



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. Naesea, Executive Director*

January 1, 2010

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

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 third 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 additional 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.

During the third year that the Act has been in place the Board has fully implemented the statute and regulations by renewing all previously licensed wholesale distributors under the new Act and requiring all new wholesale distributors in Maryland to comply with the new Act. A multitude of challenges arose over the past year. The surety bond amount of \$100,000 was difficult to obtain for many smaller wholesale distributors. The Board found that the inspection requirement was problematic primarily because a large number of states' do not have the same pedigree requirements as Maryland's law; therefore falling short of meeting the "substantially equivalent" requirement for reciprocity. This has required Board inspectors to travel out of state or to sub-contract with a vendor in order to inspect all of the wholesale distributors throughout the country

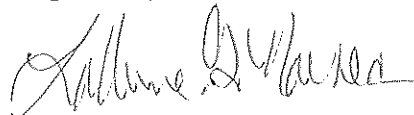
The Honorable Martin O'Malley

The Honorable Thomas V. Mike Miller, Jr.  
The Honorable Michael Erin Busch  
Page Two  
January 1, 2010

prior to licensure in Maryland. Additionally, the complexity of the criminal history records check process often delayed the processing of applications. The surety bond amount was revised through legislation in the 2009 session to lower the amount to \$50,000, if the annual gross receipts of the applicant for the previous tax year are less than \$10,000,000. The inspection requirement will be proposed for revisions in legislation for the 2010 session.

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  
Wendy Kronmiller, Chief of Staff, DHMH  
Dave Chason, Maryland Board of Pharmacy and Former Co-Chair, Wholesale  
Distributor SB 759 Workgroup  
Anne Hubbard, Director, Office of Governmental Affairs  
Anna D. Jeffers, Legislation and Regulations Manager, Maryland Board of Pharmacy  
Simon Powell, Department of Legislative Services  
Carolyn Quattrochi, Governor's Legislative Office  
Don Taylor, President, Maryland Board of Pharmacy and Former Co-Chair, Wholesale  
Distributor SB 759 Workgroup  
Kathleen Wunderlich, Department of Legislative Services



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

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

**January 1, 2010**

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

**THIRD ANNUAL REPORT**

**TABLE OF CONTENTS**

BOARD MEMBERS.....3

EXECUTIVE SUMMARY.....4

THE CHALLENGES OF NEW REGULATORY REQUIREMENTS.....4

RECOMMENDATIONS.....7

CONCLUSION.....8

APPENDIX I.....9

APPENDIX II.....11

APPENDIX III.....12

APPENDIX IV.....13

APPENDIX V.....14

APPENDIX VI.....17

APPENDIX VII.....18

APPENDIX VIII.....19

APPENDIX IX.....20

APPENDIX X.....21

**Members of the Maryland Board of Pharmacy**

Donald W. Taylor, President

Rodney Taylor, Secretary

Michael M. Souranis, Treasurer

Mayer Handelman

Dave Chason

Cynthia Anderson

Harry Finke, Jr.

Lynette Bradley-Baker

Lenna Israbian-Jamgochian

Reid A. Zimmer

Richard W. Matens

Alland Leandre

**Board of Pharmacy Staff**

LaVerne G. Naesea, Executive Director

Anna D. Jeffers, Legislation and Regulations Manager

## **EXECUTIVE SUMMARY**

This is the third annual report on the implementation of the Wholesale Distributor Permitting and Prescription Drug Integrity Act (the “Act”) as required by Health Occupations Article, Subtitle 6C, Annotated Code of Maryland. The Act, Senate Bill 759, Chapter 352, was passed in the 2007 Legislative Session. The Act imposed additional requirements for persons applying to be licensed to distribute prescription drugs or devices into Maryland. The Act further required a pedigree, or history of the distribution chain, for prescription drugs that are distributed in Maryland.

