



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 3, 2012

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 fifth 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.

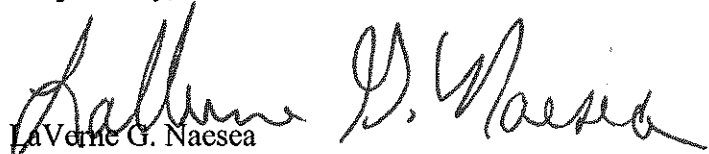
In the fall of 2012, the Board will begin the third renewal cycle. The Board is continuing to revise the implementation of the Act and recommending further legislative action to further protect the public and to simplify the application process where appropriate. The Board is now allowing "virtual" manufacturers that do not hold product, yet own the NDA or ANDA numbers of products, to apply using a less comprehensive application with the submission of key information. The Board recommends legislation that will 1) eliminate the requirement for inspections of wholesale distributors that do not hold product; 2) amend the criminal background check requirement for an in-state applicant by requiring the designated representative and the supervisor of the designated representative to submit fingerprints directly to CJIS; and 3) amend

The Honorable Martin O'Malley
The Honorable Thomas V. Mike Miller, Jr.
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the criminal background check requirement for an out of state applicant by requiring the designated representative and the supervisor of the designated representative to submit a criminal background check from their state of residence.

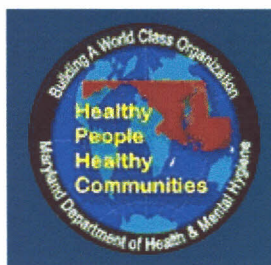
Should you have questions or additional concerns, please feel free to contact Anna D. Jeffers, Legislation and Regulations Manager at (410) 764-4794.

Respectfully,


LaVerne G. Naesaa
Executive Director

Enclosure

cc: The Honorable Joan Carter-Conway
The Honorable Roy P. Dyson
The Honorable Peter A. Hammen
The Honorable Karen S. Montgomery
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Don Taylor, Maryland Board of Pharmacy and Former Co-Chair, Wholesale Distributor SB 759 Workgroup



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

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

January 1, 2012

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

FIFTH ANNUAL REPORT

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EXECUTIVE SUMMARY

This is the fifth annual report on the implementation of the Wholesale Distributor Permitting and Prescription Drug Integrity Act (the "Act") as required by Health Occupations Article, 10-6C-13, Annotated Code of Maryland. The Act, Senate Bill 759/House Bill 1030, Chapters 352 and 353, was passed in the 2007 Legislative Session. The Act provides requirements for persons applying to be licensed to distribute prescription drugs or devices into, out of, or within Maryland. The Act further requires a pedigree, or history of the distribution chain, for prescription drugs that are distributed in Maryland outside of the normal distribution chain. As revised in 2007, it is one of the more stringent wholesale distributor acts in the country and is in the forefront of protecting the prescription drug supply chain nationwide.

The Board faced a number of challenges with the first and second renewal after the passage of the new law. Those challenges, and how they were resolved, were described in detail in the 2009, 2010, and 2011 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 fall of 2012, the Board will begin the third renewal cycle. The Board is still revising the implementation of the Program and recommending further legislative action to further protect the public and to simplify the application process where appropriate. The Board has not been able to identify approved accreditation programs to accredit wholesale distributors that do not physically handle their distributed product(s) (a.k.a. "virtual" distributors), but nonetheless direct and control their distribution. To address this challenge the Board has negotiated with NABP to act as its agent to (using Maryland inspection forms) to inspect the out of state virtual distributors.

Additionally, the criminal background check process has proven to be time consuming and, for out of state wholesale distributors, somewhat inadequate in providing the

information needed in order for the Board to determine the appropriateness of key staff that were assigned to direct day-to-day operations at wholesale distributor sites; particularly since requiring individuals from other states to submit to a Maryland criminal background check yielded little results because most of these individuals had never been to Maryland.

In last year's report, the Board made 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.

The Board diligently worked to address these issues and has resolved many of them.

The first recommendation, to eliminate the Maryland criminal background check since the FBI check includes Maryland is revised in this report because the Board learned that some Maryland violations do not appear on the FBI check. Therefore, the elimination of the Maryland criminal background check would not be prudent. The Board has revised that recommendation as noted below under the first and second recommendations.

The second and third recommendations will be addressed by the promulgation of regulations in FY 2012 and FY 2013.

