By: **Delegates Stern, Goldwater, Barve, Jones, Conway, McIntosh, Hixson, D. Davis, Rosenberg, Simmons, Elliott, Weldon, Barkley, Benson, Bronrott, Cane, V. Clagett, Cryor, Donoghue, Doory, Dumais, Feldman, Franchot, Frush, Glassman, Heller, Hubbard, James, King, Kullen, Lawton, Lee, Madaleno, Malone, Mandel, Marriott, McKee, Menes, Montgomery, Morhaim, Murray, Nathan-Pulliam, Oaks, Shank, Smigiel, Sossi, Stull, F. Turner, and V. Turner**

Introduced and read first time: February 10, 2006
Assigned to: Health and Government Operations

A BILL ENTITLED

AN ACT concerning

Prescription Drug Safety Act

FOR the purpose of requiring a wholesale distributor of prescription drugs to hold a license issued by the State Board of Pharmacy before the wholesale distributor engages in the wholesale distribution of prescription drugs in the State; requiring a nonresident wholesale distributor to hold certain licenses before the nonresident wholesale distributor engages in the wholesale distribution of prescription drugs; authorizing the Board to exempt from certain requirements a wholesale distributor accredited by a certain accreditation program; authorizing the Board to exempt a U.S. Food and Drug Administration licensed drug manufacturer from licensing requirements under certain circumstances; requiring an applicant for a license to meet certain requirements; requiring an application for a license to include certain items; requiring information on an application to be provided under oath; requiring an applicant to receive a certain inspection certificate; establishing requirements for an inspection certificate; authorizing the Board or a certain accreditation program to conduct an inspection at certain times and in a certain manner; authorizing the Board or a certain accreditation program to charge and collect fees for inspection activities; authorizing the Board to charge a fee, including a certain cost, to apply for or renew a license; requiring an applicant to submit a bond in a certain amount, or certain other equivalent means of security; authorizing the Board to waive the bond requirement under certain circumstances; requiring the Board to waive the bond requirement under certain circumstances; requiring the Board to establish a certain account; requiring the Board to apply to the Central Repository for certain criminal history records checks; establishing requirements for the criminal history records checks; authorizing the Board to conduct a financial background check; requiring the Board to issue a wholesale distributor license to an applicant that meets certain requirements; requiring the Board to give certain written notice, if the Board denies a license;

prohibiting the Board from issuing a license, unless the Board makes certain determinations; establishing the duration for a license; providing for the renewal of a license, under certain conditions; requiring the Board to establish certain continuing education requirements; authorizing the Board to take certain actions against a license of a wholesale distributor that commits certain violations; requiring a manufacturer located in the State to hold a license issued by the Board before the manufacturer invoices or ships prescription drugs in the State; requiring a nonresident manufacturer to hold a license before the nonresident manufacturer invoices or ships prescription drugs into the State; requiring an applicant for a manufacturer license to meet certain requirements; requiring an application for a license to include certain items and be certified by a notary public; requiring the Board to issue a manufacturer license to an applicant that meets certain requirements; requiring the Board to give certain written notice, if the Board denies a license; providing for the duration of a manufacturer license; providing for the renewal of a license under certain conditions; prohibiting the disclosure of certain information; providing for certain exceptions; requiring the Board to adopt regulations defining a certain emergency situation; requiring the Board to make a certain determination and take certain action, under certain circumstances; establishing requirements for prescription drug returns and exchanges; establishing certain due diligence requirements; establishing requirements for a wholesale distributor to supply and deliver prescription drugs; establishing requirements for payment and purchasing of prescription drugs; providing an exception for standard ordering and purchasing business practices; requiring a wholesale distributor to establish and maintain certain inventories and records regarding receipt and distribution or other disposition of prescription drugs; establishing pedigree requirements for the wholesale distribution of prescription drugs; requiring the Board to conduct a study of electronic pedigrees and other advanced tracking technology; authorizing the Board to mandate electronic pedigrees or other advanced tracking technology; requiring the Board to report the findings and recommendations of its study to the General Assembly on or before a certain date and adopt certain regulations within a certain time period; exempting a pharmacy benefits entity from the pedigree requirements, under certain circumstances; authorizing the Board to recognize certain laws and regulations as satisfying certain pedigree requirements; requiring the Board to issue an order to cease distribution of a prescription drug under certain circumstances; providing an opportunity for a certain hearing; authorizing the Board to vacate the order under certain circumstances; making it unlawful for a person to perform or cause to be performed or aid and abet certain acts; providing that it is not unlawful for a certain person to obtain or attempt to obtain a prescription drug for certain testing purposes; providing for certain penalties; defining certain terms; repealing certain provisions of law; and generally relating to prescription drug safety and requirements for the wholesale distribution of prescription drugs.

BY repealing
Article - Health Occupations
Section 12-602

Annotated Code of Maryland
(2005 Replacement Volume)

BY adding to
Article - Health Occupations
Section 12-6B-01 through 12-6B-20, inclusive, to be under the new subtitle "Subtitle 6B. Prescription Drug Safety Act"
Annotated Code of Maryland
(2005 Replacement Volume)

BY repealing and reenacting, with amendments,
Article - Health Occupations
Section 12-707(b)
Annotated Code of Maryland
(2005 Replacement Volume)

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That Section(s) 12-602 of Article - Health Occupations of the Annotated Code of Maryland be repealed.

SECTION 2. AND BE IT FURTHER ENACTED, That the Laws of Maryland read as follows:

Article - Health Occupations

SUBTITLE 6B. PRESCRIPTION DRUG SAFETY ACT.

12-6B-01.

(A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS INDICATED.

(B) "CHAIN PHARMACY WAREHOUSE" MEANS A PHYSICAL LOCATION FOR PRESCRIPTION DRUGS THAT ACTS, IN PART OR IN WHOLE, AS A CENTRAL WAREHOUSE AND PERFORMS INTRACOMPANY SALES OR TRANSFERS OF THE PRESCRIPTION DRUGS TO A GROUP OF CHAIN PHARMACIES OR OTHER CHAIN PHARMACY WAREHOUSES THAT ARE UNDER COMMON OWNERSHIP OR CONTROL.

(C) "FACILITY" MEANS A FACILITY OF A WHOLESALE DISTRIBUTOR IN WHICH PRESCRIPTION DRUGS ARE STORED, HANDLED, REPACKAGED, OR OFFERED FOR SALE.

(D) (1) "MANUFACTURER" MEANS A PERSON THAT MANUFACTURES OR PACKAGES PRESCRIPTION DRUGS.

(2) "MANUFACTURER" INCLUDES:

(I) AN AFFILIATE;

(II) A SUBSIDIARY;

(III) AN AGENT;

(IV) ANOTHER ENTITY UNDER COMMON OWNERSHIP AND CONTROL WITH A MANUFACTURER.

