 10.34.09.02.

I. The wholesale distributor shall provide changes in information provided pursuant to Regulation .03 of this chapter to the Board within 30 days of the effective date of the change.

J. Information and qualification requirements for obtaining a permit under this regulation, beyond that required by federal law, does not apply to a manufacturer who distributes its own prescription:

(1) Drugs approved by the U.S. Food and Drug Administration; or

(2) Devices that are approved or authorized by the U.S. Food and Drug Administration.

.03-1 Minimum Application Requirements for Virtual Manufacturers.

The information and qualification requirements for obtaining a permit under Regulation .03 of this chapter, beyond that required by federal law, do not apply to a virtual manufacturer that meets the following requirements:

A. Provides a list of drug or device products it distributes;

B. Provides a list of the NDA or ANDA numbers associated with each drug it distributes;

C. Provides a list of the UDI numbers, as available, associated with each device it distributes;

D. Provides the name and facility address of the contract manufacturer for each drug or device product it distributes;

E. Provides verification of current FDA registration for each contract manufacturing facility listed;

F. If the contract manufacturer distributes into this State, provides the wholesale distributor permit number for the contract manufacturer;

G. If the contract manufacturer does not distribute into this State, provides name and Maryland's wholesale distributor permit number for the entity that physically distributes the product into this State;

H. Provides a statement affirming that the virtual manufacturer does not contract the manufacture or distribution for drugs or devices other than those for which it owns the NDA, ANDA, or UDI numbers;

I. Provides an attestation by the owner of the virtual manufacturer that it does not hold product;

J. Provides a copy of existing licensure from the state in which it is located, if applicable; and

K. Has valid federal licensure or registration, as verified by the Board.

.05 Violations and Penalties.

A. After a hearing held under Health Occupations Article, §12-601, Annotated Code of Maryland, the Board may deny, suspend, revoke, or place on probation a permit holder, reprimand a permit holder, or impose a fine if the permit holder:

(1) Is convicted of, or pleads guilty or nolo contendere to, violations of federal, State, or local drug or device laws or regulations;

(2) Is convicted of, or pleads guilty or nolo contendere to, a felony or to a crime involving moral turpitude, whether or not any appeal or other proceeding is pending to have the conviction or plea set aside;

(3) Commits any of the following acts:

(a) Obtains or attempts to obtain a permit by:

(i) Providing false information to the Board; or

(ii) Other fraudulent or deceptive means;

(b) Fails to:

(i) Establish or maintain inventories, records, or written policies and procedures as required by Regulation .07 of this chapter;

(ii) Register with the Maryland Division of Drug Control, and with the U.S. Drug Enforcement Agency, as required by Regulation .07D of this chapter; or

(iii) Permit the Board, the Maryland Division of Drug Control, the U.S. Drug Enforcement Agency, or other authorized federal, State, or local law enforcement officials showing proper identification, to enter, inspect, copy records, or audit as required by Regulation .07D of this chapter;

(c) Willfully makes or maintains false inventories or records;

(d) Violates a provision of, or regulation promulgated under, Health Occupations Article, Title 12, Annotated Code of Maryland;

(e) Manufactures, repackages, sells, delivers, or holds or offers for sale any prescription drug or device that is adulterated, misbranded, counterfeit, suspected of being counterfeit, or has otherwise been rendered unfit for distribution or wholesale distribution;

(f) Adulterates, misbrands, or counterfeits prescription drugs or devices;

(g) Receives prescription drugs or devices that are adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit, or suspected of being counterfeit, or delivers or proffers delivery of such prescription drug or device for pay or otherwise;

(h) Alters, mutilates, destroys, obliterates, or removes the whole or any part of the product labeling of a prescription drug or device, or commits any other act with respect to a prescription drug or device that results in the prescription drug or device being misbranded;

(i) Forges, counterfeits, simulates, or falsely represents prescription drugs or devices without the authority of the manufacturer, or uses any mark, stamp, tag, label, or other identification device without the authorization of the manufacturer;

(j) Purchases or receives a prescription drug or device from a person who is not licensed to wholesale distribute prescription drugs or devices to that purchaser or recipient;

(k) Sells or transfers a prescription drug or device to a person who is not legally authorized to receive a prescription drug or device;

(l) Provides the Board, its representatives, or federal or State officials with false or fraudulent records, or makes false or fraudulent statements regarding any matter within the provisions of these regulations;

(m) Wholesale distributes prescription drugs or devices that were:

(i) Purchased by a public or private hospital, or other health care entity;

(ii) Donated or supplied at a reduced price to a charitable organization;

(iii) Stolen or obtained by fraud or deceit; or

(iv) Donated to a drop-off site or repository under the Prescription Drug Repository Program set forth in Health-General Article, Title 15, Subtitle 6, Annotated Code of Maryland;

