

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

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

January 1, 2011

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

FOURTH ANNUAL REPORT

TABLE OF CONTENTS

BOARD MEMBERS.....3
EXECUTIVE SUMMARY.....4
MEETING REGULATORY REQUIREMENTS.....5
CONCLUSION AND RECOMMENDATIONS.....6
APPENDIX I.....8

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EXECUTIVE SUMMARY

This is the fourth 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 imposes 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 outside of the normal distribution chain.

The Board faced a number of challenges with the first renewal after the passage of the new law and those challenges and resolutions are summarized in the 2009 and 2010 Annual Reports. This fall the Board is beginning the second renewal cycle with two legislative revisions in place. In addition to the \$100,000 surety bond requirement, some applicants may now be eligible for a lesser surety bond amount of \$50,000; and unless an out-of-state wholesale distributor is eligible for "deemed status," which requires that they be located in states with laws substantially equivalent to Maryland's, it must be accredited by a Board approved accreditation program. Presently, the only Board approved accreditation program is the National Association of Boards of Pharmacy (NABP) Verified-Accredited Wholesale Distributors Program (VAWD).

Although VAWD is a widely encompassing program, it does not accredit wholesale distributors that do not physically handle the distributed product(s) (a.k.a. "virtual" distributors) but nonetheless direct and control their distribution. VAWD also does not accredit entities engaged in the wholesale distribution of medical gases. The Board has been challenged with the inspections of these entities. To accommodate these entities, the Board has negotiated with NABP to act as the Board's agent to use Maryland inspection forms to inspect out of state virtual distributors and distributors of medical gases.

To simplify and clarify the Act, the Board makes the following recommendations to be addressed before the third renewal cycle:

1. Elimination of the Maryland criminal background check since the FBI check includes Maryland;
2. Promulgation of closing regulations so that distributors which cease to operate would be required to notify the Board and account for their remaining inventory and records and return their permits to the Board;
3. Addition of reinstatement requirements to discourage late renewal;
4. Address the distribution of medical gases since their inclusion in the Act may not be appropriate; and
5. Address the distribution of "virtual" manufacturers with the possible establishment of a separate licensure category.

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, 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 Distributors - Accreditation and Reciprocity, provided “deemed status” only for those wholesale distributors accredited by a Board-approved accreditation program or those wholesale distributors located in states with wholesale distribution laws substantially equivalent to Maryland’s laws. The Board may waive requirements, such as inspections, for distributors granted deemed status. The legislation relieved Board inspectors from inspecting out-of-state wholesale distributors. Prior to enactment of the bill, the Board contracted with NABP to act as the Board’s agent to inspect out-of-state distributor facilities. No regulations were required to implement this revision to the law. A detailed description of the initial challenges and resolutions for the implementation of the Act are set forth below.

Inspections

Although SB163/HB 868 was intended to address all of the Board’s inspection challenges, a few remained. For instance, the Board had previously identified those states with laws substantially equivalent to Maryland’s, but after the bill’s passage, the Board learned that at least one of those states does not perform inspections at all, due to limited resources, even though that state’s law requires inspections.. Thus, the Board has notified distributor applicants from such states that they must be accredited.

In addition, not all types of wholesale distributors are eligible for accreditation by existing accreditation bodies. “Virtual,” “own label,” “sponsor,” “contract,” or “private label” manufacturers, as well as brokers, do not physically hold prescription products, and therefore they are not eligible for accreditation by VAWD. However, many are located in states where the Board requires Board-approved accreditation. Thus, there exists a group of entities with no avenue for inspection by their own state or by VAWD. In order to remedy this problem, the Board plans to again contract with NABP for an inspection of these entities.

Also, another challenge for the Board has been the accreditation and licensing of out-of-state wholesale distributors of prescription medical gases. The VAWD program will not accredit medical gas distributors. Until the Board approves another accreditation program for medical gas distributors, the Board will again contract with NABP to act as the Board’s inspection agent for these facilities.