A multitude of challenges arose as the Board of Pharmacy (the “Board”) began implementing this Act during the first renewal period after the effective date. The surety bond amount of \$100,000 was difficult to obtain for many smaller wholesale distributors. The Board found that the inspection requirement was problematic primarily because a large number of states’ do not have the same pedigree requirements as Maryland’s law; therefore falling short of meeting the “substantially equivalent” requirement for reciprocity. This has required Board inspectors to travel out of state or to sub-contract with a vendor in order to inspect all of the wholesale distributors throughout the country prior to licensure in Maryland. Additionally, the complexity of the criminal history records check process often delayed the processing of applications. The Board eventually extended the deadline for compliance with the act for renewing wholesale distributors until August 31, 2009 in order to address the challenges presented by the surety bond and inspection requirements. The surety bond amount was revised through legislation in the 2009 session to lower the amount to \$50,000, if the annual gross receipts of the applicant for the previous tax year are less than \$10,000,000. The inspection requirement will be proposed for revisions in legislation for the 2010 session.

### **THE CHALLENGES OF NEW REGULATORY REQUIREMENTS**

During 2008, the Board utilized the statute and the revised regulations to develop new applications and permit processes. Beginning in October 2008, applications were mailed to existing wholesale distributor permit holders whose permits expired December 31, 2008. The complex new requirements for renewal of wholesale distributors created confusion among the existing permit holders. Prior to the end of the year and the initial renewal deadline, the Board was inundated with phone calls and inquiries from existing permit holders who struggled to meet the new requirements. Many permit holders found it difficult to obtain a \$100,000 surety bond or irrevocable letter of credit. Many permit holders found it complicated to obtain fingerprints or were concerned that the process of submitting the fingerprints through the Criminal Justice Information System Central Repository of the Department of Public Safety and Correctional Services (CJIS) and the Board took longer than originally anticipated. Many third party logistics providers, virtual manufacturers, own label distributors, out of state manufacturers, companies that only hold title to prescription drugs or devices, billing and invoicing facilities, and international drug manufacturers were not sure whether their businesses needed to process a permit with the Board as a wholesale distributor. As December 31, 2008 approached, the Board extended the renewal deadline to January 31, 2009 to allow more time for many permit holders to comply with the significantly changed new law and to allow the Board to address the volume of application materials received. The Board did not anticipate, at the close of 2008, the

multitude of additional challenges that would arise for the applicants and the Board staff or that additional extensions would be needed.

### **Surety Bond Requirement**

With the change in the overall economic climate, permit holders found it burdensome to obtain a \$100,000 surety bond or irrevocable letter of credit. For the smaller wholesale distributors, however; it became almost impossible without great financial hardship. Several small wholesale distributors approached Delegate Montgomery to express concern about the surety bond requirement. The Board was bound by the language of Health Occupations Article, 12-6C-05(f), Annotated Code of Maryland, that requires a surety bond of \$100,000 regardless of the size of the distributor or the number of other states where the distributor may also hold surety bonds. Some states have allowed for smaller bonds based on the wholesale distributor's size and assets in total. Other states have accepted surety bonds prepared for sister states instead of requiring a new bond specific to that state. Delegate Montgomery introduced House Bill 1195 Prescription Drugs – Wholesale Drug Distribution – Surety Bond Requirements, which 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. See Appendix I.

Even though House Bill 1195 was introduced as an emergency bill and had no opposition, the legislative process necessary for passage of the bill was not completed by the Board's new extended deadline of January 31, 2009. Therefore, the Board voted at its January 21, 2009 Public Board Meeting to extend the deadline for the submission of all renewal application materials to March 31, 2009. A notice was published on the Board's website, in the Maryland Register, and in the Winter 2008-2009 Maryland Board of Pharmacy Newsletter. See Appendices II and III. At the March 18, 2009 Public Board Meeting, the Board recognized that the emergency legislation would not be passed and signed by the Governor before March 31, 2009. Thus, in order to accommodate the passage of the bill and the upcoming emergency regulations, the Board voted to extend the deadline to June 30, 2009. Notice of the second extension was published on the Board's website and in the Maryland Register. See Appendix IV. House Bill 1195 passed and was signed by the Governor on April 14, 2009.

The Board immediately began the promulgating emergency regulations to implement House Bill 1195 and voted on a proposed draft at the April 15, 2009 Public Board Meeting. The proposed regulations were published in the Maryland Register on June 19, 2009 and the Notice of Emergency Action was published July 17, 2009, with an emergency effective date of June 18, 2009 (before the June 30, 2009 deadline). See Appendices V and VI. As soon as the Board was aware of the June 18, 2009 Emergency Effective Date, it posted a notice on the Board's website to notify permit holders of the new requirements. See Appendix VII. The Notice of Final Action for the regulations was eventually published September 25, 2009, with a final effective date of October 5, 2009. See Appendix VIII.

