HOUSE BILL 1030

J2 (7lr2476)

ENROLLED BILL

— Health and Government Operations/Education, Health, and Environmental Affairs —

Introduced by ~~**Delegate Montgomery**~~ **Delegates Montgomery, Hammen, Benson, Bromwell, Costa, Elliott, Hubbard, Kach, Kipke, Kullen, McDonough, Mizeur, Morhaim, Nathan–Pulliam, Oaks, Pena–Melnyk, Pendergrass, Riley, V. Turner, and Weldon**

Read and Examined by Proofreaders:

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Proofreader.

_____
Proofreader.

Sealed with the Great Seal and presented to the Governor, for his approval this

_____ day of _____ at _____ o'clock, _____M.

_____
Speaker.

CHAPTER _____

AN ACT concerning

~~**State Board of Pharmacy – Wholesale Drug Distribution – Permit Requirements**~~

Wholesale Distributor Permitting and Prescription Drug Integrity Act

~~FOR the purpose of altering the requirements for obtaining a wholesale distributor's permit to include a certain inspection and the posting of a certain bond; requiring a certain pedigree for prescription drugs or devices distributed in the State; requiring the State Board of Pharmacy to adopt regulations regarding~~

EXPLANATION: **CAPITALS INDICATE MATTER ADDED TO EXISTING LAW**.
[Brackets**]** indicate matter deleted from existing law.
Underlining indicates amendments to bill.
~~Strike out~~ indicates matter stricken from the bill by amendment or deleted from the law by amendment.
Italics indicate opposite chamber/conference committee amendments.

~~certain pedigree and inspection requirements; defining a certain term; and generally relating to permit requirements for wholesale drug distribution.~~

FOR the purpose of requiring a wholesale distributor to hold a permit issued by the State Board of Pharmacy before the wholesale distributor engages in the wholesale distribution of prescription drugs or devices in the State; requiring certain entities to hold a wholesale distributor permit; providing that certain requirements for obtaining a permit do not apply to a manufacturer who distributes certain prescription drugs; requiring a permit to be displayed in a certain manner; providing that a permit is not transferable; prohibiting a person from purchasing or obtaining a prescription drug or device unless it is purchased or obtained from certain persons; authorizing the Board to grant a certain deemed status to certain wholesale distributors and to issue a permit to certain wholesale distributors by reciprocity; establishing certain requirements and procedures for applying for a permit; prohibiting the Board from issuing a permit unless the Board or its designee takes certain actions; establishing requirements for certain criminal history records checks and a certain surety bond; requiring the Board to provide a certain notification to an applicant within a certain period of time; providing for the expiration and renewal of a permit; authorizing the Board to deny, suspend, or revoke a permit under certain circumstances; requiring the Board to adopt regulations that require certain inspections; authorizing the Board to adopt regulations establishing certain requirements; prohibiting the disclosure of certain information provided by a wholesale distributor, except to certain entities for certain purposes; establishing certain procedures for returns or exchanges of prescription drugs; authorizing a wholesale distributor to supply or deliver prescription drugs only to certain persons; providing for certain exceptions; prohibiting a wholesale distributor from accepting payment or allowing the use of certain credit for a certain purpose; prohibiting a wholesale distributor from operating out of a residence; requiring a pedigree for certain prescription drug distributions; requiring certain entities to be authorized distributors of record for a certain purpose; establishing certain penalties for a *certain* violation of certain provisions of this Act; requiring the Board to adopt certain regulations on or before a certain date; requiring the Board to provide a certain report to the Governor and certain legislative committees on or before a certain date each year; repealing certain provisions of law relating to permits for the distribution of prescription drugs or devices; requiring the Secretary of Health and Mental Hygiene, in conjunction with the Board, to convene a certain workgroup to recommend to the Board a certain date for implementing electronic track and trace pedigree technology; requiring the Board to establish a certain date for implementation of electronic track and trace pedigree technology; requiring the Board to submit certain reports to certain legislative committees on or before certain dates; defining certain terms; making conforming changes; and

generally relating to permit and pedigree requirements for wholesale drug distributors.

BY repealing and reenacting, with amendments,
Article – Health Occupations
Section 12–601
Annotated Code of Maryland
(2005 Replacement Volume and 2006 Supplement)

BY repealing ~~and reenacting, with amendments,~~
Article – Health Occupations
Section 12–602
Annotated Code of Maryland
(2005 Replacement Volume and 2006 Supplement)

BY adding to
Article – Health Occupations
Section 12–6C–01 through 12–6C–13 to be under the new subtitle "Subtitle 6C. Wholesale Distributor Permitting and Prescription Drug Integrity Act"
Annotated Code of Maryland
(2005 Replacement Volume and 2006 Supplement)

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

Article – Health Occupations

12–601.

(a) Subject to the hearing provisions of § 12–315 of this title, for a violation of this subtitle**, SUBTITLE 6C OF THIS TITLE,** or any regulation adopted under **[**§ 12–602 of this subtitle**]** **SUBTITLE 6C OF THIS TITLE**, the Board may:

(1) Deny a permit to an applicant;

(2) Reprimand a permit holder;

(3) Place a permit holder on probation; or

(4) Suspend or revoke a permit.

(b) A person aggrieved by a final action of the Board under this subtitle **OR SUBTITLE 6C OF THIS TITLE** may not appeal to the Secretary or the Board of Review but may appeal as provided under Title 10, Subtitle 2 of the State Government Article.

