STATE OF MARYLAND

DHMH

Maryland Department of Health and Mental Hygiene

Lawrence J. Hogan, Jr., Governor – Boyd K. Rutherford, Lt. Governor – Van T. Mitchell, Secretary

MARYLAND BOARD OF PHARMACY

4201 Patterson Avenue● Baltimore, Maryland 21215-2299

Mitra Gavgani, Board President – Richard A. Proctor, Acting Executive Director

January 1, 2016

The Honorable Larry Hogan
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: Ninth Annual Report on the Implementation of the Wholesale Distributor Permitting and Prescription Drug Integrity Act

Dear Governor Hogan, 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 ninth 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.

The present major change, and challenge, for the Board will be the effects of the U.S. Drug Supply Chain Security Act (DSCSA) which passed in November 2013. This federal legislation provides national uniformity regarding pedigrees, the national implementation timeline for electronic track and trace of pedigrees, and the licensure of third party logistics providers. Maryland, and other states, will need to re-evaluate their laws and regulations to comply with the

new federal standards. At this time the U.S. Food and Drug Administration (FDA) has issued a number of "Guidances" on the implementation of the DSCSA. Proposed federal regulations will be forthcoming in the near future that will determine the revisions the Board will make to the

Wholesale Distributor Permitting and Prescription Drug Integrity Act during the 2017 Legislative Session and the corresponding regulations.

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

Respectfully,

Richard A. Proctor
Acting Executive Director

Enclosure

cc: The Honorable Joan Carter Conway
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
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Katie Wunderlich, Governor's Legislative Office

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

NINTH ANNUAL REPORT TO THE GOVERNOR AND THE GENERAL ASSEMBLY

January 1, 2016

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

NINTH ANNUAL REPORT

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Anna D. Jeffers, Legislation and Regulations Manager

EXECUTIVE SUMMARY

This is the ninth annual report on the implementation of the Wholesale Distributor Permitting and Prescription Drug Integrity Act (the "Act") as required by Health Occupations Article, 12-6C-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 present major change, and challenge, for the Board will be the effects of the U.S. Drug Supply Chain Security Act (DSCSA) which passed in November 2013. This federal legislation provides national uniformity regarding pedigrees, the national implementation timeline for electronic track and trace of pedigrees, and the licensure of third party logistics providers. Maryland, and other states, will need to re-evaluate their laws and regulations to comply with the new federal standards. At this time the U.S. Food and Drug Administration (FDA) has issued a number of "Guidances" on the implementation of the DSCSA. Proposed regulations will be forthcoming at the end of 2015 that will determine the revisions the Board will have to make to the Wholesale Distributor Permitting and Prescription Drug Integrity Act during the 2017 Legislative Session and the corresponding regulations.

MEETING REGULATORY REQUIREMENTS

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

In 2010, Senate Bill 163/House Bill 868 State Board of Pharmacy - Wholesale Distributor Permitting and Prescription Drug Integrity Act - Revisions, 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. The Board may waive requirements, such as inspections, for distributors granted deemed status. The legislation relieved Board inspectors from inspecting out-of-state wholesale distributors. Prior to enactment of the bill, the Board contracted with the National Association of

Boards of Pharmacy to act as the Board's agent to inspect out-of-state distributor facilities. No regulations were required to implement this revision to the law.

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

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

These revisions to the law were made because over the past few years drug shortages have become a major issue in the drug supply nationwide and in Maryland. There exists a "gray market" where wholesale distributors and pharmacies buy and sell to each other drugs in short supply increasing the prices significantly before the drugs are dispensed to the patient. Oftentimes it is a pharmacy that sells "upstream" increasing the price to a wholesale distributor when drugs are in short supply. The wholesale distributor then increases the price again when the product is sold. The Board has worked closely with federal authorities over the past few years 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.

After the passage of 2012 and 2013 legislation, the Board worked diligently to revise COMAR 10.34.22.01 - .11 Licensing of Wholesale Prescription Drug or Device Distributors, to implement the new laws. In the fall of 2013 the Board approved a proposal at the September 20, 2013 Public Board Meeting to accommodate all the new laws from the 2012 and 2013 legislative sessions. A new chapter COMAR 10.34.37 Pharmacy Permit Holder – Wholesale Distribution, was included in the same proposal with the revisions to COMAR 10.34.22 to address pharmacy wholesale distribution and pharmacy reporting requirements. Both chapters became effective on July 1, 2014.

Drug Supply Chain Security Act (DSCSA)

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

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

The federal legislation is important because it establishes uniform legislation throughout the country. States will no longer be allowed to establish or continue in effect any laws or regulations for tracing products through the distribution system which are inconsistent with, more stringent than, or in addition to, any requirements applicable under the new federal law. The impact of this law on the Board's recommendations made by the Wholesale Distributor SB 759 Workgroup (Workgroup), which was convened under the 2007 legislation, is described in the 2015 Annual Report.

Additionally in the DSCSA, no State may establish or continue any laws or regulations with respect to wholesale prescription drug distributor or third-party logistics provider licensure that are inconsistent with, less stringent than, directly related to, or covered by the standards and requirements of the federal law. No State shall regulate third-party logistics providers as wholesale distributors. Consequently, Maryland no longer licenses third-party logistics providers and third-party logistics providers were not required to renew their wholesale distributor license in Maryland after the permit expires.

The Board anticipates revising Subtitle 6C. Wholesale Distributor Permitting and Prescription Drug Integrity Act, in the 2017 Legislative Sessions depending on the release of the draft federal regulations. The FDA anticipates that draft regulations will be forthcoming at the end of 2015.

CONCLUSION

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

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

changes have ensured greater compliance by the wholesale distributor industry, greater monitoring by the Board and ultimately greater protection of the prescription drug and prescription device supply in Maryland.

With the enactment of the DSCSA, Maryland's Wholesale Distributor Permitting and Prescription Drug Integrity Act will require revisions to comply with the new federal law. The emphasis for the Board continues to be protecting the public by imposing requirements for persons applying to be licensed to distribute prescription drugs or devices into Maryland; thereby protecting the supply chain of prescription drugs and devices in this State. Look for the Board to introduce legislation amending the Wholesale Distributor Permitting and Prescription Drug Integrity Act in the 2017 Legislative Session.