### **Inspections**

One substantive change in the initial statute includes a requirement for all wholesale distributor facilities to be inspected prior to licensure and upon renewal. In 2008, the Board developed

procedures and recruited inspection personnel so that required inspections could be performed at facilities located in Maryland and a few surrounding states. However, completing inspections in most other states posed a difficult problem for the Board, as there were hundreds of out-of-state facilities applying for permits in Maryland.

To an extent, the Act addresses this issue in two ways. First, Health Occ. §§ 12-6C-04(a)(1) and 12-6C-04(b) provide that a distributor who has been accredited by an accreditation organization, such as the National Association of Boards of Pharmacy (NABP) Verified-Accredited Wholesale Distributors (VAWD) Certification process, may be granted “deemed status” and is therefore exempt from the inspection requirement. However, only three states *require* VAWD accreditation for licensure: Indiana, North Dakota and Wyoming. Any wholesale distributor licensed in these three states would not need a Maryland Board of Pharmacy inspection. A number of distributors located in other states have also voluntarily obtained VAWD accreditation and are thus exempt from inspection; this amount does not comprise a majority of those distributors that have applied for licensure in Maryland.

Second, Health Occ. § 12-6C-04(c) allows the Board to grant reciprocity to a distributor if the distributor holds a license or permit under the laws of another state if the Board has determined that the other state’s requirements are “substantially equivalent” to Maryland’s requirements. The Board engaged in a thorough review of the distributor laws of all other states and determined that approximately 14 states meet these criteria. Thus, the Board has recognized the inspections performed by those other state boards as inspections performed by a Board designee in accordance with Health Occ. § 12-6C-05(d). The Board also recognizes U.S. Food and Drug Administration (FDA) or Drug Enforcement Administration (DEA) inspections reports, if applicable.

There are a number of states whose laws fall short of meeting the “substantially equivalent” requirement for reciprocity primarily because their law does not have the same pedigree requirements as Maryland’s law. In order to accommodate facilities located in these states, the Board has issued permits by reciprocity in these states for initial licensure only based on the premise that it would be impossible for a newly licensed facility to have pedigrees on file if they have not been previously required to keep them under their own state’s law. Approximately 19 more states fell into this category during the 2009. However, upon renewal under the current statute, these facilities will be required to submit to an inspection by the Board or its designee.

Throughout the extension periods in 2009, the Board was challenged with how to implement inspections of out-of-state wholesale distributors who were neither accredited nor located in states that have strengthened laws similar to Maryland’s. The Board ultimately extended the deadline a third time, to August 31, 2009. A notice to that effect was posted on the Board’s website. See Appendix IX. The only exception to this deadline was for those facilities awaiting an inspection from the Board. Fewer states than expected have laws that are similar to Maryland’s. Even fewer states required VAWD accreditation. In the end, the Board faced a dilemma regarding how to complete inspections in the remaining states. While the Board attempted to gain the cooperation of other state boards of pharmacy to complete inspections on its behalf, it was unsuccessful.



In order to remedy this challenge the Board contracted with NABP to perform inspections on behalf of the Board. NABP is able to save the Board time, money, and a strain on its limited personnel by sending its highly-trained inspectors to perform these inspections. NABP is projected to finish all out-of-state inspections by the end of November 2009.

After the August 31, 2009 extension, the Board issued Cease and Desist letters to those applicants which had failed to comply with the Act either by failing to provide a surety bond and/or fingerprints for a criminal background check, or otherwise not meeting application requirements.