~~12–602.~~

~~(a) (1) In this section the following words have the meanings indicated.~~

~~(2) "Distribution permit" means a permit issued by the Board under this section to distribute prescription drugs or devices into, out of, or within the State as a distributor, jobber, manufacturer, or wholesaler, wherever located.~~

~~(3) "PEDIGREE" MEANS A DOCUMENT OR ELECTRONIC FILE CONTAINING INFORMATION THAT RECORDS EACH DISTRIBUTION OF A PRESCRIPTION DRUG OR DEVICE.~~

~~[(3)]~~ ~~(4)~~ ~~"Prescription drugs or devices" means any drug or device that, because of its toxicity or other potential for harmful effect, the method of its use, or the collateral measures necessary for its use, is required by federal law to bear a cautionary label warning against dispensing without a prescription or is designated by the Department as not safe for use except under the supervision of a practitioner licensed to administer drugs or devices of this nature.~~

~~(b) This section does not affect any person while distributing:~~

~~(1) Feed for livestock or poultry;~~

~~(2) Fertilizers;~~

~~(3) Fungicides;~~

~~(4) Insecticide;~~

~~(5) Land plaster;~~

~~(6) Lime;~~

~~(7) Seeds; or~~

~~(8) Devices, drugs, or supplies of any kind for the treatment, care, or cure of farm animals.~~

~~(c) A person shall hold a distribution permit issued by the Board before the person may distribute prescription drugs or devices as a distributor, jobber, manufacturer, or wholesaler.~~

~~(d) To qualify for a distribution permit, an applicant shall:~~

~~(1) Satisfy the Board that the applicant will distribute prescription drugs or devices in compliance with the restrictions specified in subsection (c) of this section; [and]~~

~~(2) SUBMIT EVIDENCE OF AN INSPECTION PERFORMED:~~

~~(I) BY THE BOARD OR AN APPROVED AGENT OF THE BOARD FOR EACH FACILITY OPERATED BY THE APPLICANT; AND~~

~~(II) IN ACCORDANCE WITH REGULATIONS ADOPTED BY THE BOARD; AND~~

~~[~~(2)~~]~~ (3) ~~Comply with any pertinent regulations adopted under subsection (i) of this section.~~

~~(e) A distribution permit holder may distribute prescription drugs or devices only:~~

~~(1) To the following persons:~~

~~(i) An authorized prescriber;~~

~~(ii) A pharmacy permit holder;~~

~~(iii) A distribution permit holder; or~~

~~(iv) Any other person approved by the Board; [and]~~

~~(2) IF THE DISTRIBUTED PRESCRIPTION DRUGS OR DEVICES ARE ACCOMPANIED BY A PEDIGREE ESTABLISHED IN ACCORDANCE WITH REGULATIONS ADOPTED BY THE BOARD; AND~~

~~[~~(2)~~]~~ (3) ~~In compliance with any rules and regulations adopted under this section.~~

~~(f) To apply for a distribution permit, an applicant shall:~~

~~(1) Submit an application to the Board on the form that the Board provides; [and]~~

~~(2)~~ **SUBMIT TO THE BOARD, IN ACCORDANCE WITH REGULATIONS ADOPTED BY THE BOARD, 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; AND**

~~[(2)]~~ **(3)** ~~Pay to the Board an application fee set by the Board.~~

~~(g) The Board shall issue a distribution permit to any applicant who meets the requirements of this section.~~

~~(h) A distribution permit issued under this section authorizes the distribution permit holder to distribute prescription drugs or devices as a distributor, jobber, manufacturer, or wholesaler while the distribution permit is effective.~~

~~(i) To protect the public health and safety, the Board~~**:**

~~(1)~~ ~~[may]~~ **MAY** ~~adopt rules and regulations regarding the distribution of prescription drugs or devices including regulations regarding:~~

~~[(1)]~~ **(I)** ~~Qualifications and information required from an applicant seeking issuance or renewal of a distribution permit;~~

~~[(2)]~~ **(II)** ~~Minimum requirements for the receipt, storage, and handling of prescription drugs or devices, security precautions, quality control, record keeping, and establishment of written procedures, policy, and responsibilities of personnel;~~

~~[(3)]~~ **(III)** ~~The education and experience of personnel employed in positions responsible for duties referenced in [paragraph (2)]~~ **ITEM (II)** ~~of this [subsection]~~ **ITEM** ~~and generally responsible for carrying out those duties that are subject to State licensure requirements under this subtitle; and~~

~~[(4)]~~ **(IV)** ~~Disciplinary action to be taken against a permit holder who is convicted of or pleads guilty or nolo contendere to a violation of State, federal, or~~

~~local drug laws or who violates regulations promulgated by the Board under this section;~~ **AND**

~~(2)~~ **SHALL ADOPT REGULATIONS SPECIFYING:**

~~(I)~~ **PEDIGREE REQUIREMENTS; AND**

~~(II)~~ **ROUTINE INSPECTION REQUIREMENTS.**

~~(j) (1) A distribution permit expires on the December 31 after its effective date, unless the distribution permit is renewed for a 1–year term as provided in this subsection.~~

~~(2) At least 1 month before a distribution permit expires, the Board shall send to the distribution permit holder, by first–class mail to the last known address of the distribution permit holder, a renewal notice that contains a statement of:~~

~~(i) The date on which the current distribution permit expires;~~

~~(ii) The date by which the renewal application must be received by the Board for the renewal to be issued and mailed before the distribution permit expires; and~~

~~(iii) The amount of the renewal fee.~~

~~(3) Before a distribution permit expires, a distribution permit holder periodically may renew it for an additional 1–year term, if the distribution permit holder:~~

~~(i) Otherwise is entitled to a distribution permit;~~

~~(ii) Pays to the Board a renewal fee set by the Board; and~~

~~(iii) Submits to the Board a renewal application on the form that the Board requires.~~

~~(4) The Board shall renew the distribution permit of each distribution permit holder who meets the requirements of this section and any regulation adopted under this section.~~

~~(k) Each distribution permit shall be displayed conspicuously in the place for which it is issued.~~

~~(l) A distribution permit is not transferable.~~

~~(m) Subject to any other restriction provided by law, a person may not purchase or obtain any prescription drugs or devices unless the drug or device is obtained from a distribution permit holder, a licensed pharmacist, or an authorized prescriber.~~

~~(n) A person may not violate any rule or regulation adopted under this section.~~

~~(o) A distribution permit is void on conviction of the distribution permit holder for any violation of:~~

~~(1) This section; or~~

~~(2) Any rule or regulation adopted by the Board under this section.~~

SUBTITLE 6C. WHOLESALE DISTRIBUTOR PERMITTING AND PRESCRIPTION DRUG INTEGRITY ACT.

12–6C–01.

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

(B) "AUTHENTICATE" MEANS TO AFFIRMATIVELY VERIFY, BEFORE ANY WHOLESALE DISTRIBUTION OF A PRESCRIPTION DRUG OCCURS, THAT EACH TRANSACTION LISTED ON THE PEDIGREE FOR THE PRESCRIPTION DRUG HAS OCCURRED.