(E) "NORMAL DISTRIBUTION CHANNEL" MEANS THE ROUTE THAT A PRESCRIPTION DRUG TRAVELS:

(1) FROM A MANUFACTURER TO A WHOLESALE DISTRIBUTOR, TO A PHARMACY, AND TO A CONSUMER;

(2) FROM A MANUFACTURER TO A WHOLESALE DISTRIBUTOR, TO A CHAIN PHARMACY WAREHOUSE, TO A PHARMACY AFFILIATED WITH THE CHAIN PHARMACY WAREHOUSE, AND TO A CONSUMER;

(3) FROM A MANUFACTURER TO A CHAIN PHARMACY WAREHOUSE, TO A PHARMACY AFFILIATED WITH THE CHAIN PHARMACY WAREHOUSE, AND TO A CONSUMER; OR

(4) AS PROVIDED IN REGULATIONS ADOPTED BY THE BOARD.

(F) "PEDIGREE" MEANS A DOCUMENT OR ELECTRONIC FILE CONTAINING INFORMATION THAT RECORDS EACH DISTRIBUTION OF ANY GIVEN PRESCRIPTION DRUG INSIDE OR OUTSIDE THE NORMAL DISTRIBUTION CHANNEL.

(G) "PHARMACY BENEFITS ENTITY" MEANS AN ENTITY THAT ASSISTS IN THE ADMINISTRATION OF PHARMACY BENEFITS:

(1) UNDER CONTRACTS WITH INSURERS; OR

(2) TO A COMPANY UNDER COMMON OWNERSHIP OR CONTROL WITH THE ENTITY.

(H) (1) "PRESCRIPTION DRUG" MEANS ANY DRUG REQUIRED BY FEDERAL LAW, FEDERAL REGULATION, OR STATE LAW TO BE DISPENSED ONLY BY A PRESCRIPTION.

(2) "PRESCRIPTION DRUG" INCLUDES:

(I) ANY BIOLOGICAL PRODUCT, EXCEPT:

1. BLOOD AND BLOOD COMPONENTS INTENDED FOR TRANSFUSION; OR

2. BIOLOGICAL PRODUCTS THAT ARE ALSO MEDICAL DEVICES;

(II) FINISHED DOSAGE FORMS; AND

(III) BULK DRUG SUBSTANCES SUBJECT TO SECTION 503(B) OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.

(I) (1) "REPACKAGE" MEANS REPACKAGING OR OTHERWISE CHANGING THE CONTAINER, WRAPPER, OR LABELING TO FURTHER THE DISTRIBUTION OF A PRESCRIPTION DRUG.

(2) "REPACKAGE" DOES NOT INCLUDE REPACKAGING COMPLETED BY THE PHARMACIST WHO DISPENSES THE PRESCRIPTION DRUG TO THE CONSUMER.

(J) "REPACKAGER" MEANS A PERSON WHO REPACKAGES.

(K) "WHOLESALE DISTRIBUTOR" OR "WHOLESALER" MEANS A PERSON ENGAGED IN THE WHOLESALE DISTRIBUTION OF PRESCRIPTION DRUGS, INCLUDING:

(1) REPACKAGERS;

(2) OWN-LABEL DISTRIBUTORS;

(3) PRIVATE-LABEL DISTRIBUTORS;

(4) JOBBERS;

(5) BROKERS;

(6) WAREHOUSES, INCLUDING MANUFACTURERS' AND DISTRIBUTORS' WAREHOUSES;

(7) INDEPENDENT WHOLESALE DRUG TRADERS;

(8) RETAIL PHARMACIES THAT CONDUCT WHOLESALE DISTRIBUTION; AND

(9) CHAIN PHARMACY WAREHOUSES THAT CONDUCT WHOLESALE DISTRIBUTION.

(L) (1) "WHOLESALE DISTRIBUTION" MEANS DISTRIBUTION OF PRESCRIPTION DRUGS TO PERSONS OTHER THAN A CONSUMER.

(2) "WHOLESALE DISTRIBUTION" DOES NOT INCLUDE:

(I) INTRACOMPANY SALES OR TRANSFERS OF PRESCRIPTION DRUGS THAT INVOLVE A TRANSACTION OR TRANSFER BETWEEN ANY DIVISION, SUBSIDIARY, PARENT, OR AFFILIATED OR RELATED COMPANY UNDER COMMON OWNERSHIP AND CONTROL;

(II) THE SALE, PURCHASE, DISTRIBUTION, TRADE, OR TRANSFER OF A PRESCRIPTION DRUG OR OFFER TO SELL, PURCHASE, DISTRIBUTE, TRADE, OR TRANSFER A PRESCRIPTION DRUG IN:

1. A CATASTROPHIC HEALTH EMERGENCY PROCLAIMED BY THE GOVERNOR UNDER § 14-3A-02 OF THE PUBLIC SAFETY ARTICLE; OR

2. AN EMERGENCY SITUATION, AS DEFINED BY THE BOARD IN REGULATIONS;

(III) THE DISTRIBUTION OF PRESCRIPTION DRUG SAMPLES TO AUTHORIZED PRESCRIBERS BY MANUFACTURERS' REPRESENTATIVES;

(IV) DRUG RETURNS, WHEN CONDUCTED BY A HOSPITAL, HEALTH CARE ENTITY, OR CHARITABLE INSTITUTION IN ACCORDANCE WITH 21 C.F.R. § 203.23;

(V) THE SALE OF MINIMAL QUANTITIES OF PRESCRIPTION DRUGS BY RETAIL PHARMACIES TO AUTHORIZED PRESCRIBERS FOR OFFICE USE;

(VI) DELIVERY OF PRESCRIPTION DRUGS BY RETAIL PHARMACIES TO A CONSUMER PURSUANT TO A PRESCRIPTION;

(VII) THE SALE, TRANSFER, MERGER, OR CONSOLIDATION OF ALL OR PART OF THE BUSINESS OF A PHARMACY OR PHARMACIES FROM OR WITH ANOTHER PHARMACY OR PHARMACIES, WHETHER ACCOMPLISHED AS A PURCHASE AND SALE OF STOCK OR BUSINESS ASSETS; OR

(VIII) THE SALE OR TRANSFER FROM A RETAIL PHARMACY OR CHAIN PHARMACY WAREHOUSE OF EXPIRED, DAMAGED, RETURNED, OR RECALLED DRUGS TO THE ORIGINAL MANUFACTURER, WHOLESALER, OR THIRD PARTY RETURNS PROCESSOR.

12-6B-02.

BY REGULATION, THE BOARD MAY EXEMPT FROM ANY REQUIREMENT OF THIS SUBTITLE A WHOLESALE DISTRIBUTOR ACCREDITED BY A NATIONALLY RECOGNIZED ACCREDITATION ENTITY APPROVED BY THE BOARD.

12-6B-03.

(A) A WHOLESALE DISTRIBUTOR SHALL HOLD A LICENSE ISSUED BY THE BOARD BEFORE THE WHOLESALE DISTRIBUTOR ENGAGES IN THE WHOLESALE DISTRIBUTION OF PRESCRIPTION DRUGS IN THE STATE.

(B) BEFORE A NONRESIDENT WHOLESALE DISTRIBUTOR ENGAGES IN THE WHOLESALE DISTRIBUTION OF PRESCRIPTION DRUGS IN THE STATE, THE NONRESIDENT WHOLESALE DISTRIBUTOR SHALL BE LICENSED:

(1) IN THE STATE IN WHICH THE NONRESIDENT WHOLESALE DISTRIBUTOR IS LOCATED; AND

(2) IN EACH STATE IN WHICH THE NONRESIDENT WHOLESALE DISTRIBUTOR SHIPS PRESCRIPTION DRUGS.