The fourth recommendation in the 2010 Board report was addressed by the Board's approval of accrediting organizations for oxygen distributors and medical gas distributors (ACHC and CHAP are the first two, respectively) .

The fifth and final recommendation has been addressed in several ways. First, the Board will allow "virtual" manufacturers that do not hold product, yet own the NDA or ANDA numbers of products, to apply using a less comprehensive application with the submission of key information. Second, the Board will recommend legislation that will eliminate the requirement for inspections of wholesale distributors that do not hold product.

Based on the information provided by this report, the Board offers the following three recommendations for addressing through a legislative proposal during the 2012 Legislative Session:

1) Eliminating the requirement that it be required to physically inspect the facilities of a wholesale distributor applicant who does not physically hold prescription drugs or prescription devices at the applicant's facility address;

2) Altering the criminal background check requirement for an in-state applicant for a wholesale distributor permit by requiring that the designated representative and the supervisor of the designated representative submit fingerprints directly to the Criminal Justice Information System Central Repository of the Department of Public Safety and Correctional Services (CJIS); and

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

Passage of legislation to address the above three recommendations during the 2012 Legislative Session will allow the Board time to adequately prepare for processing the biennial submissions by "virtual" distributors of applications beginning in October 2012. (See Appendix I for the draft legislation.)

MEETING REGULATORY REQUIREMENTS

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

In 2010, Senate Bill 163/House Bill 868 State Board of Pharmacy - Wholesale Distributor Permitting and Prescription Drug Integrity Act, provided "deemed status" only for those wholesale distributors accredited by a Board-approved accreditation program or those wholesale distributors located in states with wholesale distribution laws substantially equivalent to Maryland's laws. The Board may waive requirements, such as inspections, for distributors granted deemed status. The legislation relieved Board inspectors from inspecting out-of-state wholesale distributors. Prior to enactment of the bill, the Board contracted with NABP to act as the Board's agent to inspect out-of-state distributor facilities. No regulations were required to implement this revision to the law.

Since the passage of the Act, the Board has also been challenged with entities known as "virtual manufacturers" or "virtuals." These entities hold the NDA or ANDA number for prescription products, but contract out the actual manufacturing and distribution of the product. "Virtuals" do not hold product and their businesses are conducted in an office

setting. The application for licensure includes questions and requirements that simply do not apply to this type of entity. “Virtuals” do not qualify for the Board-approved accreditation program, VAWD, and thus, required a separate inspection mechanism. These inspections were of limited value since “virtuals” only have office space and do not hold product.

Additionally, the Board has been challenged with criminal background checks in two ways. First, the Act requires that the Board, not the applicant, submit fingerprints to CJIS. Requiring the applicant to send fingerprints directly to the Board, instead of directly to CJIS, has caused delays in processing the criminal background checks. Second, the requirement for a Maryland criminal background check for a designated representative, or the supervisor of the designated representative, located in other states, does not provide the Board with useful, if any, information on those individuals. Many designated representatives and their supervisors have never set foot in Maryland.

A detailed description of these challenges and resolutions for the implementation of the Act are set forth below.

“VIRTUALS”

In last year’s report, the Board made a recommendation to address the distribution of “virtual” manufacturers with the possible establishment of a separate licensure category. “Virtual” wholesale distributors were often confused concerning which application applies to them. There are two applications available. One is a longer comprehensive application designed for the wholesale distributor that distributes product into Maryland. The other application is brief, intended for FDA manufacturers who distribute their own product into Maryland. Maryland requires manufacturers to hold a wholesale distributor permit if they are acting as a distributor. If a manufacturer is distributing into Maryland directly, or through an agent, then it would be considered a wholesale distributor.

The Maryland Pharmacy Act only allows an exemption from certain Board requirements under the Wholesale Distributor Permitting and Prescription Drug Integrity Act, beyond that required by federal law, for a manufacturer who distributes its own prescription drugs approved by the U.S. Food and Drug Administration. The Board has generally interpreted this to mean that an FDA manufacturer that physically manufactures the product and then distributes its own product into, out of, or within Maryland may complete the abbreviated form.