### **Federal and State Background Checks**

In Health Occupations Article, 12-6C-05(e), Annotated Code of Maryland, the Board is required to submit fingerprints provided by the wholesale distributor's designated representative, and the immediate supervisor of that designated representative, to the Criminal Justice Information System Central Repository of the Department of Public Safety and Correctional Services (CJIS) for a Maryland and national criminal history records check. Two complete sets of fingerprints are required from both individuals for submission to CJIS and the Director of the Federal Bureau of Investigations (FBI). The coordination of this process became overwhelming for Board staff. The CJIS criminal history records check arrived to the Board offices in the mail. The FBI criminal history records check arrived by e-mail. It was the norm that these reports would arrive weeks apart and at times, before the matching applications were received. These occurrences delayed the processing of applications. Additionally, CJIS criminal background reports were concurrently being received at the Board for the pharmacy technician program, which created a challenge in creating an effective database. Board staff found it difficult to distinguish the criminal history records reports between the pharmacy technician and wholesale distributor employees and to then subsequently match the report names with the business name of the wholesale distributor applicants. The names of the pharmacy technician, designated representative, and the immediate supervisor of the designated representative, were not searchable on a database and caused matching the criminal history records checks with the applications an arduous task. Since the national criminal history records check covers all 50 states including Maryland, the Board has found that the CJIS report is duplicative and often delays processing of applications.

### **RECOMMENDATIONS**

The inspection of out-of-state wholesale distributors under the current Wholesale Distribution Permitting and Prescription Drug Integrity Act has been burdensome. To alleviate a continuation of the NABP contract, or any other designee's contract, to inspect out of state wholesale distributors, the Board recommends that the governor and legislature approve Board proposed legislative changes to the Act during the 2010 Legislative Session that requires that a distributor either be (1) accredited by an accreditation organization such as VAWD; or (2) that the distributor holds a license or permit in a state with laws the Board has determined are substantially equivalent to Maryland's laws.

Passage of the amendment would require out-of-state distributors located in states with laws that are not substantially equivalent to Maryland's laws, to become nationally accredited. This will remove the financial burden from the Board of inspecting wholesale distributor facilities across the country. At this juncture, no other state board performs out-of-state inspections of wholesale distributor facilities. A copy of the draft bill is attached as Appendix X.

## **CONCLUSION**

The Board would like to commend Delegate Montgomery again for her leadership and perseverance during the 2009 Legislative Session in passing legislation that provided an option for a lower surety bond amount for those wholesale distributors that distribute less than \$10,000,000 of their gross receipts from sales of prescription drugs and devices in Maryland. That act has made the difference for a number of smaller wholesale distributors who otherwise may not have been able to afford to continue operating in Maryland. The passage of the new law and the Board's swift promulgation of the accompanying regulations solved one of the major challenges during 2009. With the potential passage of legislation in 2010 to revise the inspection requirement by requiring either accreditation by VAWD or a license or permit in a state with laws the Board has determined are substantially equivalent to Maryland's laws, another major challenge will be resolved.

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. At that time the emphasis was on protecting the public by imposing additional requirements for persons applying to be licensed to distribute prescription drugs or devices into Maryland and thereby protecting the supply chain of prescription drugs and devices in this State. The Act has changed how wholesale distributors in Maryland do business. Their personnel are more scrutinized. Their facilities are inspected and may not be operated in a personnel residence. They are required to have pedigrees for prescription drugs they distribute that leave, or have ever left the normal distribution channel. As the Board has implemented the Act, small changes have been necessary to ensure more reasonable compliance by the wholesale distributor industry and greater feasibility in administration by the Board. Even with the challenges and revisions, the Act has remained an important factor in protecting the prescription drug supply in Maryland.

APPENDIX I

**CHAPTER 170**

**(House Bill 1195)**

AN ACT concerning  
**Prescription Drugs – Wholesale Drug Distribution – Surety Bond  
Requirements**

FOR the purpose of altering surety bond requirements for an applicant for a wholesale distributor permit; specifying the entity to which the surety bond *or certain other security* is payable; specifying the amount of the surety bond *or other security*, depending on certain receipts of the applicant; authorizing the State Board of Pharmacy to require by regulation certain documentation; authorizing the Board to allow an applicant for a wholesale distributor permit or a wholesale distributor permit holder to rescind a surety bond *or other security* submitted before a certain date and submit a new surety bond *or other security* under certain circumstances; defining a certain term; making this Act an emergency measure; and generally relating to surety bond requirements for applicants for wholesale drug distributor permits.

BY repealing and reenacting, with amendments,  
Article – Health Occupations  
Section 12–6C–05(f)  
Annotated Code of Maryland  
(2005 Replacement Volume and 2008 Supplement)

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

**Article – Health Occupations**

12–6C–05.