(C) THE BOARD SHALL EXEMPT A FOOD AND DRUG ADMINISTRATION LICENSED DRUG MANUFACTURER INCLUDING ITS AFFILIATES, SUBSIDIARIES, AGENTS, AND OTHER ENTITIES UNDER COMMON OWNERSHIP AND CONTROL WITH THE MANUFACTURER, FROM THE LICENSING REQUIREMENTS OF THIS SECTION, IF THE MANUFACTURER, ITS AFFILIATES, SUBSIDIARIES, AGENTS, AND OTHER ENTITIES UNDER COMMON OWNERSHIP AND CONTROL WITH THE MANUFACTURER, SHIP OR INVOICE ONLY THE MANUFACTURER'S PRODUCT INTO THE STATE.

(D) TO OBTAIN A LICENSE, AN APPLICANT SHALL:

(1) SUBMIT AN APPLICATION TO THE BOARD ON THE FORM AND IN THE MANNER REQUIRED BY THE BOARD;

(2) PAY TO THE BOARD AN APPLICATION FEE, AS AUTHORIZED UNDER § 12-6B-05 OF THIS SUBTITLE;

(3) RECEIVE AN INSPECTION CERTIFICATE FROM OR APPROVED BY THE BOARD, AS REQUIRED UNDER § 12-6B-06 OF THIS SUBTITLE; AND

(4) POST THE BOND REQUIRED UNDER § 12-6B-07 OF THIS SUBTITLE.

12-6B-04.

(A) THE APPLICATION UNDER § 12-6B-03 OF THIS SUBTITLE SHALL INCLUDE:

(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 DESIGNATED REPRESENTATIVES FOR ALL FACILITIES USED BY THE APPLICANT;

(4) THE TYPE OF OWNERSHIP OR OPERATION OF THE APPLICANT;

(5) THE NAMES OF THE OWNER AND OPERATOR OF THE APPLICANT, INCLUDING:

(I) IF AN INDIVIDUAL, THE NAME OF THE INDIVIDUAL;

(II) IF A PARTNERSHIP, THE NAME OF EACH PARTNER, AND THE NAME OF THE PARTNERSHIP;

(III) IF A CORPORATION, THE NAME AND TITLE OF EACH CORPORATE OFFICER AND DIRECTOR, THE CORPORATE NAMES, AND THE STATE OF INCORPORATION; AND

(IV) IF A SOLE PROPRIETORSHIP, THE FULL NAME OF THE SOLE PROPRIETOR AND THE NAME OF THE 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) INFORMATION REGARDING THE APPLICANT'S DESIGNATED REPRESENTATIVE FOR EACH FACILITY OPERATED BY THE APPLICANT IN THE STATE, INCLUDING:

(I) NAME;

(II) RESIDENCE ADDRESSES FOR THE PAST 7 YEARS;

(III) DATE AND PLACE OF BIRTH;

(IV) OCCUPATIONS, POSITIONS OF EMPLOYMENT, AND OFFICES HELD DURING THE PAST 7 YEARS;

(V) NAME AND ADDRESS OF EACH BUSINESS, CORPORATION, OR OTHER ORGANIZATION IN WHICH THE DESIGNATED REPRESENTATIVE WAS EMPLOYED, HELD OFFICE, AND CARRIED ON AN OCCUPATION;

(VI) WHETHER THE DESIGNATED REPRESENTATIVE HAS BEEN, DURING THE PAST 7 YEARS, THE SUBJECT OF ANY PROCEEDING FOR THE REVOCATION OF ANY LICENSE OR ANY CRIMINAL VIOLATION AND, IF SO, THE NATURE OF THE PROCEEDING AND THE DISPOSITION OF THE PROCEEDING;

(VII) 1. WHETHER, DURING THE PAST 7 YEARS, A COURT OF COMPETENT JURISDICTION HAS RESTRICTED THE ABILITY OF THE DESIGNATED REPRESENTATIVE TO POSSESS, CONTROL, OR DISTRIBUTE PRESCRIPTION DRUGS; AND

2. THE REASONS FOR ANY SUCH RESTRICTION;

(VIII) A DESCRIPTION OF:

1. ANY INVOLVEMENT, INCLUDING ANY INVESTMENTS, OTHER THAN THE OWNERSHIP OF STOCK IN A PUBLICLY TRADED COMPANY OR MUTUAL FUND, BY THE DESIGNATED REPRESENTATIVE DURING THE PAST 7 YEARS, WITH ANY BUSINESS THAT MANUFACTURED, ADMINISTERED, PRESCRIBED, DISTRIBUTED, OR STORED PHARMACEUTICAL PRODUCTS; AND

2. ANY LAWSUITS IN WHICH THE BUSINESSES WERE NAMED AS A PARTY; AND

(IX) A DESCRIPTION OF ANY MISDEMEANOR OR FELONY CRIMINAL OFFENSE OF WHICH THE AUTHORIZED REPRESENTATIVE, AS AN ADULT, WAS FOUND GUILTY, REGARDLESS OF WHETHER ADJUDICATION OF GUILT WAS WITHHELD OR WHETHER THE AUTHORIZED REPRESENTATIVE PLED GUILTY OR NOLO CONTENDERE;

(8) A PHOTOGRAPH OF THE DESIGNATED REPRESENTATIVE TAKEN IN THE PREVIOUS 30 DAYS; AND

(9) THE FINGERPRINTS REQUIRED UNDER § 12-6B-08 OF THIS SUBTITLE.

(B) IF THE APPLICATION INDICATES THAT THE DESIGNATED REPRESENTATIVE HAS A CRIMINAL CONVICTION THAT IS UNDER APPEAL:

(1) THE APPLICATION SHALL INCLUDE A COPY OF THE NOTICE OF APPEAL OF THAT CRIMINAL OFFENSE; AND

(2) THE APPLICANT SHALL SUBMIT, WITHIN 15 DAYS AFTER THE DISPOSITION OF THE APPEAL, A COPY OF THE FINAL WRITTEN ORDER OF DISPOSITION.

(C) THE INFORMATION REQUIRED UNDER THIS SECTION SHALL BE PROVIDED UNDER OATH.

12-6B-05.

(A) THE BOARD MAY CHARGE A FEE, AS PROVIDED IN REGULATION, TO APPLY FOR OR RENEW A LICENSE.

(B) THE FEE SHALL INCLUDE THE COST OF PROCESSING ANY CRIMINAL HISTORY RECORDS CHECK OR FINANCIAL BACKGROUND CHECK CONDUCTED BY OR THROUGH THE BOARD.

12-6B-06.

(A) AN APPLICANT SHALL RECEIVE AN INSPECTION CERTIFICATE FROM OR APPROVED BY THE BOARD FOR EACH FACILITY OPERATED BY THE APPLICANT IN THE STATE BEFORE THE BOARD MAY ISSUE A LICENSE TO THE APPLICANT.

(B) TO RECEIVE AN INSPECTION CERTIFICATE, AN APPLICANT SHALL PASS A PHYSICAL INSPECTION OF EACH FACILITY CONDUCTED BY:

(1) THE BOARD; OR

(2) A NATIONALLY RECOGNIZED ACCREDITATION PROGRAM DESIGNATED BY THE BOARD TO CONDUCT INSPECTIONS ON THE BOARD'S BEHALF.

