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By: **Delegates Stern, Burns, and Lee**
Introduced and read first time: February 9, 2005
Assigned to: Health and Government Operations

A BILL ENTITLED

AN ACT concerning

Wholesale Prescription Drug and Device Distribution Protection and Licensing Act of 2005

FOR the purpose of prohibiting a wholesale distributor from knowingly taking certain actions with regard to prescription drugs or devices; making certain provisions of law pertaining to impoundment of drugs and records applicable to a holder of or applicant for a wholesale distributor's license; repealing requirements pertaining to a distribution permit issued by the State Board of Pharmacy; establishing requirements for a person engaging in the wholesale distribution of prescription drugs or devices within the State; providing that certain wholesale distributors shall receive certain drug or device returns in a certain manner; requiring a person to hold a wholesale distributor's license issued by the Board before the person may distribute prescription drugs or devices in the State; requiring an applicant for a wholesale distributor's license to submit a certain application and pay a certain fee; establishing requirements for a license application; making certain information submitted with a license application proprietary and confidential and not subject to disclosure, except as otherwise required by law; providing for the expiration and renewal of a license; requiring a wholesale distributor's license to be displayed in a certain place and in a certain manner; providing that a wholesale distributor's license is not transferable; requiring the Board to set fees for the issuance and renewal of licenses to cover certain costs; requiring a manufacturer of a prescription drug or device sold in the State to file a certain list and provide a certain notification to the Board; requiring the Board to publish a certain list and update the list within a certain time frame; requiring the Board to conduct certain criminal and financial background checks; specifying the items included in the background check; requiring the Board to conduct a certain inspection within a certain time frame and using an inspector who meets certain requirements; requiring an applicant for a license to submit to the Board a certain surety bond or evidence of other equivalent means of security and to keep the bond or other equivalent means of security in place for a certain period of time; providing for a certain waiver of the surety bond requirements under certain circumstances; authorizing the Board to accept a certain surety bond under certain circumstances; authorizing the Board to make a claim against the bond or other equivalent means of security under certain circumstances and within a certain

period of time; requiring a wholesale distributor to identify a certain designated representative; establishing a Prescription Drug and Device Wholesaler Advisory Council within the Board; providing for the membership, leadership, meeting frequency, staff, reimbursement, and duties of the Council; requiring a certain wholesale distributor to provide a certain statement of record before a certain sale is made; requiring the Board, on or before a certain date, to establish a certain electronic product identification tracking system; requiring the Board to report on its progress on or before a certain date and in a certain manner; requiring a purchasing wholesale distributor to obtain from a selling wholesale distributor certain items; prohibiting a person from purchasing or obtaining prescription drugs or devices unless the prescription drug or device is obtained from certain authorized persons; prohibiting a person from violating certain requirements; establishing certain penalties for violations; providing for a certain appeal; requiring the Board to adopt certain regulations; defining certain terms; and generally relating to wholesale prescription drug and device distribution protection and licensing.

BY repealing and reenacting, without amendments,
Article - Health - General
Section 21-201(a)
Annotated Code of Maryland
(2000 Replacement Volume and 2004 Supplement)

BY adding to
Article - Health - General
Section 21-201(g) and 21-258.1
Annotated Code of Maryland
(2000 Replacement Volume and 2004 Supplement)

BY repealing and reenacting, with amendments,
Article - Health - General
Section 21-1113 and 21-1215
Annotated Code of Maryland
(2000 Replacement Volume and 2004 Supplement)

BY repealing
Article - Health Occupations
Section 12-601 and 12-602
Annotated Code of Maryland
(2000 Replacement Volume and 2004 Supplement)

BY adding to
Article - Health Occupations
Section 12-6B-01 through 12-6B-14, inclusive, to be under the new subtitle "Subtitle 6B. Wholesale Prescription Drug and Device Distribution

Protection and Licensing"
Annotated Code of Maryland
(2000 Replacement Volume and 2004 Supplement)

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

Article - Health - General

21-201.

(a) In this subtitle the following words have the meanings indicated.

(G) "WHOLESALE DISTRIBUTOR" HAS THE MEANING STATED IN § 12-6B-01 OF THE HEALTH OCCUPATIONS ARTICLE.

21-258.1.