(f) (1) **IN THIS SUBSECTION, “GROSS RECEIPTS” MEANS GROSS RECEIPTS FROM SALES OF PRESCRIPTION DRUGS AND DEVICES IN THE STATE.**

**(2)** This subsection does not apply to a pharmacy warehouse that is not engaged in wholesale distribution.

**(2) (3) (1)** An applicant for a wholesale distributor permit shall submit a surety bond [of at least \$100,000,] or other equivalent means of security acceptable to the [State] **STATE**, such as an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to **THE MARYLAND STATE BOARD OF**  
Ch. 170 MARTIN O’MALLEY, Governor

**PHARMACY TO BE DEPOSITED INTO** an account established by the State under paragraph (6) **(7)** of this subsection.

**(II) THE SURETY BOND *OR OTHER SECURITY* SHALL BE IN THE AMOUNT OF:**

- 1. \$100,000, IF THE ANNUAL GROSS RECEIPTS OF THE APPLICANT FOR THE PREVIOUS TAX YEAR ARE \$10,000,000 OR MORE; OR**
- 2. \$50,000, IF THE ANNUAL GROSS RECEIPTS OF THE APPLICANT FOR THE PREVIOUS TAX YEAR ARE LESS THAN \$10,000,000.**

**(III) THE BOARD MAY REQUIRE BY REGULATION DOCUMENTATION FOR THE GROSS RECEIPTS OF THE WHOLESALE DISTRIBUTOR TO QUALIFY FOR A *SURETY BOND OR OTHER SECURITY* IN THE AMOUNT OF \$50,000 SURETY BOND.**

(3) (4) The purpose of the surety bond is to secure payment of any fines or penalties imposed by the Board and any fees and costs incurred by the State relating to the permit that:

- (i) Are authorized under State law; and
- (ii) Are not paid by the permit holder within 30 days after the fines, penalties, fees, or costs become final.

(4) (5) The State may make a claim against the surety bond or other security until 2 years after the permit holder's permit ceases to be valid.

(5) (6) A single surety bond shall cover all facilities operated by the applicant in the State.

(6) (7) The Board shall establish an account, separate from its other accounts, in which to deposit the applicant's surety bond or other security.

SECTION 2. AND BE IT FURTHER ENACTED, That, if an applicant for a wholesale distributor permit or a wholesale distributor permit holder has submitted a surety bond *or other security* in the amount of \$100,000 before the effective date of this Act but demonstrates eligibility for a surety bond *or other security* in the amount of \$50,000, as provided in § 12-6C-05(f)(3)(ii)2 of the Health Occupations Article as enacted by Section 1 of this Act, the State Board of Pharmacy may allow the applicant or permit holder to rescind the surety bond *or other security* already submitted and submit a new surety bond *or other security* in the lower amount.

SECTION 2. 3. AND BE IT FURTHER ENACTED, That this Act is an emergency measure, is necessary for the immediate preservation of the public health or safety, has been passed by a ye and nay vote supported by three-fifths of all the members elected to each of the two Houses of the General Assembly, and shall take effect from the date it is enacted.

Approved by the Governor, April 14, 2009.

## APPENDIX II

### BOARD OF PHARMACY

**Subject:** Extension for Wholesale Distributor Applications

**Add'l. Info:** The Maryland Board of Pharmacy approved, at its January 21, 2009 public meeting, a 90-day extension for the approval of incomplete applications received for permits under the Maryland Wholesale Distribution Permitting and Prescription Drug Integrity Act. This decision was made in order to provide applicants sufficient time to meet new surety bond and other important new requirements. All submitted supplemental materials must be received by the Board in sufficient time for the Board to review and make a determination by March 31, 2009. A minimum of two weeks is required to process and determine the adequacy of supplemental materials. Therefore, applicants should consider submitting materials not later than March 16, 2009.

**Contact:** Anna Jeffers (410) 764-3833

[09-04-31]

## APPENDIX III

**Winter 2008 – 2009**

### **Maryland Board of Pharmacy News**

#### ***Current Wholesale Distributor Permit Holders***

The Maryland Board of Pharmacy approved at its January 20, 2009, Public Meeting, a 90 day extension for the approval of incomplete applications received for permits under the Maryland Wholesale Distribution Permitting and Prescription Drug Integrity Act. This decision was made in order to provide applicants sufficient time to meet new surety bond and other important new requirements. All submitted supplemental materials must be received by the Board in sufficient time for the Board to review and make a determination by March 31, 2009. A minimum of two weeks is required to process and determine the adequacy of supplemental materials. Therefore, applicants should consider submitting materials no later than March 16, 2009.