(C) AN INSPECTION CERTIFICATE SHALL BE VALID FOR NO MORE THAN 3 YEARS.

(D) THE BOARD OR A NATIONALLY RECOGNIZED ACCREDITATION PROGRAM DESIGNATED BY THE BOARD TO CONDUCT INSPECTIONS ON THE BOARD'S BEHALF MAY CONDUCT AN INSPECTION OF A FACILITY OF A WHOLESALE DISTRIBUTOR IN THE MANNER AND AT THE TIMES PROVIDED IN REGULATIONS ADOPTED BY THE BOARD.

(E) AS PART OF AN INSPECTION, THE BOARD MAY REQUIRE PRESCRIPTION DRUGS AT THE FACILITY BE ANALYZED TO VERIFY THE AUTHENTICITY OF THE PRESCRIPTION DRUGS.

(F) THE BOARD OR A NATIONALLY RECOGNIZED ACCREDITATION PROGRAM DESIGNATED BY THE BOARD TO CONDUCT INSPECTIONS ON THE BOARD'S BEHALF MAY CHARGE AND COLLECT FEES FOR INSPECTION ACTIVITIES CONDUCTED UNDER THIS SECTION.

12-6B-07.

(A) THE BOARD SHALL REQUIRE EACH WHOLESALE DISTRIBUTOR APPLYING FOR A LICENSE TO SUBMIT A BOND OF AT LEAST $100,000, OR OTHER EQUIVALENT MEANS OF SECURITY ACCEPTABLE TO THE BOARD, SUCH AS AN IRREVOCABLE LETTER OF CREDIT OR A DEPOSIT IN A TRUST ACCOUNT OR FINANCIAL INSTITUTION, PAYABLE TO AN ACCOUNT ESTABLISHED BY THE BOARD IN ACCORDANCE WITH SUBSECTION (F) OF THIS SECTION.

(B) THE PURPOSE OF THE BOND IS TO SECURE PAYMENT OF ANY FINES OR PENALTIES IMPOSED BY THE BOARD AND ANY FEES AND COSTS INCURRED BY THE BOARD REGARDING A LICENSE, THAT THE LICENSEE FAILS TO PAY WITHIN 30 DAYS AFTER THE FINES, PENALTIES, OR COSTS BECOME FINAL.

(C) (1) THE BOARD MAY WAIVE THE BOND REQUIREMENT IF THE WHOLESALE DISTRIBUTOR HAS IN PLACE A COMPARABLE BOND OR OTHER EQUIVALENT MEANS OF SECURITY FOR THE PURPOSE STATED IN SUBSECTION (B) OF THIS SECTION IN ANOTHER STATE IN WHICH THE WHOLESALE DISTRIBUTOR POSSESSES A WHOLESALE DISTRIBUTOR LICENSE IN GOOD STANDING.

(2) THE BOARD SHALL WAIVE THE BOND REQUIREMENT IF THE WHOLESALE DISTRIBUTOR IS UNDER COMMON OWNERSHIP OR CONTROL WITH AN ENTITY THAT HAS BEEN LICENSED BY THE BOARD.

(D) THE STATE MAY MAKE A CLAIM AGAINST THE BOND OR SECURITY SUBMITTED BY A WHOLESALE DISTRIBUTOR UNTIL 1 YEAR AFTER THE WHOLESALE DISTRIBUTOR'S LICENSE CEASES TO BE VALID.

(E) THE BOND SHALL COVER ALL FACILITIES OPERATED BY THE APPLICANT IN THE STATE.

(F) THE BOARD SHALL ESTABLISH AN ACCOUNT, SEPARATE FROM ITS OTHER ACCOUNTS, IN WHICH TO DEPOSIT ANY FUNDS RECEIVED FROM THE BOND OR SECURITY OF A WHOLESALE DISTRIBUTOR.

12-6B-08.

(A) THE BOARD SHALL APPLY TO THE CENTRAL REPOSITORY FOR A STATE AND NATIONAL CRIMINAL HISTORY RECORDS CHECK FOR EACH DESIGNATED REPRESENTATIVE OF AN APPLICANT, AS INDICATED ON THE APPLICATION FOR A LICENSE.

(B) (1) AS PART OF THE APPLICATION FOR A CRIMINAL HISTORY RECORDS CHECK, THE BOARD SHALL SUBMIT TO THE CENTRAL REPOSITORY:

(I) TWO COMPLETE SETS OF THE DESIGNATED REPRESENTATIVE'S 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 IN § 10-221(B)(7) OF THE CRIMINAL PROCEDURE ARTICLE FOR ACCESS TO MARYLAND CRIMINAL HISTORY RECORDS; AND

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

(2) IN ACCORDANCE WITH TITLE 10, SUBTITLE 2 OF THE CRIMINAL PROCEDURE ARTICLE, THE CENTRAL REPOSITORY SHALL FORWARD TO THE DESIGNATED REPRESENTATIVE AND THE BOARD A PRINTED STATEMENT OF THE DESIGNATED REPRESENTATIVE'S CRIMINAL HISTORY RECORD INFORMATION.

(3) 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.

(C) THE BOARD MAY CONDUCT A FINANCIAL BACKGROUND CHECK ON A DESIGNATED REPRESENTATIVE OF AN APPLICANT.

12-6B-09.

(A) THE BOARD SHALL ISSUE A WHOLESALE DISTRIBUTOR LICENSE TO ANY APPLICANT THAT MEETS THE REQUIREMENTS OF THIS SUBTITLE.

(B) IF THE BOARD DENIES A WHOLESALE DISTRIBUTOR LICENSE TO AN APPLICANT, IT SHALL GIVE THE APPLICANT WRITTEN NOTICE OF ITS DECISION AND THE REASONS FOR THE DENIAL.

(C) THE BOARD MAY NOT ISSUE A WHOLESALE DISTRIBUTOR LICENSE TO AN APPLICANT, UNLESS THE BOARD DETERMINES THAT EACH DESIGNATED REPRESENTATIVE OF THE APPLICANT, AT MINIMUM:

(1) IS AT LEAST 21 YEARS OF AGE;

(2) 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;

(3) IS EMPLOYED BY THE APPLICANT FULL TIME IN A MANAGERIAL LEVEL POSITION;

(4) IS ACTIVELY INVOLVED IN AND AWARE OF THE ACTUAL DAILY OPERATION OF THE WHOLESALE DISTRIBUTOR;

(5) IS PHYSICALLY PRESENT AT THE FACILITY OF THE APPLICANT DURING REGULAR BUSINESS HOURS, EXCEPT WHEN THE ABSENCE OF THE DESIGNATED REPRESENTATIVE IS AUTHORIZED, INCLUDING SICK LEAVE AND VACATION LEAVE;

(6) IS SERVING IN THE CAPACITY OF A DESIGNATED REPRESENTATIVE FOR ONLY ONE APPLICANT AT A TIME;

(7) DOES NOT HAVE ANY CONVICTIONS UNDER ANY FEDERAL, STATE, OR LOCAL LAWS RELATING TO WHOLESALE OR RETAIL PRESCRIPTION DRUG DISTRIBUTION OR DISTRIBUTION OF CONTROLLED SUBSTANCES; AND

(8) DOES NOT HAVE ANY FELONY CONVICTIONS UNDER FEDERAL, STATE, OR LOCAL LAWS.