(C) "AUTHORIZED DISTRIBUTOR OF RECORD" MEANS A WHOLESALE DISTRIBUTOR WITH WHOM A MANUFACTURER HAS ESTABLISHED AN ONGOING RELATIONSHIP TO DISTRIBUTE THE MANUFACTURER'S PRESCRIPTION DRUG.

(D) "CO–LICENSED PARTNER" MEANS A PERSON IN A RELATIONSHIP IN WHICH TWO OR MORE PERSONS HAVE THE RIGHT TO ENGAGE IN THE MANUFACTURING OR MARKETING OF A PRESCRIPTION DRUG, CONSISTENT WITH

THE U.S. FOOD AND DRUG ADMINISTRATION'S IMPLEMENTATION OF THE FEDERAL PRESCRIPTION DRUG MARKETING ACT.

(E) "CO–LICENSED PRODUCT" MEANS A PRODUCT OF CO–LICENSED PARTNERS.

(F) "DESIGNATED REPRESENTATIVE" MEANS AN INDIVIDUAL WHO:

(1) IS DESIGNATED BY A WHOLESALE DISTRIBUTOR;

(2) SERVES AS THE PRIMARY CONTACT OF THE WHOLESALE DISTRIBUTOR WITH THE BOARD; AND

(3) IS ACTIVELY INVOLVED IN AND AWARE OF THE DAILY OPERATION OF THE WHOLESALE DISTRIBUTOR.

(G) "DROP SHIPMENT" MEANS THE SALE OF A PRESCRIPTION DRUG:

(1) TO A WHOLESALE DISTRIBUTOR BY:

(I) THE MANUFACTURER OF THE PRESCRIPTION DRUG; OR

(II) THE MANUFACTURER'S CO–LICENSED PARTNER, THIRD PARTY LOGISTICS PROVIDER, OR MANUFACTURER'S EXCLUSIVE DISTRIBUTOR; AND

(2) THROUGH WHICH:

(I) THE WHOLESALE DISTRIBUTOR OR A PHARMACY WAREHOUSE TAKES TITLE TO BUT NOT PHYSICAL POSSESSION OF THE PRESCRIPTION DRUG;

(II) THE WHOLESALE DISTRIBUTOR INVOICES THE PHARMACY, PHARMACY WAREHOUSE, OR OTHER PERSON AUTHORIZED BY LAW TO DISPENSE OR ADMINISTER THE PRESCRIPTION DRUG TO A PATIENT; AND

(III) THE PHARMACY, PHARMACY WAREHOUSE, OR OTHER AUTHORIZED PERSON RECEIVES DELIVERY OF THE PRESCRIPTION DRUG DIRECTLY FROM:

1. THE MANUFACTURER; *OR*

2. THE MANUFACTURER'S THIRD PARTY LOGISTICS PROVIDER OR THE MANUFACTURER'S EXCLUSIVE DISTRIBUTOR~~; OR~~.

~~**3. AN AUTHORIZED DISTRIBUTOR OF RECORD THAT PURCHASED THE PRESCRIPTION DRUG DIRECTLY FROM THE MANUFACTURER, THE MANUFACTURER'S THIRD PARTY LOGISTICS PROVIDER, OR THE MANUFACTURER'S EXCLUSIVE DISTRIBUTOR.**~~

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

(I) "INTRACOMPANY SALES" MEANS A:

(1) TRANSACTION OR TRANSFER OF PRESCRIPTION DRUGS BETWEEN A DIVISION, SUBSIDIARY, PARENT, OR AFFILIATED OR RELATED COMPANY UNDER COMMON OWNERSHIP AND CONTROL OF A CORPORATE ENTITY; OR

(2) TRANSACTION OR TRANSFER OF A CO–LICENSED PRODUCT BETWEEN CO–LICENSED PARTNERS.

(J) "MANUFACTURER" MEANS A PERSON LICENSED OR APPROVED BY THE U.S. FOOD AND DRUG ADMINISTRATION TO ENGAGE IN THE MANUFACTURE OF PRESCRIPTION DRUGS OR PRESCRIPTION DEVICES, CONSISTENT WITH THE DEFINITION OF "MANUFACTURER" UNDER THE U.S. FOOD AND DRUG ADMINISTRATION'S REGULATIONS AND GUIDELINES IMPLEMENTING THE PRESCRIPTION DRUG MARKETING ACT.

(K) "MANUFACTURER'S EXCLUSIVE DISTRIBUTOR" MEANS A PERSON WHO:

(1) CONTRACTS WITH A MANUFACTURER TO PROVIDE OR COORDINATE WAREHOUSING, DISTRIBUTION, OR OTHER SERVICES ON BEHALF OF THE MANUFACTURER; AND

(2) TAKES TITLE TO THE MANUFACTURER'S PRESCRIPTION DRUG, BUT DOES NOT HAVE GENERAL RESPONSIBILITY TO DIRECT THE SALE OR DISPOSITION OF THE MANUFACTURER'S PRESCRIPTION DRUG.

(L) "NORMAL DISTRIBUTION CHANNEL" MEANS A CHAIN OF CUSTODY FOR A PRESCRIPTION DRUG THAT, DIRECTLY OR BY DROP SHIPMENT, GOES:

(1) FROM:

(I) A MANUFACTURER OF THE PRESCRIPTION DRUG; OR

(II) THE MANUFACTURER'S CO–LICENSED PARTNER, THIRD PARTY LOGISTICS PROVIDER, OR MANUFACTURER'S EXCLUSIVE DISTRIBUTOR; AND

(2) TO:

(I) A PHARMACY OR OTHER DESIGNATED PERSON AUTHORIZED BY LAW TO DISPENSE OR ADMINISTER THE PRESCRIPTION DRUG TO A PATIENT;

(II) A WHOLESALE DISTRIBUTOR TO A PHARMACY OR OTHER DESIGNATED PERSON AUTHORIZED BY LAW TO DISPENSE OR ADMINISTER THE PRESCRIPTION DRUG TO A PATIENT;

(III) A WHOLESALE DISTRIBUTOR TO A PHARMACY WAREHOUSE TO THE PHARMACY WAREHOUSE'S INTRACOMPANY PHARMACY OR OTHER DESIGNATED PERSON AUTHORIZED BY LAW TO DISPENSE OR ADMINISTER THE PRESCRIPTION DRUG TO A PATIENT;

(IV) A PHARMACY WAREHOUSE TO THE PHARMACY WAREHOUSE'S INTRACOMPANY PHARMACY OR OTHER DESIGNATED PERSON AUTHORIZED BY LAW TO DISPENSE OR ADMINISTER THE PRESCRIPTION DRUG TO A PATIENT; OR

(V) AN AUTHORIZED DISTRIBUTOR OF RECORD TO ANOTHER AUTHORIZED DISTRIBUTOR OF RECORD SOLELY FOR DISTRIBUTION TO AN OFFICE–BASED HEALTH CARE PRACTITIONER AUTHORIZED BY LAW TO DISPENSE OR ADMINISTER THE PRESCRIPTION DRUG TO A PATIENT.