(n) Fails to obtain a license, or operates without a valid license when a license is required;

(o) Obtains, or attempts to obtain, a prescription drug or device by fraud, deceit, misrepresentation, or engages in misrepresentation or fraud in the distribution or wholesale distribution of a prescription drug or device;

(p) Distributes a prescription drug or device to a consumer or patient;

(q) Fails to obtain, authenticate, or pass on a pedigree when required under these regulations;

(r) Receives a prescription drug pursuant to a wholesale distribution without first receiving a pedigree, when required, that was attested to as accurate and complete by the wholesale distributor;

(s) Distributes or wholesale distributes a prescription drug or device that was previously dispensed by a pharmacy or distributed by a practitioner;

(t) Fails to report prohibited acts as listed in these regulations;

(u) Fails to exercise due diligence as provided in Regulation .08 of this chapter;

(v) Otherwise conducts the wholesale distribution of prescription drugs or devices in a manner not in accordance with the law;

(w) Accepts payment or credit for the sale of prescription drugs in violation of Health Occupations Article, §12-6C-09(d), Annotated Code of Maryland; or

(x) If the requirements of Health Occupations Article, §12-6C-09(a), Annotated Code of Maryland, are applicable and are not met, the purchasing or otherwise receiving a prescription drug from a pharmacy; or

(4) Is disciplined by a licensing or disciplinary authority of any state or country, or disciplined by a court of any state or country, for an act that would constitute a ground for

Board action against a wholesale distributor permit holder under §A or B of this regulation.

B. Acts prohibited under this regulation do not include a prescription drug manufacturer, or agent of a prescription drug manufacturer, obtaining or attempting to obtain a prescription drug for the sole purpose of testing the prescription drug for authenticity.

.09 Reinstatement.

A. The wholesale distributor permit shall expire on the last day of its term.

B. The Board may not reinstate the wholesale distributor permit unless the applicant pays a reinstatement fee set by the Board.

.10 Required Information and Procedures for Ceasing to Operate.

A. If a wholesale distributor is located in another state, a wholesale distributor anticipating ceasing to operate in Maryland shall return the permit to the Board within 10 days of ceasing to operate in Maryland.

B. Procedures for Wholesale Distributors Located in this State for Ceasing to Operate.

(1) Notification.

(a) At least 30 days before a wholesale distributor's anticipated date of ceasing to operate, the wholesale distributor shall notify the Board in writing, by certified mail, return receipt requested, or hand delivered to the Board's office, of the day on which the wholesale distributor will cease to operate.

(b) A wholesale distributor shall:

(i) Notify drug and device suppliers that supply prescription drugs and devices to the wholesale distributor, at least 30 days in advance of ceasing to operate, of the date that the wholesale distributor will cease to operate;

(ii) Notify manufacturers, wholesale distributors, licensed pharmacies and authorized prescribers that receive prescription drugs and devices from the wholesale distributor, at least 30 days in advance of ceasing to operate, of the date that the wholesale distributor will cease to operate; and

(iii) Comply with applicable federal regulations.

(2) The wholesale distributor shall submit to and pass a closing inspection conducted by the Board.

(3) With the exception of controlled dangerous substances, the wholesale distributor shall dispose of prescription drugs or devices in stock by one or more of the following means:

(a) Returning the prescription drugs or devices to a distributor or manufacturer;

(b) Transferring the prescription drugs or devices to another wholesale distributor, licensed pharmacy, authorized prescriber, or other person or entity approved by the Board; or

(c) Destroying in accordance with this regulation.

(4) Disposition of Controlled Dangerous Substances. The wholesale distributor shall comply with the procedures set forth in this regulation in addition to those set forth in COMAR 10.19.03.10 governing the transfer, return or disposal of controlled dangerous substances.

(5) At the closing inspection, the wholesale distributor shall provide to the Board the following:

(a) The exact date on which the wholesale distributor ceased to operate;

(b) A copy of the inventory of prescription drugs or devices disposed of, transferred, or returned.

(c) The names, addresses, telephone numbers, and Drug Enforcement Administration registration numbers, if applicable, of the persons or business entities to whom prescription drugs or devices in stock were returned or transferred under this regulation;

(d) The wholesale distributor permit;

(e) If prescription drugs or devices are destroyed pursuant to this regulation, a letter, signed under oath by the wholesale distributor, stating the:

(i) Date, place and manner in which the prescription drugs or devices were destroyed;

(ii) Names, addresses, and telephone numbers of the persons responsible for destroying the prescription drugs or devices; and

(iii) Name, dosage unit, and quantity of each type of prescription drug or device destroyed; and

(f) If any pedigrees or other documents are transferred, a letter, signed under oath by the wholesale distributor, stating:

(i) The date, time, place to which and manner in which the pedigrees or other documents were transferred; and

(ii) The names, addresses, and telephone numbers of the persons responsible for transferring the pedigrees or other documents.