Second Renewal

By October 4, 2010 the Board mailed renewal packets to all licensed wholesale distributors of record. The packet included a letter outlining the new requirements, fingerprint cards, and instructions for completion of the fingerprint cards. The letter is attached as Appendix I. The Board anticipates that the second renewal will proceed smoothly once the inspection issues described above are resolved. Databases have been created to track applications and corresponding fingerprint cards. Most out-of-state wholesale distributors will be required to be VAWD-accredited. NABP will periodically notify the Board of those VAWD applicants who have not cooperated with the VAWD application process so that the Board can properly evaluate their applications.

CONCLUSION AND RECOMMENDATIONS

The Board would like to again commend Senator Joan Carter Conway and Senator Karen Montgomery (formerly Delegate Montgomery) for their leadership and perseverance during the 2009 and 2010 Legislative Sessions 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 and which required accreditation for out-of-state distributors located in states without distributor laws allowed substantially equivalent to Maryland's laws. These revisions to the law have made implementation of Act easier for permit holders and for the Board. The Board is confident it will resolve the inspection issues described above.

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 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. In fact, some distributors have even sought the withdrawal of their application upon learning of the Board's inspection requirements. 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, 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.

Based on the above report, the Maryland Board of Pharmacy offers the following recommendations:

- 1. Elimination of the Maryland criminal background check.** Eliminating the Maryland criminal background check would simplify the application process for the Board and the applicant. The applicant would only have to complete and pay for one

fingerprint card for the FBI, which includes any criminal background in Maryland. The Board staff would only have to track one fingerprint card per designated representative or supervising designated representative, thus more efficiently using limited resources while reducing the time frame to process applications. This would require a future statutory change.

2. Promulgating closing regulations. The Board has the authority to promulgate closing regulations and will begin that process in the next few months. At the present time the Board requires wholesale distributors to return their original wholesale distributor permit when they close or cease to operate. However, there are no requirements regarding how drug inventory and/or closure/transfer of records should be reported; nor are there requirements that the purpose of the closure in Maryland and status of the distributorship be reported. Regulations specifying closure procedures along with sufficient notice to the Board would be a prudent requirement.

3. Adding reinstatement requirements. The statute currently does not provide for specific procedures or fees for the reinstatement of expired permits. This change is necessary to provide greater incentive for wholesale distributors to renew on time and to alert the Board of violations of the Act when distributors continued to operate beyond the expiration of their permits.

4. Addressing the distribution of medical gases. Wholesale distributors of medical gases are not eligible for VAWD accreditation. To avoid the need to contract Board agents to inspect wholesale distributors of medical gases in states beyond Maryland's immediate neighbors, it might be prudent for the Board to consider exempting this category from licensure. Some states do not regulate the wholesale distribution of medical gases since they are also regulated under federal law.

5. Addressing the distribution of "virtual" manufacturers. Although some states do not regulate wholesale distributors that do not actually hold prescription drugs and devices, (e.g., "Virtual," "own label," sponsor," "contract," and "private label" manufacturers), the Board believes they should be monitored because they direct and control the distribution of the products into, out of, and within Maryland. Since these types of entities are also not eligible for VAWD accreditation, the Board recommends establishing specific requirements for a process for these entities to acquire Maryland permits.

APPENDIX I



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

Michael Souranis, Board President - LaVerne G. Naesea, Executive Director

September 29, 2010

Dear Wholesale Drug or Device Distributor Renewal Applicant:

The Maryland Wholesale Drug and Device Distributor renewal period begins October 1, 2010 and will continue through December 31, 2010. The current permit to distribute into or out of Maryland will expire on December 31, 2010 at 11:59 p.m.

General Information for All Applicants

In order for a renewal permit to be issued and mailed before the current permit expires, a fully completed application, including the renewal fee of \$1750.00 and the results from the criminal background checks, must be received at the Maryland Board of Pharmacy (the "Board") **no later than December 17, 2010**. Please note that it takes 4-6 weeks for the Central Repository to process fingerprint cards and inform the Board of the results, so waiting until December to submit a renewal application may result in a lapse of licensure, during which time your facility may not distribute drugs within or into Maryland. The Board will not issue a renewal license until the criminal history records check is complete. See the Board's website for applications, specific instructions and a list of frequently asked questions: <http://www.dhmh.state.md.us/pharmacyboard/forms/establish.htm>.

