

Chapter 463

(House Bill 316)

AN ACT concerning

State Board of Pharmacy – Wholesale Distributor Permits – Permit and Application Requirements

FOR the purpose of exempting a manufacturer that distributes its own prescription devices that are approved or authorized by the U.S. Food and Drug Administration from certain permit requirements; altering the information required to be included in an application for a wholesale distributor permit; limiting a requirement that the State Board of Pharmacy or its designee conduct a certain inspection to apply only to applicants that hold prescription drugs or devices; altering certain requirements for a criminal history records check of a designated representative and the supervisor of a designated representative of an applicant; making stylistic changes; and generally relating to application requirements for a wholesale distributor permit issued by the State Board of Pharmacy.

BY repealing and reenacting, without amendments,
Article – Health Occupations
Section 12–6C–05(a), (c), and (h)
Annotated Code of Maryland
(2009 Replacement Volume and 2011 Supplement)

BY repealing and reenacting, with amendments,
Article – Health Occupations
Section 12–6C–03(b) and 12–6C–05(b) and (d)
Annotated Code of Maryland
(2009 Replacement Volume and 2011 Supplement)

BY repealing
Article – Health Occupations
Section 12–6C–05(e)
Annotated Code of Maryland
(2009 Replacement Volume and 2011 Supplement)

BY adding to
Article – Health Occupations
Section 12–6C–05(e) and 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-03.

(b) (1) A manufacturer engaged in wholesale distribution shall hold a wholesale distributor permit issued under this subtitle.

(2) Notwithstanding paragraph (1) of this subsection, the information and qualification requirements for obtaining a permit under this subtitle, beyond that required by federal law, do not apply to [a]:

(I) A manufacturer [who] THAT distributes its own prescription drugs THAT ARE approved by the U.S. Food and Drug Administration; OR

(II) A MANUFACTURER THAT DISTRIBUTES ITS OWN PRESCRIPTION DEVICES THAT ARE APPROVED OR AUTHORIZED BY THE U.S. FOOD AND DRUG ADMINISTRATION.

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.] 1. 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.] 2. 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] IF THE APPLICANT HOLDS PRESCRIPTION DRUGS OR DEVICES, CONDUCTS** a physical inspection of the applicant's place of business, including any facility of the applicant;

(2) 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) (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.]

(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 § 12–6C–05.1 OF THIS SUBTITLE.

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

(2) THIS SUBSECTION APPLIES TO APPLICANTS LOCATED IN THE STATE.

(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 THE CRIMINAL HISTORY RECORDS INFORMATION OF THE DESIGNATED REPRESENTATIVE AND THE IMMEDIATE SUPERVISOR OF THE DESIGNATED REPRESENTATIVE OF AN APPLICANT TO THE BOARD AND THE APPLICANT.

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

(I) IS KEPT CONFIDENTIAL;

(II) IS NOT REDISSEMINATED; AND

(III) IS 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 OUTSIDE THE STATE.

(2) THE DESIGNATED REPRESENTATIVE AND THE IMMEDIATE SUPERVISOR OF THE DESIGNATED REPRESENTATIVE OF AN APPLICANT 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:

(I) A STATE CRIMINAL HISTORY RECORDS CHECK FOR THE APPLICANT'S STATE OF RESIDENCE; AND

(II) A NATIONAL CRIMINAL HISTORY RECORDS CHECK.

(4) THE DESIGNATED REPRESENTATIVE AND THE IMMEDIATE SUPERVISOR OF THE DESIGNATED REPRESENTATIVE OF AN APPLICANT SHALL REQUEST THE APPROPRIATE ENTITY IN THE APPLICANT'S STATE OF RESIDENCE TO FORWARD THE RESULTS OF THE CRIMINAL HISTORY RECORDS CHECK TO THE BOARD AND THE APPLICANT.

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

(I) IS KEPT CONFIDENTIAL;

(II) IS NOT REDISSEMINATED; AND

(III) IS 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.

Approved by the Governor, May 22, 2012.