Given the various models employed by the pharmaceutical industry in the manufacturing of prescription drugs, the Board found that Health Occupations Article, 12-6C-03, may include entities (e.g., virtual manufacturers, own-label manufacturers, private label manufacturers) that engage contract manufacturers (CMO) to do the actual manufacturing. However, in order to ascertain whether these entities qualify under Health Occupations Article, 12-6C-03, the Board is requiring that they provide:

1. A list of drug products;
2. Proof that they own the NDA or ANDA number associated with each drug product;
3. A list of the NDA or ANDA numbers associated with each drug product;
4. The name of the contract manufacturer for each drug product;
5. If the contract manufacturer also distributes into Maryland, the distributor's permit for the manufacturer;
6. If the contract manufacturer does not distribute into Maryland, the name and Maryland permit for the contract distributor; and
7. Statement affirming that the virtual does not contract the manufacture or distribution for drugs other than those for which it owns the NDA/ANDA numbers.

The abbreviated application form is only available for those “virtual” manufacturers who contract with manufacturers for the manufacture of drugs only for which the “virtual” manufacturer owns the NDA or ANDA numbers. Additionally, the CMO that is actually manufacturing the drug must also have a wholesale distributor’s permit in Maryland if it is shipping the drugs into, out of, or within Maryland. The CMO would not qualify for the abbreviated distributor application under Health Occupations Article, 12-6C-03, unless it could verify that it is manufacturing prescription drugs for solely one entity.

This change has been welcomed by the “virtual” manufacturers because it allows them to complete a more appropriate application and eliminates burdensome requirements that simply do not apply to a “virtual.” The Board believes that the public is still protected by the change in these licensure requirements for a “virtual” because the “virtual” is meeting the same requirements as an FDA manufacturer, plus the additional items listed above.

INSPECTIONS

Although SB163/HB 868 was intended to address all of the Board’s inspection challenges, a few remained, especially for those entities that do not hold product. “Virtual” manufacturers are not 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 immediately remedy this problem, the Board contracted with NABP for an inspection of these entities.

The NABP inspectors could verify that the “virtual” location exists, but since there is no product at these locations, the inspectors were limited to examining office space and paper files. After reviewing and considering: 1) the additional expense of contracting with a third party inspector; 2) the substantial delays in formalizing third party inspector contracts; 3) the substantial delays in issuing permits to wholesale distributors who may be the only coordinating entity for the distribution of important prescription drugs into Maryland; and 4) the limited results of those inspections, the Board believes it is an unnecessary requirement to inspect wholesale distributors who do not hold product.

Additionally, few states require inspections of wholesale distributors who do not hold product and many states do not even consider these entities “wholesale distributors” requiring licensure. Thus the Board recommends legislation for the 2012 Legislative Session, eliminating inspections for wholesale distributors that do not hold product.

The Board also recommends imposing two requirements in regulations for entities that do not hold product. The first requirement would be an attestation by the owner of the wholesale distributor that it does not hold product because it is a broker, a “virtual,” or other similar entity. The second requirement would be a copy of any existing licensure the entity might have from the state in which it is located; a letter from a state agency in the state where the entity is located that indicates that the state does not license such entities; or any federal licensure/registration it might have. These changes would decrease delays in the licensure and renewal for wholesale distributors who do not hold product, yet maintain sufficient safeguards to protect the consumer. All wholesale distributors that hold product, whether in Maryland or not, would continue to be thoroughly inspected by their own state or VAWD.

CRIMINAL BACKGROUND CHECKS

Out of State Criminal Background Checks

The Act requires that a designated representative and a supervisor of the designated representative submit to federal and Maryland criminal background checks. The Board has found that requiring a criminal background check in Maryland for an out of state designated representative and the supervisor of the designated representative served little purpose for individuals who live and work in other states, many have never set foot in Maryland. It stands to reason that, for example, if an individual resides in Idaho and works for a wholesale distributor in Idaho, that a criminal background check from Idaho would be more appropriate. The Board has found consistently that the criminal background checks from Maryland for out of state individuals have indicated no violations of Maryland law. Better protection would be afforded the consumer if the state criminal background check was performed in the state where the designated representative and supervising designated representative live and work. Therefore, the Board is recommending an amendment to the Act that would substitute a criminal background check in Maryland of the designated representative and the supervising designated representative, for a criminal background check of these individuals in the state where the wholesale distributor is located.

Maryland Criminal Background Checks

The statute also requires that an applicant submit their fingerprint and fees for a criminal background check to the Board and the Board then forwards on to CJIS. The Board is recommending another amendment to the statute which would allow Maryland applicants to submit their fingerprints and fees for a criminal background check directly to CJIS.