12-6B-10.

(A) A WHOLESALE DISTRIBUTOR LICENSE SHALL BE VALID FOR A PERIOD OF 1 YEAR.

(B) A LICENSE EXPIRES ON A DATE SET BY THE BOARD, UNLESS THE LICENSE IS RENEWED FOR AN ADDITIONAL 1-YEAR PERIOD AS PROVIDED IN THIS SECTION.

(C) AT LEAST 1 MONTH BEFORE THE LICENSE EXPIRES, THE BOARD SHALL PROVIDE TO THE LICENSEE A RENEWAL NOTICE THAT STATES:

(1) THE DATE ON WHICH THE CURRENT LICENSE EXPIRES;

(2) THE DATE BY WHICH THE RENEWAL APPLICATION MUST BE RECEIVED BY THE BOARD FOR THE RENEWAL TO BE PROCESSED BEFORE THE LICENSE EXPIRES; AND

(3) THE AMOUNT OF THE RENEWAL FEE.

(D) BEFORE THE LICENSE EXPIRES, THE LICENSEE MAY RENEW THE LICENSE FOR AN ADDITIONAL 1-YEAR PERIOD, IF THE LICENSEE:

(1) SUBMITS TO THE BOARD:

(I) A RENEWAL APPLICATION ON THE FORM THE BOARD REQUIRES; AND

(II) SATISFACTORY EVIDENCE OF COMPLIANCE WITH ANY CONTINUING EDUCATION AND OTHER QUALIFICATIONS AND REQUIREMENTS SET UNDER THIS SUBTITLE FOR LICENSE RENEWAL;

(2) HAS A CURRENT INSPECTION CERTIFICATE FOR EACH FACILITY OPERATED BY THE LICENSEE IN THE STATE; AND

(3) PAYS TO THE BOARD A RENEWAL FEE SET BY THE BOARD.

(E) THE RENEWAL APPLICATION SHALL REQUIRE THE LICENSEE TO UPDATE THE INFORMATION PROVIDED UNDER § 12-6B-04 OF THIS SUBTITLE.

(F) (1) THE BOARD SHALL ESTABLISH CONTINUING EDUCATION REQUIREMENTS FOR THE DESIGNATED REPRESENTATIVE IDENTIFIED IN ACCORDANCE WITH § 12-6B-04 OF THIS SUBTITLE.

(2) CONTINUING EDUCATION SHALL INCLUDE EDUCATION REGARDING FEDERAL AND STATE LAWS GOVERNING WHOLESALE DISTRIBUTION OF PRESCRIPTION DRUGS.

12-6B-11.

SUBJECT TO THE HEARING PROVISIONS OF § 12-315 OF THIS TITLE, THE BOARD MAY FINE, CENSURE, REPRIMAND, PLACE ON PROBATION, OR SUSPEND OR REVOKE THE LICENSE OF A WHOLESALE DISTRIBUTOR THAT VIOLATES ANY PROVISION OF THIS SUBTITLE.

12-6B-12.

(A) (1) A MANUFACTURER LOCATED IN THE STATE SHALL BE LICENSED BY THE BOARD BEFORE THE MANUFACTURER INVOICES OR SHIPS ITS OWN PRESCRIPTION DRUGS.

(2) A NONRESIDENT MANUFACTURER SHALL BE LICENSED BY THE BOARD BEFORE THE NONRESIDENT MANUFACTURER INVOICES OR SHIPS PRESCRIPTION DRUGS INTO THE STATE.

(B) TO OBTAIN A LICENSE UNDER THIS SECTION, A MANUFACTURER SHALL:

(1) SUBMIT AN APPLICATION TO THE BOARD ON THE FORM AND IN THE MANNER REQUIRED BY THE BOARD; AND

(2) PAY TO THE BOARD AN APPLICATION FEE, AS SET BY THE BOARD IN REGULATION.

(C) THE APPLICATION SHALL INCLUDE:

(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 DESIGNATED REPRESENTATIVES FOR ALL FACILITIES USED BY THE APPLICANT FOR THE STORAGE, HANDLING, AND DISTRIBUTION OF PRESCRIPTION DRUGS;

(4) THE TYPE OF OWNERSHIP OR OPERATION OF THE APPLICANT;

(5) THE NAMES OF THE OWNER AND OPERATOR OF THE APPLICANT, INCLUDING:

(I) IF AN INDIVIDUAL, THE NAME OF THE INDIVIDUAL;

(II) IF A PARTNERSHIP, THE NAME OF EACH PARTNER, AND THE NAME OF THE PARTNERSHIP;

(III) IF A CORPORATION, THE NAME AND TITLE OF EACH CORPORATE OFFICER AND DIRECTOR, THE CORPORATE NAMES, AND THE STATE OF INCORPORATION; AND

(IV) IF A SOLE PROPRIETORSHIP, THE FULL NAME OF THE SOLE PROPRIETOR AND THE NAME OF THE BUSINESS ENTITY; AND

(6) A LIST OF ALL LICENSES AND PERMITS ISSUED TO THE APPLICANT BY ANY OTHER STATE THAT AUTHORIZES THE APPLICANT TO MANUFACTURE PRESCRIPTION DRUGS.

(D) THE INFORMATION REQUIRED UNDER THIS SECTION SHALL BE CERTIFIED BY A NOTARY PUBLIC.

(E) (1) THE BOARD SHALL ISSUE A MANUFACTURER LICENSE TO ANY APPLICANT THAT MEETS THE REQUIREMENTS OF THIS SECTION.

(2) IF THE BOARD DENIES A WHOLESALE DISTRIBUTOR LICENSE TO AN APPLICANT, IT SHALL GIVE THE APPLICANT WRITTEN NOTICE OF ITS DECISION AND THE REASONS FOR THE DENIAL.

(F) (1) A MANUFACTURER LICENSE SHALL BE VALID FOR A PERIOD OF 1 YEAR.

(2) A LICENSE EXPIRES ON A DATE SET BY THE BOARD, UNLESS THE LICENSE IS RENEWED FOR AN ADDITIONAL 1-YEAR PERIOD AS PROVIDED IN THIS SUBSECTION.

(3) AT LEAST 1 MONTH BEFORE THE LICENSE EXPIRES, THE BOARD SHALL PROVIDE TO THE LICENSEE A RENEWAL NOTICE THAT STATES:

(I) THE DATE ON WHICH THE CURRENT LICENSE EXPIRES;

(II) THE DATE BY WHICH THE RENEWAL APPLICATION MUST BE RECEIVED BY THE BOARD FOR THE RENEWAL TO BE PROCESSED BEFORE THE LICENSE EXPIRES; AND

(III) THE AMOUNT OF THE RENEWAL FEE.

(4) BEFORE THE LICENSE EXPIRES, THE LICENSEE MAY RENEW THE LICENSE FOR AN ADDITIONAL 1-YEAR PERIOD, IF THE LICENSEE SUBMITS TO THE BOARD:

(I) A RENEWAL APPLICATION ON THE FORM THE BOARD REQUIRES; AND

(II) PAYS TO THE BOARD A RENEWAL FEE SET BY THE BOARD.