(M) "ONGOING RELATIONSHIP" MEANS A RELATIONSHIP THAT EXISTS BETWEEN A WHOLESALE DISTRIBUTOR, INCLUDING ANY AFFILIATED GROUP OF THE WHOLESALE DISTRIBUTOR, AS DEFINED IN § 1504 OF THE INTERNAL REVENUE CODE, AND A MANUFACTURER WHEN THE WHOLESALE DISTRIBUTOR:

(1) HAS A WRITTEN AGREEMENT CURRENTLY IN EFFECT WITH THE MANUFACTURER EVIDENCING THE ONGOING RELATIONSHIP; AND

(2) IS LISTED ON THE MANUFACTURER'S CURRENT LIST OF AUTHORIZED DISTRIBUTORS OF RECORD.

(N) "PEDIGREE" MEANS A DOCUMENT OR ELECTRONIC FILE CONTAINING INFORMATION THAT RECORDS EACH WHOLESALE DISTRIBUTION OF A PRESCRIPTION DRUG.

(O) "PHARMACY WAREHOUSE" MEANS A PHYSICAL LOCATION FOR STORAGE OF PRESCRIPTION DRUGS THAT:

(1) SERVES AS A CENTRAL WAREHOUSE; AND

(2) PERFORMS INTRACOMPANY SALES OR TRANSFERS OF THE PRESCRIPTION DRUGS TO A GROUP OF PHARMACIES THAT ARE UNDER COMMON OWNERSHIP AND CONTROL WITH THE PHARMACY WAREHOUSE.

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

(2) "PRESCRIPTION DRUG" INCLUDES:

(I) A BIOLOGICAL PRODUCT; AND

(II) FINISHED DOSAGE FORMS AND BULK DRUG SUBSTANCES SUBJECT TO § 503(B) OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.

(3) "PRESCRIPTION DRUG" DOES NOT INCLUDE BLOOD AND BLOOD COMPONENTS INTENDED FOR TRANSFUSION OR BIOLOGICAL PRODUCTS THAT ARE ALSO MEDICAL DEVICES.

(Q) "PRESCRIPTION DEVICE" MEANS ANY DEVICE REQUIRED BY FEDERAL LAW OR REGULATION TO BE DISPENSED ONLY BY A PRESCRIPTION.

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

(2) "REPACKAGE" DOES NOT INCLUDE CHANGES TO A CONTAINER, WRAPPER, OR LABELING OF A PRESCRIPTION DRUG COMPLETED BY THE PHARMACIST RESPONSIBLE FOR DISPENSING THE PRESCRIPTION DRUG TO A PATIENT.

(S) "REPACKAGER" MEANS A PERSON WHO REPACKAGES PRESCRIPTION DRUGS.

(T) "THIRD PARTY LOGISTICS PROVIDER" MEANS A PERSON WHO:

(1) CONTRACTS WITH A MANUFACTURER TO PROVIDE OR COORDINATE WAREHOUSING, DISTRIBUTION, OR OTHER SERVICES ON BEHALF OF THE MANUFACTURER; BUT

(2) DOES NOT TAKE TITLE TO THE PRESCRIPTION DRUG OR HAVE GENERAL RESPONSIBILITY TO DIRECT THE PRESCRIPTION DRUG'S SALE OR DISPOSITION.

(U) (1) "WHOLESALE DISTRIBUTION" MEANS THE DISTRIBUTION OF PRESCRIPTION DRUGS OR PRESCRIPTION DEVICES TO PERSONS OTHER THAN A CONSUMER OR PATIENT.

(2) "WHOLESALE DISTRIBUTION" DOES NOT INCLUDE:

(I) INTRACOMPANY SALES;

(II) THE SALE, PURCHASE, DISTRIBUTION, TRADE, OR TRANSFER OF A PRESCRIPTION DRUG OR AN OFFER TO SELL, PURCHASE, DISTRIBUTE, TRADE, OR TRANSFER A PRESCRIPTION DRUG FOR EMERGENCY MEDICAL REASONS;

(III) THE DISTRIBUTION OF SAMPLES OF A PRESCRIPTION DRUG BY A MANUFACTURER'S REPRESENTATIVE;

(IV) PRESCRIPTION DRUG RETURNS CONDUCTED BY A HOSPITAL, HEALTH CARE ENTITY, OR CHARITABLE INSTITUTION IN ACCORDANCE WITH 21 CFR § 203.23;

(V) THE SALE OF MINIMAL QUANTITIES OF PRESCRIPTION DRUGS BY RETAIL PHARMACIES TO LICENSED HEALTH CARE PRACTITIONERS FOR OFFICE USE;

(VI) THE SALE, PURCHASE, OR TRADE OF A PRESCRIPTION DRUG, AN OFFER TO SELL, PURCHASE, OR TRADE A PRESCRIPTION DRUG, OR THE DISPENSING OF A PRESCRIPTION DRUG IN ACCORDANCE WITH A PRESCRIPTION;

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

(VIII) THE SALE, PURCHASE, DISTRIBUTION, TRADE, OR TRANSFER OF A PRESCRIPTION DRUG FROM ONE AUTHORIZED DISTRIBUTOR OF RECORD TO ONE ADDITIONAL AUTHORIZED DISTRIBUTOR OF RECORD IF:

1. THE MANUFACTURER HAS STATED IN WRITING TO THE RECEIVING AUTHORIZED DISTRIBUTOR OF RECORD THAT THE MANUFACTURER IS UNABLE TO SUPPLY THE PRESCRIPTION DRUG; AND

