



STATE OF MARYLAND

**DHMH**

Department of Health and Mental Hygiene

*Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – John M. Colmers, Secretary*

**MARYLAND BOARD OF PHARMACY**

**4201 Patterson Avenue • Baltimore, Maryland 21215-2299**

*Donald Taylor, Board President - LaVerne G. Naesed, Executive Director*

January 1, 2013

The Honorable Martin O'Malley  
Office of the Governor  
State House  
Annapolis, Maryland 21401-1925

The Honorable Thomas V. Mike Miller, Jr.  
President of Senate  
State House, H-107  
Annapolis, MD 21401 - 1991

The Honorable Michael Erin Busch  
Speaker of House of Delegates  
State House, H-101  
Annapolis, MD 21401 - 1991

RE: Sixth Annual Report on the Implementation of the Wholesale Distributor Permitting and Prescription Drug Integrity Act

Dear Governor O'Malley, President Miller and Speaker Busch:

The Maryland Board of Pharmacy (the "Board") respectfully submits the enclosed Wholesale Distributor Permitting and Prescription Drug Integrity Act Annual Report to the Governor and General Assembly as required by Health Occupations Article, §12-6C-13, Annotated Code of Maryland.

This is the sixth annual report on the implementation of the Wholesale Distributor Permitting and Prescription Drug Integrity Act (the "Act"). The purpose of the Act is to impose strict requirements for persons applying to be licensed to distribute prescription drugs or devices into Maryland. The Act further requires a pedigree, or history of the distribution chain, for prescription drugs that are distributed in Maryland. 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.

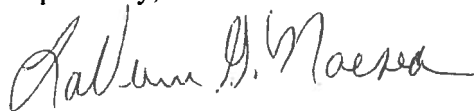
In the 2012 Legislative Session, SB 133/HB 316 State Board of Pharmacy – Wholesale Distributor Permits – Permit and Application Requirements, Chapters 462 and 463, proposed three amendments to the existing Wholesale Distribution Permitting and Prescription Drug Integrity Act. The first amendment removed 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

The Honorable Martin O'Malley  
The Honorable Thomas V. Mike Miller, Jr.  
The Honorable Michael Erin Busch  
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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 passed. Additionally, the HB 283 State Board of Pharmacy – Sunset Extension and Revisions, Chapter 658, 2012, moved the renewal date from December 31<sup>st</sup> every two years to May 31<sup>st</sup> every two years beginning in 2013. This change was requested to better utilize staff resources and to time renewals for the permit holders away from end-of-year obligations.

Should you have questions or additional concerns, please feel free to contact Anna D. Jeffers, Legislation and Regulations Manager, at (410) 764-4794.

Respectfully,



LaVerne G. Naesea  
Executive Director

Enclosure

cc: The Honorable Joan Carter Conway  
The Honorable Roy P. Dyson  
The Honorable Peter A. Hammen  
The Honorable Karen S. Montgomery  
The Honorable Dan K. Morhaim  
Sarah Albert, Department of Legislative Services, MSAR #6598  
Linda Bethman, Board Counsel, Maryland Board of Pharmacy  
Dave Chason, Maryland Board of Pharmacy and Former Co-Chair, Wholesale Distributor SB 759 Workgroup  
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Simon Powell, Department of Legislative Services  
Michael N. Souranis, President, Maryland Board of Pharmacy  
Don Taylor, Maryland Board of Pharmacy and Former Co-Chair, Wholesale Distributor SB 759 Workgroup



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

**SIXTH ANNUAL REPORT TO THE  
GOVERNOR  
AND  
THE GENERAL ASSEMBLY**

**January 1, 2013**

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

**SIXTH ANNUAL REPORT**

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**Members of the Maryland Board of Pharmacy**

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**Board of Pharmacy Staff**

LaVerne G. Naesea, Executive Director

Anna D. Jeffers, Legislation and Regulations Manager

## EXECUTIVE SUMMARY

This is the sixth 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 and second renewal after the passage of the new law. Those challenges, and how they were resolved, were described in detail in the 2009, 2010, 2011 and 2012 Annual Reports. In summary, the passage of House Bill 1195 Prescription Drugs – Wholesale Drug Distribution – Surety Bond Requirements, Chapter 170, during the 2009 Legislative Session, reduced the surety bond requirement from \$100,000 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 relieved the burden on smaller distributors who had difficulty meeting the previous bonding requirement. During the 2010 Legislative Session, the passage of Senate Bill 163/House Bill 868 State Board of Pharmacy - Wholesale Distributor Permitting and Prescription Drug Integrity Act, Chapters 239 and 240, 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. This relieved the financial burden faced by the Board to inspect all out of state distributors whose home state boards did not have distributor laws that were at least as restrictive as Maryland’s. Accreditation programs approved by the Board include: the National Association of Board’s of Pharmacy (NABP) Verified-Accredited Wholesale Distributors (VAWD) for wholesale distributors who hold product; the American Commission for Healthcare, Inc. (ACHC) for wholesale distributors of oxygen; and the Community Health Accreditation Program (CHAP) for the wholesale distributors of other medical gases.