A WHOLESALE DISTRIBUTOR MAY NOT KNOWINGLY:

(1) TAMPER WITH, COUNTERFEIT, ADULTERATE, MISBRAND, OR DIVERT PRESCRIPTION DRUGS OR DEVICES;

(2) PURCHASE, TRANSFER, SELL, OR DISTRIBUTE PRESCRIPTION DRUGS OR DEVICES TO OR FROM PERSONS NOT AUTHORIZED TO POSSESS PRESCRIPTION DRUGS OR DEVICES;

(3) PURCHASE, TRANSFER, SELL, OR DISTRIBUTE PRESCRIPTION DRUGS OR DEVICES THAT HAVE BEEN TAMPERED WITH, COUNTERFEITED, ADULTERATED, MISBRANDED, OR DIVERTED; OR

(4) FORGE, COUNTERFEIT, OR TAMPER WITH DOCUMENTATION REQUIRED UNDER § 12-6B-11 OF THE HEALTH OCCUPATIONS ARTICLE OR ANY OTHER STATE OR FEDERAL LAW REGULATING THE PURCHASE, TRANSFER, DELIVERY, OR SALE OF PRESCRIPTION DRUGS OR DEVICES.

21-1113.

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

(2) "Authorized prescriber" means a licensed dentist, licensed physician, licensed podiatrist, licensed veterinarian, certified nurse midwife to the extent permitted under § 8-601 of the Health Occupations Article, certified nurse practitioner to the extent permitted under § 8-508 of the Health Occupations Article, or other individual authorized by law to prescribe prescription or nonprescription drugs or devices.

(3) "Board" means a health occupation licensing board authorized to issue a permit, license, or certificate under the Health Occupations Article.

(4) (i) "Controlled dangerous substance" means a drug, substance, or immediate precursor listed in Schedule I through Schedule V in Title 5 of the Criminal Law Article.

(ii) "Controlled dangerous substance" does not include tobacco or a distilled spirit, wine, or malt beverage.

(5) "Drug" means a prescription or nonprescription drug.

(6) "LICENSE HOLDER" MEANS A HOLDER OF, OR APPLICANT FOR, A WHOLESALE DISTRIBUTOR'S LICENSE ISSUED BY THE STATE BOARD OF PHARMACY UNDER TITLE 12 OF THE HEALTH OCCUPATIONS ARTICLE.

[(6)] (7) "Nonprescription drug" means a drug which may be sold without a prescription and which is labeled for consumer use in accordance with the requirements of the laws and regulations of this State and the federal government.

[(7)] (8) "Permit holder" means a holder of, or applicant for:

(i) A pharmacy permit, manufacturer's permit, or HOME HEMODIALYSIS distributor's permit issued by the State Board of Pharmacy under Title 12 of the Health Occupations Article; or

(ii) A dispensing permit issued by a board under the authority of § 12-102(c)(2) of the Health Occupations Article.

[(8)] (9) "Prescription drug" means a drug that under § 21-220 of this article may be dispensed only on the prescription of a health practitioner who is authorized by law to prescribe the drug.

(b) (1) The Department may issue an order of impoundment and immediately impound drugs or prescription records of a LICENSE OR permit holder or an authorized prescriber if:

(i) A LICENSE HOLDER'S LICENSE, A permit holder's permit, or authorized prescriber's license has expired or has been revoked or suspended;

(ii) An application for a permit or license has been denied;

(iii) A board has:

1. Determined that the LICENSE OR permit holder or authorized prescriber failed to comply with a board order, letter of surrender, or law regarding the disposition of drugs or prescription records; and

2. Requested that the Department impound the drugs or prescription records;

(iv) The drugs pose an imminent threat to the public health, safety, or welfare; or

(v) The confidentiality of the prescription records is in imminent danger of being compromised.

(2) The Department may not impound the drugs or prescription records of a LICENSE OR permit holder or authorized prescriber who is in compliance with a board order or law specifically providing for the manner of the disposition of drugs or prescription records.

(c) (1) Except as otherwise provided in paragraph (2) of this subsection, the Department shall:

(i) Attempt to serve written notice of an impoundment on the LICENSE OR permit holder or authorized prescriber;

(ii) Provide the LICENSE OR permit holder or authorized prescriber with an opportunity to avoid impoundment by allowing the LICENSE OR permit holder or authorized prescriber to dispose of the drugs or prescription records in a manner acceptable to the Department;

(iii) Provide the LICENSE OR permit holder or authorized prescriber with an opportunity prior to impoundment to review the nature, type, and amount of information upon which the Department issued the impoundment order; and

(iv) Provide the LICENSE OR permit holder or authorized prescriber with an opportunity to avoid impoundment by providing the Department with information upon which the Department could reasonably conclude that the impoundment is not warranted.

(2) If drugs pose an imminent threat to the public health, safety, or welfare, or if the confidentiality of prescription records is in imminent danger of being compromised, the Department may:

(i) Issue an impoundment order; and

(ii) Immediately impound drugs or prescription records without prior notice to the LICENSE OR permit holder or authorized prescriber.