This change would eliminate a step in the application process and would result in alleviating some current delays in the approval of wholesale distributor applications.

CONCLUSION

The Board, legislators and stakeholders were aware in 2007 that the Wholesale Distributor Permitting and Prescription Drug Integrity Act would be a challenge to implement. The emphasis was and continues to be protecting the public by imposing additional requirements for persons applying to be licensed to distribute prescription drugs or devices into Maryland 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.

To alleviate a continuation of the NABP contract, or any other designee's contract, to inspect out of state wholesale distributors who do not hold product, the Board recommends legislative changes to the Act during the 2012 Legislative Session. Specifically, the Board recommends:

- 1) Eliminating the requirement that it be required to physically inspect a facility of a wholesale distributor applicant who does not physically hold prescription drugs or prescription devices at the applicant's facility address;
- 2) Altering the criminal background check requirement for an in-state applicant for a wholesale distributor permit by requiring that the designated representative and the supervisor of the designated representative submit fingerprints directly to CJIS; and
- 3) Altering the criminal background check requirement for an out of state applicant for a wholesale distributor permit by requiring the designated representative and the supervisor of the designated representative to submit a criminal background check from their state of residence.

APPENDIX I

A BILL ENTITLED

AN ACT concerning

Health Occupations – Wholesale Distributors - Criminal Background Checks and Inspections

FOR the purpose of eliminating the requirement that the Board inspect an applicant for a wholesale distributor permit who does not physically hold prescription drugs or prescription devices at the applicant's permit address; altering the criminal background check requirement for an in state applicant for a wholesale distributor permit by requiring that the designated representative and the supervisor of the designated representative submit fingerprints directly to the central repository; altering the criminal background check requirement for an out of state applicant for a wholesale distributor permit by requiring the designated representative and the supervisor of the designated representative to submit a criminal background check from their state of residence; and generally relating to requirements for an applicant for a wholesale drug distributor permit.

BY repealing and reenacting, with amendments,
Article – Health Occupations
Section 12-6C-05
Annotated Code of Maryland
(2009 Replacement Volume and 2011 Supplement)

BY adding to
Article – Health Occupations
Section 12-6C-05.1
Annotated Code of Maryland
(2009 Replacement Volume and 2011 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.

(a) To apply for a wholesale distributor permit, an applicant shall:

(1) Pay to the Board an application fee set by the Board; and

(2) Submit an application to the Board on the form that the Board

requires.

(b) The application shall include the following:

(1) The name, full business address, and telephone number of the applicant;

(2) All trade or business names used by the applicant;

(3) Addresses, telephone numbers, and the names of contact persons for the facility used by the applicant for the storage, handling, and distribution of prescription drugs;

(4) The type of business form under which the applicant operates, such as partnership, corporation, or sole proprietorship;

(5) The name of each owner and operator of the applicant, including:

(i) If an individual, the name of the individual;

(ii) If a partnership, the name of the partnership and of each partner;

(iii) If a corporation, the name of the corporation, the name and title of each corporate officer and director, and the state of incorporation; and

(iv) If a sole proprietorship, the full name of the sole proprietor and the name of the sole proprietor's business entity;

(6) A list of all licenses and permits issued to the applicant by any other state that authorizes the applicant to purchase or possess prescription drugs;

(7) For the designated representative and the immediate supervisor of the designated representative at the applicant's place of business, **THE FOLLOWING:**

[(i) Fingerprints necessary to conduct a criminal history records check; and

(ii) The following:]

[1.] (I) Name;

[2.] (II) Places of residence for the past 7 years;

[3.] (III) Date and place of birth;

[4.] (IV) The name and address of each business where the individual was employed during the past 7 years, and the individual's job title or office held at each business;

[5.] (V) A statement of whether, during the past 7 years, the individual has been the subject of any proceeding for the revocation of any professional or business license or any criminal violation and, if so, the nature and disposition of the proceeding;

[6.] (VI) A statement of whether, during the past 7 years, the individual has been enjoined, either temporarily or permanently, by a court of competent jurisdiction from violating any federal or state law regulating the possession, control, or distribution of prescription drugs, together with details concerning the event;

[7.] (VII) A description of any involvement, including any investments other than the ownership of stock in a publicly traded company or mutual

fund, by the individual during the past 7 years with any business that manufactures, administers, prescribes, distributes, or stores prescription drugs, and any lawsuits in which the business was named as a party;

[8.] (VIII) A. A description of any misdemeanor or felony offense of which the individual, as an adult, was found guilty, regardless of whether adjudication of guilt was withheld or whether the individual pled guilty or nolo contendere; and

B. If the individual indicates that a criminal conviction is under appeal and submits a copy of the notice of appeal, within 15 days after the disposition of the appeal, a copy of the final written order of disposition; and

[9.] (IX) A photograph of the individual taken in the previous 180 days.

