



STATE OF MARYLAND

DHMH

Department of Health and Mental Hygiene
*Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor –
Joshua M. Sharfstein, MD, Secretary*

MARYLAND BOARD OF PHARMACY

4201 Patterson Avenue • Baltimore, Maryland 21215-2299

Lenna Israbian-Jamgochian, Board President - LaVerne G. Naesea, Executive Director

January 1, 2014

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: Seventh 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 seventh 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 2013 Legislative Session, 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 and required certain reporting requirements. 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. This legislation is

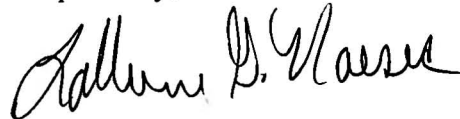
The Honorable Martin O'Malley
The Honorable Thomas V. Mike Miller, Jr.
The Honorable Michael Erin Busch
Page Two

important because it prevents pharmacies from selling prescription drugs that are in short supply upstream to a wholesale distributor which often has contributed to inflated prices of hard to obtain prescription drugs.

This report includes as an Appendix proposed regulations to implement the 2012 and 2013 legislation.

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

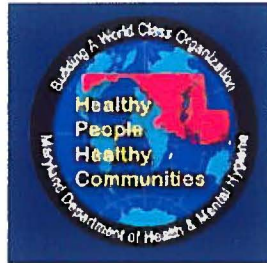
Respectfully,



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
Patrick Dooley, Chief of Staff, DHMH
Harry Finke, Chair, Practice Committee, Maryland Board of Pharmacy
Lenna Israbian-Jamgochian, President, Maryland Board of Pharmacy
Christi Megna, Assistant Director, Office of Governmental Affairs
Anna D. Jeffers, Legislation and Regulations Manager, Maryland Board of Pharmacy
Thomas Kim, Deputy Secretary of Operations, DHMH
Drew Vetter, Governor's Legislative Office
Simon Powell, Department of Legislative Services



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

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

January 1, 2014

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

SEVENTH 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 seventh 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 2013 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.

In the 2012 Legislative Session, SB 133/HB 316 State Board of Pharmacy – Wholesale Distributor Permits – Permit and Application Requirements, 2012, Chapter 462, 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. It altered 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). Finally,

it altered 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.

In the 2013 Legislative Session, 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 and required certain reporting requirements. 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. This legislation is important because it prevents pharmacies from selling prescription drugs that are in short supply upstream to a wholesale distributor which often has contributed to inflated prices of hard to obtain prescription drugs.

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 the 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 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 distribute 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 has been diligently working to revise COMAR 10.34.22.01 - .08 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. 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. Although the proposal was published in the Maryland Register, 40:8 Md.R. 742-745 (April 19, 2013), new legislation was introduced and passed during the 2013 Legislative Session. The Board withdrew the April proposal and approved a revised version at the September 20, 2013 Public Board Meeting to accommodate both 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. A copy of the proposed regulations implementing the 2012 and 2013 legislation is included in the Appendix, although further revisions may occur before publication in the Maryland Register.

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

Transmittal Sheet PROPOSED OR REPROPOSED Actions on Regulations	Date Filed with AELR Committee	TO BE COMPLETED BY DSD
		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
10	34	37	01-.03

3. Name of Promulgating Authority

Department of Health and Mental Hygiene

4. Name of Regulations Coordinator	Telephone Number
Michele Phinney	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	Telephone No.
Anna Jeffers	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: June 7, 2013.

- 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 Linda 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
Subtitle 34 BOARD OF PHARMACY
10.34.37 Pharmacy Permit Holder – Wholesale Distribution
Authority: See Attached

Notice of Proposed Action

[]

The Secretary of Health and Mental Hygiene proposes to :

- 1) 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; and
- 2) Adopt new Regulations .01—.03 under a new chapter COMAR 10.34.37 Pharmacy Permit Holder – Wholesale Distribution.

At this time, the Secretary is also withdrawing amendments to Regulations .02, .03, and .05, and new Regulations .03-1, and .09—.11 under COMAR 10.34.22 Licensing of Wholesale Prescription Drug or Device Distributors as proposed in the 40:8 Md.R. 742-745 (April 19, 2013).

This action was considered by the Board of Pharmacy at a public meeting held November 20, 2013, notice of which was given by publication on the Board of Pharmacy website, <http://dhmh.maryland.gov/pharmacy/SitePages/Home.aspx>, from October 30, 2013 through November 20, 2013, pursuant to the State Government Article, §10-506(c), Annotated Code of Maryland.