**APPENDIX IV**  
**BOARD OF PHARMACY**

**Subject:** Public Meeting

**Date and Time:** May 20, 2009, 9 a.m.—5 p.m.

**Place:** 4201 Patterson Ave., Baltimore, MD

**Add'l. Info.:** Effective with the announcement of the Public Meeting on May 20, 2009, the Maryland Board of Pharmacy will no longer announce its Public Board Meetings in the Maryland Register. Future notices of Public Board meetings will be posted on the Maryland Board of Pharmacy's website at [www.mdbop.org](http://www.mdbop.org) and will also be posted in the lobby for the Maryland Board of Pharmacy offices located at 4201 Patterson Avenue, Baltimore, MD 21215.

The Maryland Board of Pharmacy approved, at its March 18, 2009, public meeting, another extension for the approval of incomplete applications received for renewal permits under the Maryland Wholesale Distribution Permitting and Prescription Drug Integrity Act until June 30, 2009. This decision was made in order to provide renewal applicants sufficient time to meet revised surety bond and other important new requirements. The decision was also made to accommodate legislation currently under consideration which may impact the surety bond requirements. (See Emergency House Bill 1195, Prescription Drugs —Wholesale Drug Distribution — Surety Bond Requirements, available on [www.mlis.state.md.us](http://www.mlis.state.md.us).) To avoid delays in processing applications, all supplemental materials must be received by the Board as early as possible in order to allow sufficient time for the Board to review the materials and make a determination by June 30, 2009.

**Contact:** LaVerne Naesea (410) 764-4755

[09-09-50]

## APPENDIX V

Issue Date: June 19, 2009

Volume 36 • Issue 13 • Pages 855—946

Page 928

### 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

[09-183-P]

The Secretary of Health and Mental Hygiene proposes to amend Regulations **.02** and **.03** 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 April 15, 2009, notice of which was given by publication in The Sun, Legal Notices Section, April 13 and 14, 2009, pursuant to State Government Article, §10-506(c), Annotated Code of Maryland.

##### Statement of Purpose

The purpose of this action is to revise the regulations to comply with Emergency Bill, HB 1195 (2009) Prescription Drugs—Wholesale Drug Distribution—Surety Bond Requirements, which alters the surety bond requirement for applicants for a wholesale distributor permit to \$50,000 for those applicants with annual gross receipts under \$10,000,000 from sales of prescription drugs and devices in Maryland. The surety bond remains \$100,000 for those applicants with annual gross receipts of \$10,000,000 or more from sales of prescription drugs and devices in Maryland.

##### Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

##### Estimate of Economic Impact

**I. Summary of Economic Impact.** The economic impact of imposing two separate surety bond amounts based on the gross receipts from sales of prescription drugs and devices in Maryland is two-fold. For the wholesale distributor with gross receipts less than \$10,000,000 from sales of prescription drugs and devices in Maryland, the amount of the surety bond is decreased by 50 percent. This could be a savings between approximately \$1,000 and \$7,500 per wholesale distributor depending on how many surety bonds the wholesale distributor holds for the different states in which they do business. For the Board, however, wholesale distributors with gross receipts from the sales of prescription drugs and devices in Maryland that are less than \$10,000,000, the collection of fines or penalties will be limited to \$50,000 if the wholesale distributor is disciplined and unable to pay any fines or penalties imposed.



<b>II. Types of Economic Impact.</b>	Revenue (R+/R-) Expenditure (E+/E-)	Magnitude
A. On issuing agency:	(R-)	Indeterminable
B. On other State agencies:	NONE	
C. On local governments:	NONE	
	Benefit (+) Cost (-)	Magnitude
D. On regulated industries or trade groups:	(+)	\$1,000 —\$7,500/wholesale distributor
E. On other industries or trade groups:	NONE	
F. Direct and indirect effects on public:	(+)	Indeterminable

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

A. The Board cannot determine at this time the number of wholesale distributors, with gross receipts from the sales of prescription drugs and devices in Maryland that are less than \$10,000,000, that may be unable to pay any fines or penalties imposed by the Board pursuant to disciplinary actions.