(c) The information required under subsection (b) of this section shall be provided under oath.

(d) The Board may not issue a wholesale distributor permit to an applicant unless the Board or its designee:

(1) Conducts a physical inspection of the applicant's place of business, including any facility of the applicant **WHERE THE APPLICANT HOLDS PRESCRIPTION DRUGS OR PRESCRIPTION DEVICES;**

(2) Finds that the place of business and facility, if any, meets the Board's requirements;

(3) Determines that the designated representative of the applicant meets the following qualifications:

(i) Is at least 21 years of age;

(ii) Has been employed full time for at least 3 years in a pharmacy or with a wholesale distributor in a capacity related to the dispensing and distribution of, and record keeping relating to, prescription drugs;

(iii) Is employed by the applicant full time in a managerial level position;

(iv) Is actively involved in and aware of the daily operation of the wholesale distributor;

(v) Is physically present, except for an authorized absence such as sick leave or vacation leave, at the facility of the applicant during regular business hours;

(vi) Is serving as a designated representative for only one applicant at a time, or for two or more wholesale distributors who are located in the same facility and are members of an affiliated group, as defined in § 1504 of the Internal Revenue Code;

(vii) Does not have any convictions for a violation of any federal, state, or local laws relating to wholesale or retail prescription drug distribution or distribution of controlled substances; and

(viii) Does not have any convictions for a felony under federal, state, or local laws; and

(4) Determines that the immediate supervisor of the designated representative of the applicant meets the following qualifications:

(i) Is at least 21 years of age;

(ii) Has been employed full time for at least 3 years in a pharmacy or with a wholesale distributor in a capacity related to the dispensing and distribution of, and record keeping relating to, prescription drugs;

(iii) Is employed by the applicant full time in a managerial level position;

(iv) Is actively involved in and aware of the daily operation of the wholesale distributor;

(v) Does not have any convictions for a violation of any federal, state, or local laws relating to wholesale or retail prescription drug distribution or distribution of controlled substances; and

(vi) Does not have any convictions for a felony under federal, state, or local laws.

(e) THE DESIGNATED REPRESENTATIVE AND THE IMMEDIATE SUPERVISOR OF THE DESIGNATED REPRESENTATIVE OF AN APPLICANT SHALL SUBMIT TO A CRIMINAL HISTORY RECORDS CHECK IN ACCORDANCE WITH SECTION 12-6C-05.1 OF THIS SUBTITLE. [(1) In this subsection, "Central Repository" means the Criminal Justice Information System Central Repository of the Department of Public Safety and Correctional Services.

(2) In accordance with the requirements of this subsection, the Board shall submit the fingerprints provided with a permit application to the Central Repository for a State and national criminal history records check of the designated representative and the immediate supervisor of the designated representative

(3) As part of an application to the Central Repository for a State and national criminal history records check, the Board shall submit to the Central Repository:

(i) Two complete sets of legible fingerprints taken on forms approved by the director of the Central Repository and the Director of the Federal Bureau of Investigation;

(ii) The fee authorized under § 10-221(b)(7) of the Criminal Procedure Article for access to State criminal history records; and

(iii) The processing fee required by the Federal Bureau of Investigation for a national criminal history records check.

(4) In accordance with §§ 10–201 through 10–228 of the Criminal Procedure Article, the Central Repository shall forward to the Board and to the applicant the criminal history record information of the applicant.

(5) Information obtained from the Central Repository under this subsection:

(i) Shall be confidential;

(ii) May not be disseminated; and

(iii) Shall be used only for the permitting purpose authorized by this subtitle.

(6) The subject of a criminal history records check under this subsection may contest the contents of the printed statement issued by the Central Repository as provided in § 10–223 of the Criminal Procedure Article.]

(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.

(3) (i) An applicant for a wholesale distributor permit shall submit a surety bond 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 paragraph (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.

(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.

(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.