(6) At the closing inspection, the wholesale distributor shall provide to the Division of Drug Control the following pertaining to controlled dangerous substances:

(a) The exact date on which the wholesale distributor ceased to operate;

(b) A copy of the closing inventory of controlled dangerous substances required by the Drug Enforcement Administration.

(c) The names, addresses, telephone numbers, Drug Enforcement Administration registration numbers, Division of Drug Control registration numbers, and Board permit numbers, if applicable, of the persons or business entities to whom controlled dangerous substances in stock were returned or transferred under this regulation; and

(d) The State Department of Health and Mental Hygiene Controlled Dangerous Substance Registration for cancellation.

.11 Relocation.

A. At least 30 days before relocation, a permit holder shall submit an application to the Board.

B. If relocation is due to a catastrophic event or State of Emergency, the relocation applicant shall:

(1) Notify the Board within 48 hours; and

(2) Submit an application to the Board within 30 days.

C. A relocation applicant:

(1) If the applicant holds products, shall comply with Regulation .07 of this chapter;

(2) Shall submit a surety bond or other equivalent means of security acceptable to the State specific to the permit holder's relocation, in accordance with Regulation .03 if this chapter; and

(3) Shall indicate on the application changes in product or personnel from the original application to the Board.

D. A new or different designated representative or immediate supervisor of a designated representative functioning at the relocated facility shall be required to undergo a criminal history records check as set forth in Regulation .03 of this chapter.

E. As part of the application process, a relocation applicant located in this State shall submit to and pass an opening inspection conducted by the Board, which shall include:

(1) Documentation of the permit holder's notification to suppliers of prescription drugs and devices of the permit holder's relocation; and

(2) Documentation from the permit holder evidencing the appropriate transfer, return, or disposal of any prescription drugs or devices not transferred to the facility's relocation.

F. A relocation applicant located in another state shall provide to the Board:

(1) Evidence of approval of the permit holder's relocation from the accreditation organization that accredited the permit holder's original location; or

(2) If the relocation applicant is not required to be accredited by an accreditation organization in accordance with Maryland law, inspection reports from the state in which the relocation applicant is located pertaining to the permit holder's relocation.

Administrative History

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Regulation .03B amended effective November 7, 1994 (21:22 Md. R. 1877)

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Regulations .01—.10 repealed and new Regulations .01—.09 adopted effective March 28, 2005 (32:6 Md. R. 636)

Regulations .01—.09 repealed and new Regulations .01—.08 adopted effective April 7, 2008 (35:7 Md. R. 748)

Regulation .02B amended as an emergency provision effective June 18, 2009 (36:15 Md. R. 1163); amended permanently effective October 5, 2009 (36:20 Md. R. 1529)

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Regulation .11 adopted effective July 1, 2014 (41:10 Md. R. 561)

Appendix II

Title 10 DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 34 BOARD OF PHARMACY

Chapter 37 Pharmacy Permit Holder — Wholesale Distribution

Authority: Health-Occupations Article, §§12-205 and 12-406, Annotated Code of Maryland

.01 Scope.

This chapter establishes requirements for a pharmacy licensed by the Maryland Board of Pharmacy that engages in wholesale distribution.

.02 Pharmacies Issued a Waiver Permit.

A. A pharmacy that is issued a waiver permit by the Board under Health Occupations Article, §12–403(c), Annotated Code of Maryland, may engage in wholesale distribution, provided that:

(1) The waiver pharmacy only engages in wholesale distribution with another pharmacy; and

(2) The wholesale distribution business does not exceed 5 percent of the waiver pharmacy's annual sales.

B. Record Keeping Requirements. A waiver pharmacy that conducts wholesale distribution as set forth in §A of this regulation shall:

(1) Maintain records of the waiver pharmacy's wholesale distribution separately from its other records; and

(2) Make records of wholesale distribution available for inspection by the Board.

.03 Requirements for Wholesale Distribution.

A. General Requirements.

(1) A full service pharmacy may conduct wholesale distribution provided that the wholesale distribution business does not exceed 5 percent of the full service pharmacy's annual sales.

(2) A full service pharmacy may conduct wholesale distribution:

(a) With another pharmacy; or

(b) With a wholesale distributor, if the full service pharmacy reports to the Board within a week, on a form approved by the Board, of the full service pharmacy's wholesale distribution to a wholesale distributor.

B. Recordkeeping Requirements. A full service pharmacy that conducts wholesale distribution as set forth in §A of this regulation shall:

(1) Maintain records of wholesale distribution separately from its other records;

(2) Maintain records of wholesale distribution to wholesale distributors separately from its records of wholesale distribution to pharmacies; and

(3) Make records of wholesale distribution available for inspection by the Board.

Administrative History

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