(d) An order of impoundment constitutes a final order subject to judicial review under the State Administrative Procedure Act.

(e) The Department shall provide the LICENSE OR permit holder or authorized prescriber with a list of all drugs and prescription records impounded.

(f) The Department may charge reasonable fees to recover the costs of the collection, storage, and disposition of drugs or prescription records.

(g) The Department shall adopt regulations governing the disposition of impounded drugs and prescription records.

(h) Prior to issuing an order of impoundment, the Department, with the approval of the Board of Pharmacy, shall develop regulations concerning:

(1) The nature, type, and amount of information upon which the Department may rely to issue an order of impoundment;

(2) The level of investigation the Department must pursue to verify the information upon which the order of impoundment was based under subsection (b)(1)(iv) or (v) or (c)(2) of this section; and

(3) The measures the Department must pursue to attempt service on the LICENSE OR permit holder or authorized prescriber prior to impoundment under subsection (c) of this section.

(i) Prior to destroying or transferring impounded drugs or prescription records, the Department shall publish a notice for 2 consecutive weeks in a daily newspaper that is circulated locally:

(1) Stating the date that the drugs or prescription records will be destroyed or transferred; and

(2) Designating a date, time, and location where the drugs or prescription records may be retrieved by the LICENSE OR permit holder or authorized prescriber if certain conditions are met.

(j) A board shall immediately notify the Division of Drug Control of the surrender, suspension, or revocation of a LICENSE HOLDER'S LICENSE, A permit holder's permit, or an authorized prescriber's license.

21-1215.

(a) This section does not apply to a violation of § 21-220(b)(4) of this title.

(b) A person who violates any provision of Subtitle 2 of this title or any regulation adopted under Subtitle 2 of this title is guilty of a misdemeanor and on conviction is subject to:

(1) A fine not exceeding $10,000 or imprisonment not exceeding 1 year or both; or

(2) If the person has been convicted once of violating Subtitle 2 of this title, a fine not exceeding $25,000 or imprisonment not exceeding 3 years or both.

(c) In addition to any criminal penalties imposed under this section, a person who violates any provision of Subtitle 2 of this title, any rule or regulation adopted under Subtitle 2 of this title, or any term, condition, or limitation of any license or registration issued under Subtitle 2 of this title OR TITLE 12, SUBTITLE 6B OF THE HEALTH OCCUPATIONS ARTICLE:

(1) Is subject to a civil penalty not exceeding $5,000, in an action in any District Court; and

(2) May be enjoined from continuing the violation.

(d) Each day on which a violation occurs is a separate violation under this section.

Article - Health Occupations

[12-601.

(a) Subject to the hearing provisions of § 12-315 of this title, for a violation of this subtitle or any regulation adopted under § 12-602 of this subtitle, 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 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) "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 (e) of this section; and

(2) 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) 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) 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 may adopt rules and regulations regarding the distribution of prescription drugs or devices including regulations regarding:

(1) Qualifications and information required from an applicant seeking issuance or renewal of a distribution permit;

(2) Minimum requirements for the receipt, storage, and handling of prescription drugs or devices, security precautions, quality control, recordkeeping, and establishment of written procedures, policy, and responsibilities of personnel;

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

(4) 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.

(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 6B. WHOLESALE PRESCRIPTION DRUG AND DEVICE DISTRIBUTION PROTECTION AND LICENSING.

12-6B-01.

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

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

(C) "CHAIN PHARMACY WAREHOUSE" MEANS A PHARMACY STOREHOUSE FOR DRUGS OR DEVICES THAT ACTS AS A CENTRAL WAREHOUSE AND PERFORMS INTRACOMPANY SALES OR TRANSFERS OF DRUGS OR DEVICES TO AND AMONG A GROUP OF CHAIN PHARMACIES WHERE THE CENTRALIZED PHARMACY STOREHOUSE AND EACH OF THE PHARMACIES HAVE AND MAINTAIN THE SAME COMMON OWNERSHIP AND CONTROL. CHAIN PHARMACY WAREHOUSES SHALL BE LICENSED ACCORDING TO BOARD OF PHARMACY REGULATIONS ADOPTED UNDER THIS ACT.