D. A wholesale distributor, with gross receipts from the sales of prescription drugs and devices in Maryland that are less than \$10,000,000, may have a savings of between approximately \$1,000 and \$7,500, depending on the number of surety bonds the wholesale distributor holds for the different states in which they do business.

F. The direct or indirect effects on the public would be positive because these regulations will allow more wholesale distributors of prescription drugs and devices to be able to afford to do business in Maryland. This will provide Maryland health care providers with more options to obtain the prescription drugs and devices, including the small niche prescription drugs and devices, which may not be available from the larger wholesale distributors.

**Economic Impact on Small Businesses**

The proposed action has a meaningful economic impact on small businesses. An analysis of this economic impact follows.

This proposed action has a meaningful economic impact on smaller wholesale distributors of prescription drugs or devices whose gross receipts of prescription drugs and devices in Maryland are less than \$10,000,000. These wholesale distributors will now be allowed to submit a surety bond of \$50,000 instead of a surety bond of \$100,000. This will result in a substantial savings for the smaller wholesale distributors of approximately \$1,000 to \$7,500 depending on the number of surety bonds the wholesale distributor holds for the different states in which they do business. For some wholesale distributors, this change will make the difference between being able to afford to do business in Maryland or not. At this time the number of wholesale distributors that may take advantage of the lower bond amount is not known because the Board does not track permit holders who are also 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, Baltimore, MD 21201, or call 410-767-6499, or email to [regs@dhhmh.state.md.us](mailto:regs@dhhmh.state.md.us), or fax to 410-333-7687. Comments will be accepted through July 20, 2009. A public hearing has not been scheduled.

**.02 Definitions.**

A. (text unchanged)

B. Terms Defined.

(1)—(10) (text unchanged)

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

[(11)] (12)—[(22)] (23) (text unchanged)

**.03 Minimum Application Requirements for Applicant.**

A.—D. (text unchanged)

E. Surety Bond.

(1) An applicant for a wholesale distributor permit shall submit a surety bond [of at least \$100,000,] 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)(6)] *§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) The 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.*

[(2)] (4)—[(3)] (5) (text unchanged)

F.—I. (text unchanged)

JOHN M. COLMERS  
Secretary of Health and Mental Hygiene

## APPENDIX VI

Issue Date: July 17, 2009

Volume 36 • Issue 15 • Pages 1101—1236

Page 1163

### 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 Emergency Action

[09-183-E]

The Joint Committee on Administrative, Executive, and Legislative Review has granted emergency status to amendments to Regulations .02 and .03 under **COMAR 10.34.22 Licensing of Wholesale Prescription Drug or Device Distributors**.

**Emergency status began: June 18, 2009.**

**Emergency status expires: November 10, 2009.**

Editor's Note: The text of this document will not be printed here because it appeared as a Notice of Proposed Action in 36:13 Md. R. 928—929 (June 19, 2009), referenced as [09-183-P].

JOHN M. COLMERS  
Secretary of Health and Mental Hygiene

## APPENDIX VII

### **New Surety Bond Amount:**

All Wholesale distributors may now submit either a \$50,000 bond or a \$100,000 surety bond, depending on the annual gross receipts of the applicant from sales of prescription drugs and devices in Maryland.

A \$100,000 surety bond would be is required if the annual gross receipts of the applicant from sales of prescription drugs and devices in Maryland for the previous tax year are \$10,000,000 or more.

A \$50,000 surety bond would be is required if the annual gross receipts of the applicant from sales of prescription drugs and devices in Maryland for the previous tax year are less than \$10,000,000.

### **Documentation required:**

The 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.

## APPENDIX VIII

Issue Date: September 25, 2009

Volume 36 • Issue 20 • Pages 1529

### 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 Final Action

[09-183-F]

On September 8, 2009, the Secretary of Health and Mental Hygiene adopted amendments to Regulations **.02** and **.03** under **COMAR 10.34.22 Licensing of Wholesale Prescription Drug or Device Distributors**. This action, which was proposed for adoption in 36:13 Md. R. 928—929 (June 19, 2009), has been adopted as proposed.

**Effective Date: October 5, 2009.**

JOHN M. COLMERS  
Secretary of Health and Mental Hygiene

## APPENDIX IX

Attention All Wholesale Distributor Applicants: The application deadline for wholesale distributor applications that are only pending an inspection by the Board or its designee is extended until such time that the Board or its designees has completed the inspection. However, applications for which other information is pending (such as evidence of a surety bond), must be completed and submitted to the Board no later than August 31, 2009. All pending applications which have not been completed by August 31, 2009 will be denied.