12-6B-13.

INFORMATION PROVIDED UNDER THIS SUBTITLE MAY NOT BE DISCLOSED TO ANY INDIVIDUAL OR ENTITY EXCEPT:

(1) THE BOARD OR OTHER STATE OR FEDERAL REGULATORY OR LAW ENFORCEMENT AGENCY; AND

(2) FOR A LAWFUL PURPOSE.

12-6B-14.

(A) THE BOARD SHALL ADOPT REGULATIONS DEFINING AN EMERGENCY SITUATION THAT WOULD PERMIT AN IMMEDIATE TRANSFER, WITHOUT PEDIGREE INFORMATION, OF PRESCRIPTION DRUGS BETWEEN ENTITIES LICENSED BY THE BOARD.

(B) THE REGULATIONS SHALL REQUIRE NOTIFICATION OF THE IMMEDIATE TRANSFER TO THE BOARD WITH 24 HOURS OF THE TRANSFER.

(C) THE BOARD SHALL DETERMINE WHETHER THE IMMEDIATE TRANSFER MEETS THE DEFINITION OF AN EMERGENCY SITUATION.

(D) IF THE BOARD DETERMINES THAT THE IMMEDIATE TRANSFER DOES NOT MEET THE DEFINITION OF AN EMERGENCY SITUATION, THE BOARD MAY TAKE ACTION UNDER § 12-6B-11 OR § 12-6B-20 OF THIS SUBTITLE.

12-6B-15.

(A) A WHOLESALE DISTRIBUTOR SHALL RECEIVE PRESCRIPTION DRUG RETURNS OR EXCHANGES FROM A PHARMACY OR CHAIN PHARMACY WAREHOUSE IN ACCORDANCE WITH THE TERMS AND CONDITIONS OF THE AGREEMENT BETWEEN THE WHOLESALE DISTRIBUTOR AND THE PHARMACY OR CHAIN PHARMACY WAREHOUSE.

(B) RETURNS MAY INCLUDE EXPIRED, DAMAGED, OR RECALLED PRESCRIPTION DRUGS BEING RETURNED TO EITHER THE ORIGINAL MANUFACTURER OR A THIRD PARTY RETURNS PROCESSOR.

(C) RETURNS OR EXCHANGES ARE NOT SUBJECT TO THE REQUIREMENTS OF § 12-6B-17 OF THIS SUBTITLE.

(D) THE BOARD SHALL REQUIRE WHOLESALE DISTRIBUTORS TO:

(1) POLICE AND MAINTAIN THE SECURITY OF THEIR RETURNS PROCESS; AND

(2) PREVENT THE ENTRY OF ADULTERATED OR COUNTERFEIT PRESCRIPTION DRUGS INTO THE PRESCRIPTION DRUG DISTRIBUTION SYSTEM.

12-6B-16.

(A) (1) BEFORE THE INITIAL PURCHASE OR SALE OF PRESCRIPTION DRUGS TO OR FROM A WHOLESALE DISTRIBUTOR, THE WHOLESALE DISTRIBUTOR SHALL ADHERE TO THE DUE DILIGENCE REQUIREMENTS AND STANDARDS SET BY THE BOARD.

(2) THE BOARD MAY WAIVE THE DUE DILIGENCE REQUIREMENTS IF THE INFORMATION HAS BEEN VERIFIED BY A THIRD PARTY WORKING ON BEHALF OF THE BOARD.

(B) A WHOLESALE DISTRIBUTOR:

(1) MAY SUPPLY PRESCRIPTION DRUGS ONLY TO A RECIPIENT LICENSED BY THE BOARD; AND

(2) SHALL CONTACT THE BOARD TO VERIFY THE AUTHENTICITY OF THE LICENSE.

(C) (1) EXCEPT AS PROVIDED IN PARAGRAPH (2) OF THIS SUBSECTION, A WHOLESALE DISTRIBUTOR MAY DELIVER PRESCRIPTION DRUGS ONLY TO:

(I) THE PREMISES LISTED ON THE RECIPIENT'S LICENSE; OR

(II) AN AUTHORIZED AGENT OF THE RECIPIENT AT THE PREMISES OF THE WHOLESALE DISTRIBUTOR IF:

1. THE IDENTITY AND AUTHORIZATION OF THE AUTHORIZED AGENT IS PROPERLY ESTABLISHED; AND

2. THIS METHOD OF RECEIPT IS EMPLOYED ONLY TO MEET THE IMMEDIATE NEEDS OF A PARTICULAR PATIENT.

(2) (I) PRESCRIPTION DRUGS MAY BE SUPPLIED TO A HOSPITAL PHARMACY RECEIVING AREA PROVIDED THAT A PHARMACIST OR AUTHORIZED RECEIVING PERSONNEL OF THE HOSPITAL PHARMACY SIGNS, AT THE TIME OF DELIVERY, A RECEIPT INDICATING THE TYPE AND QUANTITY OF THE PRESCRIPTION DRUG RECEIVED.

(II) ANY DISCREPANCY BETWEEN THE TYPE AND QUANTITY OF THE PRESCRIPTION DRUG INDICATED ON THE RECEIPT AND THE TYPE AND QUANTITY OF THE PRESCRIPTION DRUG ACTUALLY RECEIVED SHALL BE REPORTED TO THE DELIVERING WHOLESALE DISTRIBUTOR BY THE NEXT BUSINESS DAY AFTER THE DELIVERY TO THE HOSPITAL PHARMACY RECEIVING AREA.

(D) (1) EXCEPT AS PROVIDED IN PARAGRAPH (3) OF THIS SUBSECTION, ONLY THE OWNER OF RECORD, THE CHIEF EXECUTIVE OFFICER, OR THE CHIEF FINANCIAL OFFICER OF AN ENTITY LICENSED TO RECEIVE PRESCRIPTION DRUGS MAY:

(I) PROVIDE PAYMENT FOR PRESCRIPTION DRUGS TO A WHOLESALE DISTRIBUTOR; OR

(II) USE CREDIT TO ESTABLISH AN ACCOUNT WITH A WHOLESALE DISTRIBUTOR FOR THE PURCHASE OF PRESCRIPTION DRUGS.

(2) ANY ACCOUNT ESTABLISHED FOR THE PURCHASE OF PRESCRIPTION DRUGS MUST BEAR THE NAME OF THE LICENSEE.

(3) (I) NOTWITHSTANDING PARAGRAPH (1) OF THIS SUBSECTION, STANDARD ORDERING AND PURCHASING BUSINESS PRACTICES MAY OCCUR BETWEEN:

1. PHARMACIES;

2. CHAIN PHARMACY WAREHOUSES;

3. WHOLESALE DISTRIBUTORS; AND

4. MANUFACTURERS.

(II) STANDARD ORDERING AND PURCHASING BUSINESS PRACTICES INCLUDE PRACTICES IN WHICH:

1. PRESCRIPTION DRUGS ARE SHIPPED BY A MANUFACTURER OR MANUFACTURERS TO A PHARMACY OR CHAIN PHARMACY WAREHOUSE AND THE PAYMENT PROCESSED THROUGH A WHOLESALER;

2. A PHARMACY OR CHAIN PHARMACY WAREHOUSE ORDERS PRESCRIPTION DRUGS FROM ONE OR MORE DIFFERENT MANUFACTURERS AND THE ORDERS ARE AGGREGATED BY A WHOLESALER AND DELIVERED TO THE PHARMACY OR CHAIN PHARMACY WAREHOUSE IN THE SAME DELIVERY; OR

3. THE BOARD AUTHORIZES THE PRACTICE IN REGULATION.

12-6B-17.