As the Board anticipated the third renewal cycle, it sought introduction of legislation during the 2012 Legislative Session that would remedy many of the outstanding issues that were identified in last year’s annual report. Specifically:

- 1) Eliminating the requirement that the Board be required to physically inspect the facilities of a wholesale distributor applicant who does not physically hold prescription drugs or prescription devices at the applicant’s facility address;
- 2) Altering the criminal background check requirement for an in-state applicant for a wholesale distributor permit by requiring that the designated representative and the supervisor of the designated representative submit fingerprints directly to the Criminal

Justice Information System Central Repository of the Department of Public Safety and Correctional Services (CJIS); and

3) Altering the criminal background check requirement for an out of state applicant for a wholesale distributor permit by requiring the designated representative and the supervisor of the designated representative to submit a criminal background check from their state of residence.

SB 133/HB 316 State Board of Pharmacy – Wholesale Distributor Permits – Permit and Application Requirements, 2012, Chapter 462, passed and became effective October 1, 2012. See: [http://mlis.state.md.us/2012rs/chapters\\_noln/Ch\\_462\\_sb0133T.pdf](http://mlis.state.md.us/2012rs/chapters_noln/Ch_462_sb0133T.pdf)

Since SB 133 was signed by the Governor, the Board has been diligently working to revise COMAR 10.34.22.01 - .08 Licensing of Wholesale Prescription Drug or Device Distributors, to address the remaining issues from last year's report. Specifically:

1. Promulgation of closing regulations so that distributors which cease to operate would be required to notify the Board and account for their remaining inventory and records and return their permits to the Board;
2. Addition of reinstatement requirements to discourage late renewal; and
3. Address the distribution of “virtual” manufacturers with the possible establishment of a separate licensure category.

A draft of the revisions to COMAR 10.34.22 was approved by the Board at the August 15, 2012 Public Board Meeting and was released for informal comment to stakeholders between August 15, 2012 and September 7, 2012. Three informal comments were received. The Board approved responses to those comments and revisions to the proposed regulations as a result of those comments at the October 17, 2012 Public Board Meeting. A copy of the proposed regulations is included in the Appendix, although further revisions may occur before publication in the Maryland Register.

## **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, 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 NABP 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, Chapter 462, proposed three amendments to the Wholesale Distribution Permitting and Prescription Drug Integrity Act (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.

## **Justification for the Amendments**

### **1. Inspections**

The Act required that initial and routine inspections of wholesale distributor facilities be performed by the Board or the Board's designee. The Board has the resources to inspect wholesale distributors located in Maryland, ensuring that they exist, that they store and inventory product appropriately, and that the integrity of the distribution chain has been maintained. From the initial passage of the Act, the Board had limited resources to inspect out of state wholesale distributors. Thus, in 2010 legislation was passed so that out of state wholesale distributors with deemed status would no longer be required to be inspected by Board inspectors. Deemed status became based on whether a wholesale distributor was accredited by a Board approved accreditation program or the wholesale distributor was located in a state with laws that are substantially equivalent to Maryland's. The National Association of Board of Pharmacy's Verified-Accredited Wholesale Distributors (VAWD) program and Accreditation Commission for Health Care, Inc. (ACHC) were approved by the Board as accreditation programs. This helped resolve the Board's issue of limited resources to inspect out of state wholesale distributors that held prescription products.