2. THE SUPPLYING AUTHORIZED DISTRIBUTOR OF RECORD STATES IN WRITING THAT THE PRESCRIPTION DRUG BEING SUPPLIED HAD UNTIL THAT TIME BEEN EXCLUSIVELY IN THE NORMAL DISTRIBUTION CHANNEL;

(IX) THE DELIVERY OF, OR OFFER TO DELIVER, A PRESCRIPTION DRUG BY A COMMON CARRIER SOLELY IN THE COMMON CARRIER'S USUAL COURSE OF BUSINESS OF TRANSPORTING PRESCRIPTION DRUGS, IF THE COMMON CARRIER DOES NOT STORE, WAREHOUSE, OR TAKE LEGAL OWNERSHIP OF THE PRESCRIPTION DRUG; OR

(X) THE SALE OR TRANSFER FROM A RETAIL PHARMACY OR PHARMACY WAREHOUSE OF EXPIRED, DAMAGED, RETURNED, OR RECALLED

PRESCRIPTION DRUGS TO THE ORIGINAL MANUFACTURER OR TO A THIRD PARTY RETURNS PROCESSOR.

(V) (1) "WHOLESALE DISTRIBUTOR" MEANS A PERSON THAT IS ENGAGED IN THE WHOLESALE DISTRIBUTION OF PRESCRIPTION DRUGS OR PRESCRIPTION DEVICES.

(2) "WHOLESALE DISTRIBUTOR" INCLUDES:

(I) A MANUFACTURER;

(II) A REPACKAGER;

(III) AN OWN–LABEL DISTRIBUTOR;

(IV) A PRIVATE–LABEL DISTRIBUTOR;

(V) A JOBBER;

(VI) A BROKER;

(VII) A WAREHOUSE, INCLUDING A MANUFACTURER'S OR DISTRIBUTOR'S WAREHOUSE;

(VIII) A MANUFACTURER'S EXCLUSIVE DISTRIBUTOR OR AN AUTHORIZED DISTRIBUTOR OF RECORD;

(IX) A DRUG WHOLESALER OR DISTRIBUTOR;

(X) AN INDEPENDENT WHOLESALE DRUG TRADER;

(XI) A THIRD PARTY LOGISTICS PROVIDER;

(XII) A RETAIL PHARMACY THAT CONDUCTS WHOLESALE DISTRIBUTION, IF THE WHOLESALE DISTRIBUTION BUSINESS ACCOUNTS FOR MORE THAN 5% OF THE RETAIL PHARMACY'S ANNUAL SALES; AND

(XIII) A PHARMACY WAREHOUSE THAT CONDUCTS WHOLESALE DISTRIBUTION.

(W) "WHOLESALE DISTRIBUTOR PERMIT" MEANS A PERMIT ISSUED BY THE BOARD UNDER THIS SUBTITLE TO DISTRIBUTE PRESCRIPTION DRUGS OR PRESCRIPTION DEVICES INTO, OUT OF, OR WITHIN THE STATE AS A WHOLESALE DISTRIBUTOR.

12–6C–02.

THIS SUBTITLE DOES NOT AFFECT ANY PERSON WHILE DISTRIBUTING:

(1) FEED FOR LIVESTOCK OR POULTRY;

(2) FERTILIZERS;

(3) FUNGICIDES;

(4) INSECTICIDE;

(5) LAND PLASTER;

(6) LIME;

(7) SEEDS; OR

(8) DEVICES, DRUGS, OR SUPPLIES OF ANY KIND FOR THE TREATMENT, CARE, OR CURE OF FARM ANIMALS.

12–6C–03.

(A) A WHOLESALE DISTRIBUTOR SHALL HOLD A PERMIT ISSUED BY THE BOARD BEFORE THE WHOLESALE DISTRIBUTOR ENGAGES IN WHOLESALE DISTRIBUTION IN THE STATE.

(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 MANUFACTURER WHO DISTRIBUTES ITS OWN PRESCRIPTION DRUGS APPROVED BY THE U.S. FOOD AND DRUG ADMINISTRATION.

(C) A MANUFACTURER'S EXCLUSIVE DISTRIBUTOR AND A THIRD–PARTY LOGISTICS PROVIDER SHALL HOLD A WHOLESALE DISTRIBUTOR PERMIT ISSUED UNDER THIS SUBTITLE.

(D) A WHOLESALE DISTRIBUTOR PERMIT SHALL BE DISPLAYED CONSPICUOUSLY IN THE PLACE OF BUSINESS FOR WHICH THE PERMIT IS ISSUED.

(E) A WHOLESALE DISTRIBUTOR PERMIT IS NOT TRANSFERABLE.

(F) SUBJECT TO ANY OTHER RESTRICTION PROVIDED BY LAW, A PERSON MAY NOT PURCHASE OR OBTAIN A PRESCRIPTION DRUG OR PRESCRIPTION DEVICE UNLESS THE PRESCRIPTION DRUG OR PRESCRIPTION DEVICE IS PURCHASED OR OBTAINED FROM A PERSON WHO HOLDS A WHOLESALE DISTRIBUTOR PERMIT, A LICENSED PHARMACIST, OR AN AUTHORIZED PRESCRIBER.

12–6C–04.

(A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE MEANINGS INDICATED.

(2) "ACCREDITATION ORGANIZATION" MEANS A PRIVATE ENTITY THAT CONDUCTS INSPECTIONS AND SURVEYS OF WHOLESALE DISTRIBUTORS BASED ON NATIONALLY RECOGNIZED AND DEVELOPED STANDARDS.

(3) "DEEMED STATUS" MEANS A STATUS UNDER WHICH A WHOLESALE DISTRIBUTOR MAY BE EXEMPT FROM ROUTINE INSPECTIONS AND OTHER PERMIT REQUIREMENTS OF THE BOARD.

(B) IF THE BOARD DETERMINES THAT THE STANDARDS OF AN ACCREDITATION ORGANIZATION ARE EQUAL TO OR MORE STRINGENT THAN STATE PERMIT REQUIREMENTS, THE BOARD MAY:

(1) ACCEPT THE ACCREDITATION OF A WHOLESALE DISTRIBUTOR BY AN ACCREDITATION ORGANIZATION AS EVIDENCE THAT THE WHOLESALE DISTRIBUTOR HAS MET STATE PERMIT REQUIREMENTS; AND

(2) GRANT THE WHOLESALE DISTRIBUTOR DEEMED STATUS.