(A) (1) A WHOLESALE DISTRIBUTOR SHALL ESTABLISH AND MAINTAIN INVENTORIES AND RECORDS OF ALL TRANSACTIONS REGARDING THE RECEIPT AND DISTRIBUTION OR OTHER DISPOSITION OF PRESCRIPTION DRUGS.

(2) RECORDS SHALL INCLUDE PEDIGREES FOR WHOLESALE DISTRIBUTIONS OF ALL PRESCRIPTION DRUGS THAT OCCUR BOTH INSIDE AND OUTSIDE THE NORMAL DISTRIBUTION CHANNEL.

(B) A WHOLESALE DISTRIBUTOR OF A PRESCRIPTION DRUG, INCLUDING A REPACKAGER, BUT EXCLUDING THE ORIGINAL MANUFACTURER OF THE FINISHED

FORM OF THE PRESCRIPTION DRUG, THAT IS IN POSSESSION OF A PEDIGREE FOR A PRESCRIPTION DRUG AND ATTEMPTS TO FURTHER DISTRIBUTE THAT PRESCRIPTION DRUG, SHALL AFFIRMATIVELY VERIFY BEFORE ANY DISTRIBUTION OF A PRESCRIPTION DRUG OCCURS THAT EACH TRANSACTION LISTED ON THE PEDIGREE HAS OCCURRED.

(C) (1) THE PEDIGREE SHALL INCLUDE ALL NECESSARY IDENTIFYING INFORMATION CONCERNING EACH SALE IN THE CHAIN OF DISTRIBUTION OF THE PRESCRIPTION DRUG FROM THE MANUFACTURER, THROUGH ACQUISITION AND SALE BY EACH WHOLESALE DISTRIBUTOR OR REPACKAGER, UNTIL FINAL SALE TO A CHAIN PHARMACY WAREHOUSE, OR TO A PHARMACY OR OTHER PERSON DISPENSING OR ADMINISTERING THE DRUG.

(2) THE NECESSARY CHAIN OF DISTRIBUTION INFORMATION SHALL INCLUDE:

(I) NAME, ADDRESS, TELEPHONE NUMBER, AND IF AVAILABLE, THE ELECTRONIC MAIL ADDRESS, OF EACH OWNER AND EACH WHOLESALE DISTRIBUTOR OF THE PRESCRIPTION DRUG;

(II) NAME AND ADDRESS OF EACH LOCATION FROM WHICH THE PRODUCT WAS SHIPPED, IF DIFFERENT FROM THE OWNER'S;

(III) TRANSACTION DATES; AND

(IV) CERTIFICATION THAT EACH RECIPIENT HAS AUTHENTICATED THE PEDIGREE.

(3) THE PEDIGREE SHALL ALSO INCLUDE:

(I) THE NAME OF THE PRESCRIPTION DRUG;

(II) DOSAGE FORM AND STRENGTH OF THE PRESCRIPTION DRUG;

(III) SIZE OF THE CONTAINER;

(IV) NUMBER OF CONTAINERS;

(V) LOT NUMBER OF THE PRESCRIPTION DRUG; AND

(VI) NAME OF THE MANUFACTURER OF THE FINISHED DOSAGE FORM.

(D) EACH PEDIGREE SHALL BE:

(1) MAINTAINED BY THE PURCHASER AND THE WHOLESALE DISTRIBUTOR FOR 3 YEARS FROM THE DATE OF SALE OR TRANSFER; AND

(2) AVAILABLE FOR INSPECTION OR USE WITHIN 2 CALENDAR DAYS ON A REQUEST OF AN AUTHORIZED OFFICER OF THE LAW.

(E) (1) THE BOARD SHALL CONDUCT A STUDY OF ELECTRONIC PEDIGREES AND OTHER ADVANCED TECHNOLOGY FOR TRACKING PRESCRIPTION DRUGS.

(2) THE STUDY SHALL BE CONDUCTED IN CONSULTATION WITH PARTICIPANTS CHOSEN BY THE BOARD.

(3) BASED ON THE STUDY, THE BOARD MAY MANDATE ELECTRONIC PEDIGREES OR OTHER ADVANCED TRACKING TECHNOLOGY.

(4) THE IMPLEMENTATION DATE FOR ANY MANDATED ELECTRONIC PEDIGREE OR OTHER ADVANCED TRACKING TECHNOLOGY SHALL BE NO SOONER THAN DECEMBER 31, 2007.

(5) THE BOARD SHALL REPORT THE FINDINGS AND RECOMMENDATIONS OF ITS STUDY TO THE GOVERNOR AND, IN ACCORDANCE WITH § 2-1246 OF THE STATE GOVERNMENT ARTICLE, THE GENERAL ASSEMBLY, ON OR BEFORE JANUARY 1, 2007.

(6) THE BOARD SHALL ADOPT REGULATIONS RELATING TO MANDATED ELECTRONIC PEDIGREES OR OTHER ADVANCED TRACKING TECHNOLOGY AT LEAST 180 DAYS PRIOR TO THE IMPLEMENTATION DATE.

(F) THE BOARD SHALL EXEMPT A PHARMACY BENEFITS ENTITY FROM THIS SECTION, IF:

(1) THE PHARMACY BENEFITS ENTITY'S PURCHASES ARE SOLELY FROM A MANUFACTURER OR A WHOLESALE DISTRIBUTOR IN THE NORMAL DISTRIBUTION CHANNEL; AND

(2) ANY SUBSEQUENT SALE OR FURTHER DISTRIBUTIONS ARE:

(I) WITHIN THE NORMAL DISTRIBUTION CHANNEL;

(II) TO A HOSPITAL; OR

(III) TO A PHYSICIAN.

(G) A DISTRIBUTION FROM A PHARMACY BENEFITS ENTITY TO A WHOLESALE DISTRIBUTOR IS SUBJECT TO THE REQUIREMENTS OF SUBSECTIONS (A) THROUGH (D) OF THIS SECTION.

(H) THE BOARD MAY RECOGNIZE THE LAWS AND REGULATIONS OF OTHER STATES AND U.S. TERRITORIES PERTAINING TO PRESCRIPTION DRUG PEDIGREE REQUIREMENTS AS SATISFYING THE PEDIGREE REQUIREMENTS OF THIS SECTION.

12-6B-18.