All distributors must complete the same form unless they are a manufacturer distributing their own prescription drugs (see below).

Incomplete applications will be returned without the application processing fee. The processing fee may be applied to re-submissions for up to a year from the Board's receipt of the returned application.

Note: When corresponding with the Board, please provide the permit number highlighted on the mailing label of this packet.

Manufacturers Distributing Their Own Prescription Drugs (in-State or out-of-State)

Actual manufacturers distributing their own prescription drugs approved by the U.S. Food and Drug Administration are eligible to complete an abbreviated application form. Applicants completing this form must satisfy the definition of "manufacturer" as provided in 21 C.F.R. 205.3(d): "Manufacturer means anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug."

“Virtual,” “own label,” “sponsor,” “contract,” or “private label” manufacturers, brokers and third-party logistics providers are not eligible to complete the abbreviated application form.

Manufacturers distributing their own prescription drugs approved by the U.S. Food and Drug Administration must provide the following items are with their application:

- A copy of the facility’s most recent FDA inspection.
- Documentation of FDA registration as an establishment approved to distribute prescription drugs.

Out-of-State Applicants

Please be advised that § 12-6C-04 of the Wholesale Distribution Permitting and Prescription Drug Integrity Act was amended during the 2010 Maryland legislative session. Effective October 1, 2010, out-of-state distributors will fall into one of the two categories listed below and must comply with the instructions listed in the appropriate category in order to receive a renewal permit:

1. The wholesale distributor is located in a state that has requirements that are substantially equivalent to Maryland’s wholesale distributor requirements and includes requirements for pedigrees, routine inspections, a prohibition against operating in a commercial, non-residential facility, and security measures. Distributors operating in States that may qualify for this category may include AZ; CO; FL; GA; ID; IL; IN; KY; NE; NV; OK for human drugs only; and OR, WY.

- A completed wholesale distributor application, to include a surety bond or irrevocable letter of credit and completed fingerprint cards for background checks for the designated representative and the designated representative’s supervisor; and
- A copy of an inspection report issued by that state’s Board of Pharmacy and completed within the previous renewal period must be submitted with the renewal application;

NOTE: The state must enforce all requirements in order for an out-of-state wholesale distributor to qualify for this category. (e.g., Routine inspections must be performed.)

OR

2. The wholesale distributor is accredited by a Board-recognized accreditation organization.

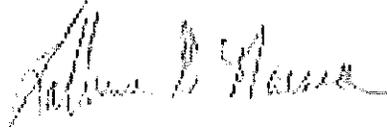
- A completed wholesale distributor application, to include a surety bond or irrevocable letter of credit and completed fingerprint cards for background checks for the designated representative and the designated representative’s supervisor;
- Proof of accreditation by a Board-recognized accreditation program.
- If not yet accredited, include proof of submission of an accreditation application with the renewal application;

Currently, the National Association of Boards of Pharmacy’s (NABP) is the only Board-recognized accreditation organization. The NABP *Verified Accredited Wholesale Distributor* (VAWD) accreditation process includes a physical inspection of the facility and may take six months or more to complete. If you plan to renew your permit, you are encouraged to begin the accreditation process with NABP immediately. VAWD Program requirements may be viewed online at: <http://www.nabp.net/programs/accreditation/vawd/>. Please contact NABP at vawd@nabp.net with questions relating to the wholesale distributor accreditation application. Failure to comply with NABP’s requirements in the accreditation process, including failure to respond to requests for information, will result in denial of your application. Out-of-State distributors of medical gases will

be notified under separate cover of the accreditation program(s) recognized by the Board since VAWD does not accredit medical gas distributors.

Please be advised that operating without a permit is punishable by a fine not to exceed \$500,000. Md. Code Ann., Health Occ. § 12-6C-11.

Sincerely,

A handwritten signature in cursive script, appearing to read "LaVerne G. Naesea".

LaVerne G. Naesea
Executive Director