There still remained, however; wholesale distributors that did not hold product. These entities, such as brokers or "virtual" manufacturers/distributors, contract with other parties to manufacture and distribute prescription drugs or devices. Since they do not hold product, they also do not qualify for VAWD accreditation. Many of these entities are located in states with laws that are NOT substantially equivalent to Maryland's; thus, the conundrum. In order for the Board to fully implement the Act, the Board had no other alternative but to contract with a third party to inspect these locations. Third party inspectors could verify that the locations existed, but since there was no product at these



locations, the inspectors could only examine office space and paper files. After reviewing and considering: 1) the additional expense of contracting with a third party inspector; 2) the substantial delays in formalizing third party inspector contracts; 3) the substantial delays in issuing permits to wholesale distributors who may be the only coordinating entity for the distribution of important prescription drugs into Maryland; and 4) the limited results of those inspections, the Board determined that it was unnecessary to require inspections of out of state wholesale distributors that do not hold product. Additionally, few other states require inspections of wholesale distributors who do not hold product and many states do not even define these entities as “wholesale distributors” requiring licensure. SB 133/HB 316 State Board of Pharmacy – Wholesale Distributor Permits – Permit and Application Requirements, Chapter 462, addressed these issues and the Board has subsequently proposed implementing regulations for entities that do not hold product. The proposed regulations will decrease delays in the licensure and renewal for out of state wholesale distributors who do not hold product, yet maintain sufficient safeguards to protect the consumer. All wholesale distributors that hold product, whether in Maryland or not, would continue to be thoroughly inspected by their own state or VAWD. The proposed regulatory language follows:

*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.*

## **2. Out of State Criminal Background Checks**

The Act had previously required all wholesale distributors' designated representatives and supervisors of the designated representatives to submit to federal and Maryland criminal background checks. The second amendment changed the Act to require designated representatives and their supervisors to provide criminal background checks from the states where the wholesale distributors are physically located. The Board found that requiring criminal background checks in Maryland for out of state designated representatives and their supervisors served little purpose for individuals who live and work in other states and have never set foot in Maryland. The Board found consistently that the criminal background checks from Maryland for out of state individuals indicated no violations of Maryland law. It therefore stood to reason that, an individual residing in Idaho and working for a wholesale distributor in Idaho, for example, should receive a criminal background check by the State of Idaho. Better protection would be afforded the consumer if the state criminal background check was performed in the state where the designated representative and supervising designated representative live and work.

### **3. Maryland Criminal Background Checks**

The revised Act required that the applicant submit their fingerprint and fees for a criminal background check to the Board and the Board forwards on to the Criminal Justice Information System Central Repository of the Department of Public Safety and Correctional Services (CJIS). The third amendment allows Maryland applicants to submit their fingerprints and fees for a criminal background check directly to CJIS. This change eliminated a step in the application process and resulted in alleviating delays in the approval of wholesale distributor applications.

## **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. The emphasis was 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. 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.

## APPENDIX I

### MARYLAND REGISTER

#### Proposed Action on Regulations

<b>Transmittal Sheet</b>  <b>PROPOSED OR REPROPOSED</b>  <b>Actions on Regulations</b>	<b>Date Filed with AELR Committee</b>	<b>TO BE COMPLETED BY DSD</b>
		Date Filed with Division of State Documents
		Document Number
		Date of Publication in MD Register

**1. Desired date of publication in Maryland Register:**

**2. COMAR Codification**

**Title Subtitle Chapter Regulation**

10 34 22 02,.03,.03-1,.05,.09-.11

**3. Name of Promulgating Authority**

Department of Health and Mental Hygiene

**4. Name of Regulations Coordinator**  
Michele Phinney

**Telephone Number**  
410-767-5623

**Mailing Address**

201 W. Preston Street

**City State Zip Code**  
Baltimore MD 21201

**Email**

michele.phinney@maryland.gov

**5. Name of Person to Call About this Document**  
Anna Jeffers

**Telephone No.**  
410-764-3833

**Email Address**

anna.jeffers@maryland.gov

**6. Check applicable items:**

☒- New Regulations

☒- Amendments to Existing Regulations

Date when existing text was downloaded from COMAR online: October 19, 2012.

☐ Repeal of Existing Regulations

☐ Recodification

☐ Incorporation by Reference of Documents Requiring DSD Approval

☐ Reproposal of Substantively Different Text:

: Md. R  
(vol.) (issue) (page nos) (date)

Under Maryland Register docket no.: --P.

**7. Is there emergency text which is identical to this proposal:**

☐ Yes ☒- No

**8. Incorporation by Reference**

☐ Check if applicable: Incorporation by Reference (IBR) approval form(s) attached and 18 copies of documents proposed for incorporation submitted to DSD. (Submit 18 paper copies of IBR document to DSD and one copy to AELR.)

**9. Public Body - Open Meeting**

☒- OPTIONAL - If promulgating authority is a public body, check to include a sentence in the Notice of Proposed Action that proposed action was considered at an open meeting held pursuant to State Government Article, §10-506(c), Annotated Code of Maryland.