(C) THE BOARD MAY ISSUE A PERMIT BY RECIPROCITY TO A WHOLESALE DISTRIBUTOR WHO HOLDS A LICENSE OR PERMIT UNDER THE LAWS OF ANOTHER STATE IF THE BOARD DETERMINES THAT THE REQUIREMENTS OF THAT STATE ARE SUBSTANTIALLY EQUIVALENT TO THE REQUIREMENTS OF THIS STATE.

(D) THE BOARD OR ITS DESIGNEE MAY INSPECT A WHOLESALE DISTRIBUTOR WHO IS ACCREDITED OR HAS BEEN ISSUED A PERMIT BY RECIPROCITY TO:

(1) DETERMINE COMPLIANCE WITH ANY PERMIT REQUIREMENT UNDER THIS SUBTITLE; OR

(2) INVESTIGATE A COMPLAINT.

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:

(I) FINGERPRINTS NECESSARY TO CONDUCT A CRIMINAL HISTORY RECORDS CHECK; AND

(II) THE FOLLOWING:

1. NAME;

2. PLACES OF RESIDENCE FOR THE PAST 7 YEARS;

3. DATE AND PLACE OF BIRTH;

4. 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. 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. 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. 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. 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. 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;

(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 RECORDKEEPING 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 RECORDKEEPING 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 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.

(F) (1) THIS SUBSECTION DOES NOT APPLY TO A PHARMACY WAREHOUSE THAT IS NOT ENGAGED IN WHOLESALE DISTRIBUTION.

(2) AN APPLICANT FOR A WHOLESALE DISTRIBUTOR PERMIT SHALL SUBMIT A SURETY BOND OF AT LEAST $100,000, 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 AN ACCOUNT ESTABLISHED BY THE STATE UNDER PARAGRAPH (6) OF THIS SUBSECTION.

(3) 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.

(4) 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.

(5) A SINGLE SURETY BOND SHALL COVER ALL FACILITIES OPERATED BY THE APPLICANT IN THE STATE.

(6) 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–06.

(A) A WHOLESALE DISTRIBUTOR PERMIT EXPIRES ON DECEMBER 31 AFTER ITS EFFECTIVE DATE, UNLESS THE WHOLESALE DISTRIBUTOR PERMIT IS RENEWED FOR AN ADDITIONAL 2–YEAR TERM AS PROVIDED IN THIS SECTION.

(B) (1) EXCEPT AS PROVIDED IN PARAGRAPH (2) OF THIS SUBSECTION, AT LEAST 1 MONTH BEFORE A WHOLESALE DISTRIBUTOR PERMIT EXPIRES, THE BOARD SHALL SEND TO THE WHOLESALE DISTRIBUTOR PERMIT HOLDER A RENEWAL NOTICE BY FIRST–CLASS MAIL TO THE LAST KNOWN ADDRESS OF THE PERMIT HOLDER.

(2) IF REQUESTED BY A WHOLESALE DISTRIBUTOR PERMIT HOLDER, THE BOARD SHALL SEND TO THE PERMIT HOLDER, AT LEAST TWO TIMES WITHIN THE MONTH BEFORE A WHOLESALE DISTRIBUTOR PERMIT EXPIRES, A RENEWAL NOTICE BY ELECTRONIC MEANS TO THE LAST KNOWN ELECTRONIC ADDRESS OF THE PERMIT HOLDER.

(3) IF A RENEWAL NOTICE SENT BY ELECTRONIC MEANS UNDER PARAGRAPH (2) OF THIS SUBSECTION IS RETURNED TO THE BOARD AS UNDELIVERABLE, THE BOARD SHALL SEND TO THE WHOLESALE DISTRIBUTOR PERMIT HOLDER A RENEWAL NOTICE BY FIRST–CLASS MAIL TO THE LAST KNOWN ADDRESS OF THE PERMIT HOLDER.

(4) A RENEWAL NOTICE SENT UNDER THIS SUBSECTION SHALL STATE:

(I) THE DATE ON WHICH THE CURRENT WHOLESALE DISTRIBUTOR PERMIT EXPIRES;

(II) THE DATE BY WHICH THE RENEWAL APPLICATION MUST BE RECEIVED BY THE BOARD FOR THE RENEWAL TO BE ISSUED AND MAILED BEFORE THE CURRENT WHOLESALE DISTRIBUTOR PERMIT EXPIRES; AND

(III) THE AMOUNT OF THE RENEWAL FEE.

(5) BEFORE A WHOLESALE DISTRIBUTOR PERMIT EXPIRES, A WHOLESALE DISTRIBUTOR PERMIT HOLDER PERIODICALLY MAY RENEW IT FOR AN ADDITIONAL 2–YEAR TERM, IF THE WHOLESALE DISTRIBUTOR PERMIT HOLDER:

(I) OTHERWISE IS ENTITLED TO A WHOLESALE DISTRIBUTOR PERMIT;

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

(III) SUBMITS TO THE BOARD A RENEWAL APPLICATION ON THE FORM THAT THE BOARD REQUIRES.

(6) (I) THE RENEWAL APPLICATION FORM SHALL SET FORTH THE INFORMATION THAT THE WHOLESALE DISTRIBUTOR PROVIDED UNDER § 12–6C–05 OF THIS SUBTITLE.

(II) WITHIN 30 DAYS AFTER RECEIVING THE FORM, THE WHOLESALE DISTRIBUTOR SHALL IDENTIFY AND STATE UNDER OATH TO THE BOARD ALL CHANGES OR CORRECTIONS TO THE INFORMATION THAT WAS PROVIDED UNDER § 12–6C–05 OF THIS SUBTITLE.

(7) THE BOARD SHALL RENEW THE WHOLESALE DISTRIBUTOR PERMIT OF A WHOLESALE DISTRIBUTOR PERMIT HOLDER WHO MEETS THE REQUIREMENTS OF THIS SUBTITLE AND ANY REGULATIONS ADOPTED UNDER THIS SUBTITLE.

(8) THE BOARD MAY DENY, SUSPEND, OR REVOKE THE PERMIT OF A WHOLESALE DISTRIBUTOR IF THE BOARD DETERMINES THAT THE WHOLESALE DISTRIBUTOR NO LONGER QUALIFIES FOR A PERMIT.

12–6C–07.