(A) THE BOARD SHALL ISSUE AN ORDER REQUIRING THE APPROPRIATE PERSON, INCLUDING THE WHOLESALE DISTRIBUTOR OR RETAILER OF A PRESCRIPTION DRUG, TO IMMEDIATELY CEASE DISTRIBUTION OF THE DRUG IF THE BOARD FINDS A REASONABLE PROBABILITY THAT:

(1) A WHOLESALE DISTRIBUTOR HAS:

(I) VIOLATED A PROVISION IN THIS SUBTITLE;

(II) FALSIFIED A PEDIGREE; OR

(III) SOLD, DISTRIBUTED, TRANSFERRED, MANUFACTURED, REPACKAGED, HANDLED, OR HELD A COUNTERFEIT PRESCRIPTION DRUG INTENDED FOR HUMAN USE;

(2) THE PRESCRIPTION DRUG AT ISSUE AS A RESULT OF A VIOLATION IN PARAGRAPH (1) OF THIS SUBSECTION COULD CAUSE SERIOUS, ADVERSE HEALTH CONSEQUENCES OR DEATH; AND

(3) OTHER PROCEDURES WOULD RESULT IN UNREASONABLE DELAY.

(B) (1) AN ORDER UNDER SUBSECTION (A) OF THIS SECTION SHALL PROVIDE THE PERSON SUBJECT TO THE ORDER WITH AN OPPORTUNITY FOR AN INFORMAL HEARING BEFORE THE BOARD, TO BE HELD NOT LATER THAN 10 DAYS AFTER THE DATE OF THE ISSUANCE OF THE ORDER, ON THE ACTIONS REQUIRED BY THE ORDER.

(2) IF, AFTER PROVIDING AN OPPORTUNITY FOR A HEARING, THE BOARD DETERMINES THAT INADEQUATE GROUNDS EXIST TO SUPPORT THE ACTIONS REQUIRED BY THE ORDER, THE BOARD SHALL VACATE THE ORDER.

12-6B-19.

(A) A PERSON MAY NOT PERFORM OR CAUSE THE PERFORMANCE OF OR AID AND ABET ANY OF THE FOLLOWING ACTS:

(1) (I) FAILURE TO OBTAIN A LICENSE IN ACCORDANCE WITH THIS SUBTITLE; OR

(II) OPERATING WITHOUT A VALID LICENSE WHEN A LICENSE IS REQUIRED BY THIS SUBTITLE;

(2) THE SALE, DISTRIBUTION, OR TRANSFER OF A PRESCRIPTION DRUG TO A PERSON THAT IS NOT AUTHORIZED BY LAW TO RECEIVE THE PRESCRIPTION DRUG, IN VIOLATION OF § 12-6B-16(B) OF THIS SUBTITLE;

(3) FAILURE TO DELIVER PRESCRIPTION DRUGS TO SPECIFIED PREMISES, AS REQUIRED UNDER § 12-6B-16(C) OF THIS SUBTITLE;

(4) ACCEPTING PAYMENT OR CREDIT FOR THE SALE OF PRESCRIPTION DRUGS IN VIOLATION OF § 12-6B-16(D) OF THIS SUBTITLE;

(5) FAILURE TO MAINTAIN OR PROVIDE PEDIGREES AS REQUIRED UNDER THIS SUBTITLE;

(6) FAILURE TO OBTAIN, PASS, OR AUTHENTICATE A PEDIGREE, AS REQUIRED UNDER THIS SUBTITLE;

(7) FAILURE TO PROVIDE INFORMATION TO A PURCHASER OR SELLER OF PRESCRIPTION DRUGS THAT IS NECESSARY TO CREATE, OBTAIN, PASS, OR AUTHENTICATE A PEDIGREE;

(8) PROVIDING THE BOARD OR ANY OF ITS REPRESENTATIVES OR ANY FEDERAL OFFICIAL WITH FALSE OR FRAUDULENT RECORDS OR MAKING FALSE OR FRAUDULENT STATEMENTS REGARDING ANY MATTER WITHIN THE PROVISIONS OF THIS SUBTITLE;

(9) OBTAINING OR ATTEMPTING TO OBTAIN A PRESCRIPTION DRUG BY FRAUD, DECEIT, MISREPRESENTATION, OR ENGAGING IN MISREPRESENTATION OR FRAUD IN THE WHOLESALE DISTRIBUTION OF A PRESCRIPTION DRUG;

(10) EXCEPT FOR THE WHOLESALE DISTRIBUTION BY MANUFACTURERS OF A PRESCRIPTION DRUG THAT HAS BEEN DELIVERED INTO COMMERCE PURSUANT TO AN APPLICATION APPROVED UNDER FEDERAL LAW BY THE U.S. FOOD AND DRUG ADMINISTRATION, THE MANUFACTURE, REPACKAGING, SALE, TRANSFER, DELIVERY, HOLDING, OR OFFERING FOR SALE OF ANY PRESCRIPTION DRUG THAT IS:

(I) ADULTERATED;

(II) MISBRANDED;

(III) COUNTERFEIT;

(IV) SUSPECTED OF BEING COUNTERFEIT; OR

(V) OTHERWISE RENDERED UNFIT FOR DISTRIBUTION;

(11) EXCEPT FOR THE WHOLESALE DISTRIBUTION BY MANUFACTURERS OF A PRESCRIPTION DRUG THAT HAS BEEN DELIVERED INTO COMMERCE PURSUANT TO AN APPLICATION APPROVED UNDER FEDERAL LAW BY THE FOOD AND DRUG ADMINISTRATION, THE ADULTERATION, MISBRANDING, OR COUNTERFEITING OF ANY PRESCRIPTION DRUG;

(12) (I) THE RECEIPT OF ANY PRESCRIPTION DRUG WITH KNOWLEDGE THAT THE DRUG IS ADULTERATED, MISBRANDED, STOLEN, OBTAINED BY FRAUD OR DECEIT, COUNTERFEIT, OR SUSPECTED OF BEING COUNTERFEIT; OR

(II) THE DELIVERY OR PROFFERED DELIVERY OF SUCH DRUG FOR PAY OR OTHERWISE; OR

(13) (I) THE ALTERATION, MUTILATION, DESTRUCTION, OBLITERATION, OR REMOVAL OF THE WHOLE OR ANY PART OF THE LABELING OF A PRESCRIPTION DRUG; OR

(II) THE COMMISSION OF ANY OTHER ACT WITH RESPECT TO A PRESCRIPTION DRUG THAT RESULTS IN THE PRESCRIPTION DRUG BEING MISBRANDED.

(B) IT IS NOT UNLAWFUL FOR A PRESCRIPTION DRUG MANUFACTURER OR AGENT OF A PRESCRIPTION DRUG MANUFACTURER TO OBTAIN OR ATTEMPT TO OBTAIN A PRESCRIPTION DRUG FOR THE SOLE PURPOSE OF TESTING THE PRESCRIPTION DRUG FOR AUTHENTICITY.

12-6B-20.

A PERSON WHO VIOLATES ANY PROVISION OF THIS SUBTITLE IS GUILTY OF A FELONY AND ON CONVICTION IS SUBJECT TO A FINE NOT TO EXCEED $500,000 OR IMPRISONMENT NOT TO EXCEED 25 YEARS OR BOTH.

12-707.

(b) A person who violates any provision of the following sections of this title is guilty of a misdemeanor and on conviction is subject to a fine not exceeding $1,000 or imprisonment not exceeding 1 year or both:

[(1) § 12-602 ("Distribution permits");]

[(2)] (1) § 12-701 ("Practicing pharmacy without license");

[(3)] (2) § 12-702 ("License obtained by false representation");

[(4)] (3) § 12-703 ("Operating a pharmacy without permit"); and

[(5)] (4) § 12-704 ("Misrepresentations").

SECTION 3. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2006.