☐- OPTIONAL - If promulgating authority is a public body, check to include a paragraph that final action will be considered at an open meeting.

**10. Children's Environmental Health and Protection**

☐ Check if the system should send a copy of the proposal to the Children's Environmental Health and Protection Advisory Council.

**11. Certificate of Authorized Officer**

I certify that the attached document is in compliance with the Administrative Procedure Act. I also certify that the attached text has been approved for legality by Lynda Bethman, Assistant Attorney General, (telephone #410-767-6906) on . A written copy of the approval is on file at this agency.

**Name of Authorized Officer**

Joshua M. Sharfstein, M.D.

**Title**

Secretary

**Date**

**Telephone No.**

410-767-6500

**Title 10**  
**DEPARTMENT OF HEALTH AND MENTAL HYGIENE**  
**Subtitle 34 BOARD OF PHARMACY**

**10.34.22 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

**Notice of Proposed Action**

[]

The Secretary of Health and Mental Hygiene proposes to amend Regulations .02, .03, and .05, and adopt new Regulations .03-1, and .09—.11 under COMAR 10.34.22 Licensing of Wholesale Prescription Drug or Device Distributors.

This action was considered by the Board of Pharmacy at a public meeting held October 17, 2012, notice of which was given by publication on the Board of Pharmacy website, <http://dhmh.maryland.gov/pharmacy/SitePages/Home.aspx>, from September 28, 2012, through October 17, 2012, pursuant to the State Government Article, §10-506(c), Annotated Code of Maryland.

**Statement of Purpose**

The purpose of this action is to revise COMAR 10.34.22 to comply with statutory requirements as amended by SB 133/HB 316 State Board of Pharmacy – Wholesale Distributor Permits – Application Requirements, 2012. The revisions include: adding definitions for “ANDA,” “NDA,” and “UDI” numbers. Other new definitions include “cease to operate,” “central repository,” and “virtual manufacturer.” Revisions have been made: concerning criminal background checks so that applicants may submit their request for criminal background checks directly to the central repository instead of to the Board; adding a section that requires out of state applicants to obtain criminal background checks from the state in which they are located; and revising the inspection requirement so that only entities that hold product are required to be inspected. The proposed action also includes three new regulations which clarify procedures. The new Regulation .09 addresses reinstatement for expired wholesale distributor permits. The new Regulation .10 addresses required information and procedures for closing. The new Regulation .11 addresses relocation requirements. Finally, the proposal includes clarifying revisions to the surety bond requirement and Regulation .05 Violations and Penalties.

**Comparison to Federal Standards**

There is no corresponding federal standard to this proposed action.

**Estimate of Economic Impact**

**I. Summary of Economic Impact.**

The revisions to this chapter add minimum application requirements for virtual manufacturers. It also includes new regulations for reinstatement, procedures for ceasing to operate, and relocation. These revisions impose a positive economic impact on the issuing agency since less time will be required of Board staff to process applications. These revisions impose a positive impact on virtual manufacturers because they may now utilize less time staff time completing the application.

II. Types of Economic Impact.	Revenue (R+/R-)	Magnitude
	Expenditure (E+/E-)	
A. On issuing agency:	(R+)	Indeterminate
B. On other State agencies:	NONE	
C. On local governments:	NONE	
	Benefit (+) Cost (-)	Magnitude
D. On regulated industries or trade groups:	(+)	Indeterminate
E. On other industries or trade groups:	NONE	
F. Direct and indirect effects on public:	(+)	Indeterminate

### III. Assumptions. (Identified by Impact Letter and Number from Section II.)

A. The revisions in this proposal simplify the application process and, as a consequence, require less staff time to process applications.

D. The regulated industry will welcome the simpler application process for certain virtual manufacturers since it will save staff time for the regulated industry.

F. This proposal has an indirect and positive effect on the public as virtual manufacturers will be able to apply for licensure in less time making certain prescription drugs available to Maryland consumers in less time without sacrificing public safety.

### Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

### Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

### Opportunity for Public Comment

Comments may be sent to Michele A. Phinney, Director, Office of Regulation and Policy Coordination, Department of Health and Mental Hygiene, 201 West Preston Street, Room 512, Baltimore, MD 21201, or call 410-767-6499; TTY:800-735-2258, or email to [dhnh.regs@maryland.gov](mailto:dhnh.regs@maryland.gov), or fax to 410-767-6483. Comments will be accepted through . A public hearing has not been scheduled.