THE BOARD:

(1) SHALL ADOPT REGULATIONS THAT REQUIRE ROUTINE INSPECTIONS OF WHOLESALE DISTRIBUTOR FACILITIES; AND

(2) MAY ADOPT REGULATIONS ESTABLISHING:

(I) MINIMUM REQUIREMENTS FOR THE RECEIPT, STORAGE, AND HANDLING OF PRESCRIPTION DRUGS OR PRESCRIPTION DEVICES, SECURITY PRECAUTIONS, QUALITY CONTROL, RECORD KEEPING, AND PROCEDURES, POLICY, AND RESPONSIBILITIES OF PERSONNEL; AND

(II) EDUCATION AND EXPERIENCE REQUIREMENTS FOR PERSONNEL EMPLOYED IN POSITIONS RESPONSIBLE FOR CARRYING OUT THE DUTIES:

1. REFERENCED IN ITEM (I) OF THIS ITEM; OR

2. RELATED TO STATE PERMIT REQUIREMENTS UNDER THIS SUBTITLE.

12–6C–08.

INFORMATION PROVIDED BY A WHOLESALE DISTRIBUTOR OR AN APPLICANT FOR A WHOLESALE DISTRIBUTOR PERMIT UNDER THIS SUBTITLE MAY NOT BE DISCLOSED TO ANY PERSON OR ENTITY EXCEPT A STATE LICENSING OR PERMITTING AUTHORITY, STATE BOARD, OR GOVERNMENT AGENCY THAT NEEDS THE INFORMATION FOR LICENSING, PERMITTING, MONITORING, OR LAW ENFORCEMENT PURPOSES.

12–6C–09.

(A) (1) A WHOLESALE DISTRIBUTOR SHALL RECEIVE PRESCRIPTION DRUG RETURNS OR EXCHANGES FROM A PHARMACY OR PHARMACY WAREHOUSE ACCORDING TO THE TERMS AND CONDITIONS OF THE AGREEMENT BETWEEN THE WHOLESALE DISTRIBUTOR AND THE PHARMACY OR PHARMACY WAREHOUSE.

(2) RETURNS OF EXPIRED, DAMAGED, RECALLED, OR OTHERWISE NONSALEABLE PRESCRIPTION DRUGS SHALL BE DISTRIBUTED BY THE RECEIVING WHOLESALE DISTRIBUTOR ONLY TO EITHER THE ORIGINAL MANUFACTURER OR A THIRD PARTY RETURNS PROCESSOR.

(3) RETURNS OR EXCHANGES OF PRESCRIPTION DRUGS, SALEABLE OR OTHERWISE, INCLUDING ANY REDISTRIBUTION BY A RECEIVING WHOLESALER, ARE NOT SUBJECT TO THE PEDIGREE REQUIREMENTS OF § 12–6C–10 OF THIS SUBTITLE IF THEY ARE EXEMPT FROM THE PEDIGREE REQUIREMENT OF THE U.S. FOOD AND DRUG ADMINISTRATION'S CURRENTLY APPLICABLE PRESCRIPTION DRUG MARKETING ACT GUIDELINES.

(4) WHOLESALE DISTRIBUTORS AND PHARMACIES SHALL BE ACCOUNTABLE FOR:

(I) ADMINISTERING THEIR RETURNS PROCESS; AND

(II) ENSURING THAT THE RETURNS PROCESS IS SECURE AND DOES NOT PERMIT THE ENTRY OF ADULTERATED AND COUNTERFEIT PRODUCT.

(B) A WHOLESALE DISTRIBUTOR MAY SUPPLY PRESCRIPTION DRUGS ONLY TO A PERSON AUTHORIZED BY LAW TO DISPENSE OR RECEIVE PRESCRIPTION DRUGS.

(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 PERMIT; OR

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

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

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

(2) (I) PRESCRIPTION DRUGS MAY BE SUPPLIED TO A HOSPITAL PHARMACY RECEIVING AREA IF A PHARMACIST OR AUTHORIZED RECEIVING PERSONNEL OF THE HOSPITAL PHARMACY SIGNS, AT THE TIME OF DELIVERY, A RECEIPT SHOWING 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 RECEIVED:

1. SHALL BE REPORTED TO THE DELIVERING WHOLESALE DISTRIBUTOR BY THE NEXT BUSINESS DAY AFTER THE DELIVERY TO THE HOSPITAL PHARMACY RECEIVING AREA; AND

2. MAY BE REPORTED TO THE BOARD FOR INVESTIGATION.

(D) (1) A WHOLESALE DISTRIBUTOR MAY NOT ACCEPT PAYMENT OR ALLOW THE USE OF A PERSON'S CREDIT TO ESTABLISH AN ACCOUNT FOR THE PURCHASE OF PRESCRIPTION DRUGS FROM ANY PERSON OTHER THAN THE OWNER OF RECORD, THE CHIEF EXECUTIVE OFFICER, OR THE CHIEF FINANCIAL OFFICER LISTED ON THE LICENSE OR PERMIT OF A PERSON LEGALLY AUTHORIZED TO RECEIVE PRESCRIPTION DRUGS.

(2) ANY ACCOUNT ESTABLISHED FOR THE PURCHASE OF PRESCRIPTION DRUGS SHALL BEAR THE NAME OF THE LICENSE OR PERMIT HOLDER.

(E) A WHOLESALE DISTRIBUTOR MAY NOT OPERATE OUT OF A RESIDENCE.

12–6C–10.

(A) A PERSON WHO IS ENGAGED IN THE WHOLESALE DISTRIBUTION OF A PRESCRIPTION DRUG THAT LEAVES, OR HAS EVER LEFT, THE NORMAL DISTRIBUTION CHANNEL SHALL PROVIDE, BEFORE EACH WHOLESALE DISTRIBUTION OF THE PRESCRIPTION DRUG, A PEDIGREE TO THE PERSON WHO RECEIVES THE PRESCRIPTION DRUG.

(B) A RETAIL PHARMACY OR PHARMACY WAREHOUSE SHALL COMPLY WITH THE REQUIREMENTS OF THIS SECTION ONLY IF THE PHARMACY OR PHARMACY WAREHOUSE ENGAGES IN THE WHOLESALE DISTRIBUTION OF A PRESCRIPTION DRUG IN THE STATE.