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

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

(g) If a wholesale distributor distributes prescription drugs or prescription devices from more than one facility, the wholesale distributor shall obtain a permit for each facility.

(h) Within 30 days after the date the Board receives a completed application, including the results of all required criminal history records checks, the Board shall notify the applicant of the Board's acceptance or rejection of the application.

12-6C-05.1

(A) (1) THIS SUBSECTION APPLIES TO APPLICANTS LOCATED IN THIS STATE.

(2) IN THIS SUBSECTION, "CENTRAL REPOSITORY" MEANS THE CRIMINAL JUSTICE INFORMATION SYSTEM CENTRAL REPOSITORY OF THE DEPARTMENT OF PUBLIC SAFETY AND CORRECTIONAL SERVICES.

(3) AS PART OF AN APPLICATION TO THE CENTRAL REPOSITORY FOR A STATE AND NATIONAL CRIMINAL HISTORY RECORDS CHECK, THE DESIGNATED REPRESENTATIVE AND THE IMMEDIATE SUPERVISOR OF THE DESIGNATED REPRESENTATIVE OF AN APPLICANT SHALL SUBMIT TO THE CENTRAL REPOSITORY:

(I) TWO COMPLETE SETS OF LEGIBLE FINGERPRINTS TAKEN ON FORMS APPROVED BY THE DIRECTOR OF THE CENTRAL REPOSITORY AND THE DIRECTOR OF THE FEDERAL BUREAU OF INVESTIGATION;

(II) THE FEE AUTHORIZED UNDER § 10-221(B)(7) OF THE CRIMINAL PROCEDURE ARTICLE FOR ACCESS TO STATE CRIMINAL HISTORY RECORDS; AND

(III) THE PROCESSING FEE REQUIRED BY THE FEDERAL BUREAU OF INVESTIGATION FOR A NATIONAL CRIMINAL HISTORY RECORDS CHECK.

(4) IN ACCORDANCE WITH §§ 10-201 THROUGH 10-228 OF THE CRIMINAL PROCEDURE ARTICLE, THE CENTRAL REPOSITORY SHALL FORWARD TO THE BOARD AND TO THE APPLICANT THE CRIMINAL HISTORY RECORD INFORMATION OF THE APPLICANT.

(5) THE BOARD SHALL ENSURE THAT INFORMATION OBTAINED FROM THE CENTRAL REPOSITORY UNDER THIS SUBSECTION:

(I) SHALL BE CONFIDENTIAL;

**(II) MAY NOT BE REDISSEMINATED; AND
(III) SHALL BE USED ONLY FOR THE PERMITTING
PURPOSE AUTHORIZED BY THIS SUBTITLE.**

**(6) THE SUBJECT OF A CRIMINAL HISTORY RECORDS
CHECK UNDER THIS SUBSECTION MAY CONTEST THE CONTENTS OF
THE PRINTED STATEMENT ISSUED BY THE CENTRAL REPOSITORY AS
PROVIDED IN § 10-223 OF THE CRIMINAL PROCEDURE ARTICLE.**

**(B) (1) THIS SUBSECTION APPLIES TO APPLICANTS
LOCATED OUT OF THIS STATE**

**(2) THE DESIGNATED REPRESENTATIVE AND THE
IMMEDIATE SUPERVISOR OF THE DESIGNATED REPRESENTATIVE
SHALL 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.**

**(3) THE CRIMINAL HISTORY RECORDS CHECK SHALL
CONSIST OF BOTH A STATE CRIMINAL HISTORY RECORDS CHECK FOR
THE APPLICANT'S STATE OF RESIDENCE AND A NATIONAL CRIMINAL
HISTORY RECORDS CHECK.**

**(4) THE APPROPRIATE ENTITY IN THE APPLICANT'S STATE
OF RESIDENCE SHALL FORWARD THE RESULTS OF THE CRIMINAL
HISTORY RECORDS CHECK TO THE BOARD AND THE APPLICANT.**

**(5) THE BOARD SHALL ENSURE THAT INFORMATION
OBTAINED IN ACCORDANCE WITH THIS SUBSECTION:**

(I) SHALL BE CONFIDENTIAL;

(II) MAY NOT BE REDISSEMINATED; AND

**(III) SHALL BE USED ONLY FOR THE PERMITTING
PURPOSE AUTHORIZED BY THIS SUBTITLE.**

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
October 1, 2012.