### **Economic Impact Statement Part C**

A. Fiscal Year in which regulations will become effective: FY 2013

B. Does the budget for the fiscal year in which regulations become effective contain funds to implement the regulations?

C. If 'yes', state whether general, special (exact name), or federal funds will be used:

D. If 'no', identify the source(s) of funds necessary for implementation of these regulations:

E. If these regulations have no economic impact under Part A, indicate reason briefly:

F. If these regulations have minimal or no economic impact on small businesses under Part B, indicate the reason and attach small business worksheet.

The Board is not required to obtain information concerning which licensees operate small businesses. The regulations generally simplify processes for criminal background checks and wholesale distributors who do not hold product. These revisions would have a positive economic impact on wholesale distributors who are also small businesses.

G. Small Business Worksheet:

Attached Document:

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## **Title 10**

# **DEPARTMENT OF HEALTH AND MENTAL HYGIENE**

## **Subtitle 34 BOARD OF PHARMACY**

### **10.34.22 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

10.34.22.02 (October 19, 2012)

#### **.02 Definitions.**

A. (text unchanged)

**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)] (1-1) (text unchanged)

(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) (8) (text unchanged)

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

(9) (14) (text unchanged)

(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) (18) (text unchanged)

(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.

(18-3) "Retail 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.

(19) (21) (text unchanged)

(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) (23) (text unchanged)

**10.34.22.03 (October 19, 2012)**

**.03 Minimum Application Requirements for [Applicant] Applicants Holding Product.**

A. (text unchanged)

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

(1) [Two complete sets of legible fingerprints taken on forms] *Electronically or digitally captured fingerprints at approved electronic fingerprint locations approved by the Director of the Central Repository [and the Director of the Federal Bureau of Investigation];*

(2) (3) (text unchanged)

*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.*

C. (text unchanged)

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



(1) [Conducts] *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)—(4) (text unchanged)

E. Surety Bond.

(1)—(2) (text unchanged)

(3) [The] *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[, if the applicant's total annual gross receipts within or without the State are less than \$10,000,000]; or

(b) An annual sales report specifying the sales of prescription drugs and devices in the State audited by a certified public accountant[, if the applicant's total annual gross receipts within or without the State are \$10,000,000 or more].

(4) (text unchanged)

(5) [A single surety bond shall cover all facilities operated by the applicant in the State] *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.—1. (text unchanged)

*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.*

#### **ALL NEW**

##### **.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.

#### **END NEW**

**10.34.22.05 (October 19, 2012)**

##### **.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)—(2) (text unchanged)

(3) Commits any of the following acts:

(a)—(o) (text unchanged)

(p) Distributes a prescription drug or device to [the] *a consumer or patient* [without a prescription or prescription order from a practitioner licensed by law to use or prescribe the prescription drug or device];

(q)—(x) (text unchanged)

(4) (text unchanged)

B. (text unchanged)

#### **ALL NEW**

##### **.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, in addition to the renewal fee, 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 closing.

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 manufacturers, wholesale distributors, and licensed pharmacies 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) Within 72 hours before or after ceasing to operate, the wholesale distributor shall request a closing inspection from 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; or

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

(4) Disposition of Controlled Dangerous Substances.

(a) 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.

(b) The wholesale distributor shall provide the names, address, telephone numbers, and Drug Enforcement Administration registration numbers of the persons or business entities to whom prescription drugs or devices in stock were returned or transferred under this section to the Board.

(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 wholesale distributor permit and the State Department of Health and Mental Hygiene Controlled Dangerous Substance Registration for cancellation, if applicable;

(d) If prescription drugs or devices are destroyed pursuant to this regulation, the wholesale distributor shall provide the Board with 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;

(e) If prescription drugs or devices are destroyed pursuant to this regulation, the wholesale distributor shall provide the Board with 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;

(f) If any pedigrees or other documents are transferred, the wholesale distributor shall provide the Board with 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; and

(g) Evidence that the surety bond or other security will remain in effect until 2 years after the wholesale distributor's permit ceases to be valid.

**.11 Relocation.**

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

C. A relocation applicant:

(1) If located in this State, shall request an opening inspection of the Board;

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

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

D. New personnel shall be required to undergo a criminal history records check as set forth in Regulation .03 of this chapter.

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

(1) Evidence of notification to the accreditation organization that accredited the relocation applicant for deemed status; or

(2) If the relocation applicant is not accredited by an accreditation organization, subsequent inspection reports from the state in which the relocation applicant is located,

**END NEW**

**JOSHUA M. SHARFSTEIN, M.D.**

**Secretary of Health and Mental Hygiene**