## APPENDIX X

### A BILL ENTITLED

AN ACT concerning

#### **Health Occupations—Wholesale Distributors— Reciprocity and Accreditation**

FOR the purpose of defining “accreditation organization”, “substantially equivalent”, and providing requirements for out-of-state wholesale drug distributors.

BY repealing and reenacting, with amendments

Chapters 352 and 353 of the Acts of the General Assembly of 2007

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

§ 12–6C–04. Accreditation [and reciprocity.] AND RECIPROCITY

(a) *Definitions.* – (1) In this section the following words have the meanings indicated.

(2) “Accreditation organization” means a private entity that IS RECOGNIZED BY THE BOARD AND WHICH conducts inspections and surveys of wholesale distributors based on nationally recognized national and developed standards.

(3) “SUBSTANTIALLY EQUIVALENT” MEANS THAT THE LAWS OF ANOTHER STATE REQUIRE, AT MINIMUM, ROUTINE INSPECTIONS, PEDIGREES, OPERATION IN A COMMERCIAL NON-RESIDENTIAL FACILITY, AND SECURITY MEASURES.

[(3) “Deemed status” means a status under which a wholesale distributor may be exempt from routine inspections and other permit requirements of the Board.]

[(b) *Accreditation.* – If the Board determines that the standards of an accreditation organization are equal to or more stringent than State permit requirements, the Board may:

(1) Accept the accreditation of a wholesale distributor by an accreditation organization as evidence that the wholesale distributor has met State permit requirements; and

(2) Grant the wholesale distributor deemed status.]

(b) IN-STATE WHOLESAL DISTRIBUTORS. A WHOLESAL DISTRIBUTOR LOCATED IN THE STATE WHICH IS CURRENTLY ACCREDITED BY AN ACCREDITATION ORGANIZATION SHALL BE DEEMED TO SATISFY THE INITIAL AND ROUTINE INSPECTION REQUIREMENTS UNDER THIS SUBTITLE.

[(c) *Reciprocity.* – The Board may issue a permit by reciprocity to a wholesale distributor who holds a license or permit under the laws of another state if the Board determines that the requirements of that state are substantially equivalent to the requirements of this State.]

(c) OUT-OF-STATE WHOLESAL DISTRIBUTORS.

(1) RECIPROCITY. (A) THE BOARD MAY ISSUE A PERMIT BY RECIPROCITY TO A WHOLESALE DISTRIBUTOR WHO HOLDS A LICENSE OR PERMIT UNDER THE LAWS OF ANOTHER STATE IF THE BOARD DETERMINES THAT THE REQUIREMENTS OF THAT STATE ARE SUBSTANTIALLY EQUIVALENT TO THE REQUIREMENTS OF THIS STATE.

(B) A WHOLESALE DISTRIBUTOR THAT APPLIES FOR A PERMIT BY RECIPROCITY SHALL ALSO COMPLY WITH THE REQUIREMENTS OF §§ 12-6C-05(E) AND 12-6C-05(F).

[(1)] (2) ACCREDITATION—IN ADDITION TO THE OTHER REQUIREMENTS OF THIS SUBTITLE, A WHOLESALE DISTRIBUTOR LOCATED OUTSIDE OF THIS STATE WHICH IS NOT ELIGIBLE FOR RECIPROCITY SHALL BE CURRENTLY ACCREDITED BY AN ACCREDITATION ORGANIZATION.

[(2)] (3) A WHOLESALE DISTRIBUTOR WHICH IS CURRENTLY ACCREDITED OR HAS BEEN GRANTED RECIPROCITY BY THE BOARD[THE ACCREDITATION] SHALL BE DEEMED TO SATISFY THE INITIAL AND ROUTINE INSPECTION REQUIREMENTS UNDER THIS SUBTITLE.

(d) *Inspection.* – The Board or its designee may inspect a wholesale distributor who is accredited [or has been issued a permit by reciprocity] or has been issued a permit by reciprocity to:

- (1) Determine compliance with any permit requirement under this subtitle; or
- (2) Investigate a complaint.