Statement of Purpose

The purpose of this action is to :

- 1) 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 and SB 595/ HB 591 State Board of Pharmacy – Wholesale Distribution – Pharmacies, 2013. The revisions include: adding definitions for “ANDA,” “NDA,” “pharmacy,” “UDI” numbers, “cease to operate,” “central repository,” “intracompany sales,” and “virtual manufacturer.” “Original wholesale distributor” was added to § B(22)(b)(x) of the definition of “wholesale distribution” where wholesale distribution does not include 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. The word “retail” was stricken from § B(23)(b)(xii) of the definition of “Wholesale Distributor” so that all pharmacies distributing more than 5% of their annual sales would be required to obtain a wholesale distributor permit. 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 four new regulations which clarify procedures. The new Regulation .03-1 addresses minimum application requirements for virtual manufacturers. 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; and

2) Adopt new regulations under a new chapter COMAR 10.34.37 Pharmacy Permit Holder – Wholesale Distribution to comply with statutory requirements as amended by SB 595/HB 591 State Board of Pharmacy – Wholesale Distribution – Pharmacies, 2013. The requirements do not allow wholesale distribution by a pharmacy with a waiver permit to a wholesale distributor. Waiver pharmacies will be required to keep proper records of wholesale distribution. Full service pharmacies may distribute to a wholesale distributor with proper record keeping and by submission to the Board of a “Reporting Form” within a week of the wholesale distribution.

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 COMAR 10.34.22 Licensing of Wholesale Prescription Drug or Device Distributors, 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.

The adoption of a new chapter COMAR 10.34.37 Pharmacy Permit Holder – Wholesale Distribution, has no fiscal impact on the Board as a change to inspections forms, which is done on an annual basis in any event, would be the only known change as a result of the proposed legislation. The receipt of “Reporting Forms” should be minimal as this practice is limited to unusual or emergency circumstances.

II. Types of Economic Impact.	Revenue (R+/R-)	Expenditure (E+/E-)	Magnitude
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 COMAR 10.34.22 Licensing of Wholesale Prescription Drug or Device Distributors, simplify the application process and, as a consequence, require less staff time to process applications.

The new regulations in COMAR 10.34.37 Pharmacy Permit Holder – Wholesale Distribution, would have minimal impact on the Board. Inspections forms would be required to be revised, but are revised annually as a matter of course. Receipt of “Reporting Forms” should be infrequent and may easily be stored in the permit holder’s file.

D. For COMAR 10.34.22 Licensing of Wholesale Prescription Drug or Device Distributors, the regulated industry will welcome the simpler application process for certain virtual manufacturers since it will save staff time for the regulated industry. For COMAR 10.34.37 Pharmacy Permit Holder – Wholesale Distribution, the regulated pharmacies should find the “Reporting Form” a short and brief. It should not be a burden to complete as wholesale distribution to wholesale distributors should be an infrequent occurrence.

F. The revisions in COMAR 10.34.22 Licensing of Wholesale Prescription Drug or Device Distributors 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. The adoption of a new chapter COMAR 10.34.37 Pharmacy Permit Holder – Wholesale Distribution, will have a positive effect on the public by tracking the sale of prescription drugs from a pharmacy to a wholesale distributor. This may alert the Board when prescription drugs are in shortage and sold by pharmacies instead of by wholesale distributors.

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 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 410-767-6500; TTY:800-735-2258, or email to dhmh.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 2014
- 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. The requirement of a "Reporting Form" would be minimal on a small business pharmacy as the usage of this form should be minimal.
- G. Small Business Worksheet:

Attached Document:

Title 10

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 34 BOARD OF PHARMACY

10.34.22 Licensing of Wholesale Prescription Drug or Device Distributors

10.34.22.02 (June 7, 2013)

.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)—(5) (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)—(12) (text unchanged)

(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)—(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)—(16) (text unchanged)

(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)—(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.

(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) Wholesale Distribution.

(a) (text unchanged)

(b) "Wholesale distribution" does not include:

(i) [Intra-company] Intracompany sales;

(ii)—(ix) (text unchanged)

(x) The sale or transfer from a [retail] pharmacy or pharmacy warehouse of expired, damaged, returned, or recalled prescription drugs to the original wholesale distributor, the original manufacturer, or [to] a third-party returns processor.

(23) Wholesale Distributor.

(a) (text unchanged)

(b) "Wholesale distributor" includes:

(i)—(xi) (text unchanged)

(xii) A [retail] pharmacy that conducts wholesale distribution, if the wholesale distribution business accounts for more than 5 percent of the [retail] pharmacy's annual sales; and

(xiii) (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.*

(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. (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.—I. (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.*

.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.

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)

.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 a 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.

10.34.37 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.

JOSHUA M. SHARFSTEIN, M.D.

Secretary of Health and Mental Hygiene