(C) (1) TO BE CONSIDERED PART OF THE NORMAL DISTRIBUTION CHANNEL, A WHOLESALE DISTRIBUTOR, A MANUFACTURER'S EXCLUSIVE DISTRIBUTOR, AND A MANUFACTURER'S THIRD PARTY LOGISTICS PROVIDER ALSO MUST BE AN AUTHORIZED DISTRIBUTOR OF RECORD.

(2) NOTWITHSTANDING PARAGRAPH (1) OF THIS SUBSECTION, A PHARMACY WAREHOUSE THAT IS NOT AN AUTHORIZED DISTRIBUTOR OF RECORD SHALL BE CONSIDERED PART OF THE NORMAL DISTRIBUTION CHANNEL.

(D) EACH PERSON WHO ENGAGES IN THE WHOLESALE DISTRIBUTION OF A PRESCRIPTION DRUG, INCLUDING REPACKAGERS BUT EXCLUDING THE ORIGINAL MANUFACTURER OF THE FINISHED FORM OF THE PRESCRIPTION DRUG, WHO IS PROVIDED A PEDIGREE FOR THE PRESCRIPTION DRUG AND ATTEMPTS TO FURTHER DISTRIBUTE THE PRESCRIPTION DRUG, SHALL AUTHENTICATE, BEFORE ANY DISTRIBUTION OF THE PRESCRIPTION DRUG OCCURS, THAT EACH TRANSACTION LISTED ON THE PEDIGREE HAS OCCURRED.

(E) THE PEDIGREE SHALL INCLUDE:

(1) ALL NECESSARY IDENTIFYING INFORMATION RELATING TO EACH SALE IN THE CHAIN OF DISTRIBUTION OF THE PRESCRIPTION DRUG FROM THE MANUFACTURER OR THE MANUFACTURER'S THIRD PARTY LOGISTICS PROVIDER, CO–LICENSED PARTNER, OR MANUFACTURER'S EXCLUSIVE DISTRIBUTOR, THROUGH ACQUISITION AND SALE BY ANY WHOLESALE DISTRIBUTOR OR REPACKAGER, UNTIL FINAL SALE TO A PHARMACY OR OTHER PERSON DISPENSING OR ADMINISTERING THE PRESCRIPTION DRUG, INCLUDING:

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

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

(III) TRANSACTION DATES; AND

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

(2) THE NAME OF THE PRESCRIPTION DRUG;

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

(4) THE SIZE OF THE CONTAINER;

(5) THE NUMBER OF CONTAINERS;

(6) THE LOT NUMBER AND NATIONAL DRUG CODE OF THE PRESCRIPTION DRUG; AND

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

(F) EACH PEDIGREE FOR A PRESCRIPTION DRUG 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 5 BUSINESS DAYS ON REQUEST OF THE BOARD, THE BOARD'S DESIGNEE, OR AN AUTHORIZED LAW ENFORCEMENT OFFICER.

12–6C–11.

(A) (1) IF A PERSON *KNOWINGLY* VIOLATES ANY PROVISION OF THIS SUBTITLE OR ANY REGULATION ADOPTED UNDER THIS SUBTITLE, THE BOARD MAY IMPOSE A FINE NOT TO EXCEED $500,000.

(2) BEFORE THE BOARD IMPOSES A FINE, THE BOARD SHALL CONSIDER THE APPROPRIATENESS OF THE FINE IN RELATION TO:

(I) THE SIZE OF THE WHOLESALE DISTRIBUTOR;

(II) THE GRAVITY OF THE VIOLATION FOR WHICH THE FINE IS TO BE IMPOSED;

(III) THE GOOD FAITH OF THE WHOLESALE DISTRIBUTOR; AND

(IV) ANY PREVIOUS VIOLATIONS BY THE WHOLESALE DISTRIBUTOR.

(B) IN ADDITION TO THE PENALTY PROVIDED IN SUBSECTION (A) OF THIS SECTION, THE BOARD ALSO MAY TAKE DISCIPLINARY ACTION AGAINST A PERMIT HOLDER WHO IS CONVICTED OF OR PLEADS GUILTY OR NOLO CONTENDERE TO A VIOLATION OF STATE, FEDERAL, OR LOCAL DRUG LAWS.

12–6C–12.

ON OR BEFORE JANUARY 1, 2008, THE BOARD SHALL ADOPT REGULATIONS TO IMPLEMENT THIS SUBTITLE.

12–6C–13.

ON OR BEFORE JANUARY 1, 2008, AND ON OR BEFORE JANUARY 1 OF EACH SUBSEQUENT YEAR, THE BOARD SHALL REPORT TO THE GOVERNOR AND, IN ACCORDANCE WITH § 2–1246 OF THE STATE GOVERNMENT ARTICLE, TO THE GENERAL ASSEMBLY ON THE IMPLEMENTATION OF THIS SUBTITLE.

SECTION 2. AND BE IT FURTHER ENACTED, That:

(a) The Secretary of Health and Mental Hygiene, in conjunction with the State Board of Pharmacy, shall convene a workgroup of manufacturers, distributors, and pharmacies that sell and distribute prescription drugs in the State to recommend to the Board a target date for implementation of electronic track and trace pedigree technology.

(b) The workgroup shall:

(1) survey the availability of electronic track and trace pedigree technology across the entire prescription pharmaceutical supply chain;

(2) determine when electronic track and trace pedigree technology will be universally available across the entire prescription pharmaceutical supply chain; and

(3) based on its determination of the universal availability of electronic track and trace pedigree technology, make recommendations to the Board for a target date, no sooner than July 1, 2010, for implementation of electronic track

and trace pedigree technology across the entire prescription pharmaceutical supply chain.

(c) Taking into consideration the recommendations of the workgroup, the Board shall establish a target date, no sooner than July 1, 2010, for implementation of electronic track and trace pedigree technology.

(d) In accordance with § 2–1246 of the State Government Article, the Board shall submit to the Senate Education, Health, and Environmental Affairs Committee and the House Health and Government Operations Committee:

(1) on or before January 1, 2009, a report with the recommendations of the workgroup; and

(2) on or before July 1, 2009, the target date for implementation of electronic track and trace pedigree technology established by the Board.

SECTION ~~2.~~ 3. AND BE IT FURTHER ENACTED, That this Act shall take effect July 1, 2007.

Approved:

_____

Governor.

_____

Speaker of the House of Delegates.

_____

President of the Senate.