(D) "ONGOING RELATIONSHIP" MEANS A RELATIONSHIP IN WHICH A WHOLESALE DRUG DISTRIBUTOR, INCLUDING ANY AFFILIATED GROUP, AS DEFINED IN § 1504 OF THE INTERNAL REVENUE CODE, OF WHICH THE WHOLESALE DRUG DISTRIBUTOR IS A MEMBER:

(1) IS LISTED ON THE MANUFACTURER'S LIST AND THE LIST IS UPDATED MONTHLY;

(2) HAS A WRITTEN AGREEMENT CURRENTLY IN EFFECT WITH THE MANUFACTURER; OR

(3) HAS A VERIFIABLE ACCOUNT WITH A LINE OF CREDIT WITH THE MANUFACTURER AND MINIMAL TRANSACTION OR VOLUME REQUIREMENT THRESHOLDS OF:

(I) 5,000 SALES UNITS PER COMPANY WITHIN THE MOST RECENT 12-MONTH PERIOD FOR WHICH FIGURES ARE AVAILABLE; OR

(II) 12 PURCHASING INVOICES FROM THE MANUFACTURER AT THE MANUFACTURER'S MINIMUM PURCHASING REQUIREMENTS PER PURCHASING INVOICE WITHIN THE MOST RECENT 12-MONTH PERIOD FOR WHICH FIGURES ARE AVAILABLE.

(E) "SALES UNIT" MEANS THE UNIT OF MEASURE THE MANUFACTURER USES TO INVOICE ITS CUSTOMER FOR THE PARTICULAR PRODUCT.

(F) "SPECIFIED DRUG" MEANS A PRESCRIPTION DRUG ON A NATIONAL LIST, CREATED BY A NATIONAL DRUG ADVISORY COALITION IN CONJUNCTION WITH THE U.S. FOOD AND DRUG ADMINISTRATION AND OTHERS, OF PRESCRIPTION DRUGS CONSIDERED TO BE POTENTIAL TARGETS FOR ADULTERATION, COUNTERFEITING, OR DIVERSION.

(G) "VERIFIABLE ACCOUNT" MEANS:

(1) AN ACCOUNT WHICH THE MANUFACTURER CONFIRMS, IN WRITING OR ORALLY, IS ASSIGNED TO THE WHOLESALER; OR

(2) COPIES OF THE MANUFACTURER'S PURCHASING INVOICES CONTAINING A PRINTED ACCOUNT NUMBER AND THE NAME AND ADDRESS OF THE WHOLESALER.

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

(2) "WHOLESALE DISTRIBUTION" DOES NOT INCLUDE:

(I) INTRACOMPANY SALES INCLUDING THOSE THAT INVOLVE A CHAIN PHARMACY WAREHOUSE;

(II) THE PURCHASE OR OTHER ACQUISITION BY A HOSPITAL OR OTHER HEALTH CARE ENTITY THAT IS A MEMBER OF A GROUP PURCHASING ORGANIZATION OF A DRUG OR DEVICE FOR ITS OWN USE FROM THE GROUP PURCHASING ORGANIZATION OR FROM OTHER HOSPITALS OR HEALTH CARE ENTITIES THAT ARE MEMBERS OF THE GROUP PURCHASING ORGANIZATION;

(III) THE SALE, PURCHASE, OR TRADE OF A DRUG OR DEVICE OR AN OFFER TO SELL, PURCHASE, OR TRADE A DRUG OR DEVICE BY A CHARITABLE ORGANIZATION TO A NONPROFIT AFFILIATE OF THE ORGANIZATION TO THE EXTENT OTHERWISE AUTHORIZED BY LAW;

(IV) THE SALE, PURCHASE, OR TRADE OF A DRUG OR DEVICE OR AN OFFER TO SELL, PURCHASE, OR TRADE A DRUG OR DEVICE AMONG HOSPITALS OR OTHER HEALTH CARE ENTITIES THAT ARE UNDER COMMON CONTROL;

(V) THE SALE, PURCHASE, OR TRADE OF A DRUG OR DEVICE OR AN OFFER TO SELL, PURCHASE, OR TRADE A DRUG OR DEVICE FOR EMERGENCY MEDICAL REASONS, AS SPECIFIED BY THE BOARD;

(VI) THE DISTRIBUTION OF DRUG OR DEVICE SAMPLES BY REPRESENTATIVES OF MANUFACTURERS AND AUTHORIZED DISTRIBUTORS;

(VII) THE SALE, PURCHASE, OR TRADE OF BLOOD OR BLOOD COMPONENTS INTENDED FOR TRANSFUSION;

(VIII) THE SALE, AS OTHERWISE AUTHORIZED BY LAW, OF MINIMAL QUANTITIES OF DRUGS OR DEVICES BY RETAIL PHARMACIES TO LICENSED HEALTH CARE PRACTITIONERS FOR OFFICE USE;

(IX) A PHARMACY, PHARMACIST, OR PRACTITIONER RETURNING A DRUG OR DEVICE TO THE WHOLESALER FROM WHICH IT WAS ORIGINALLY PURCHASED OR RECEIVED FOR EXCHANGE, REFUND, OR CREDIT; OR

(X) A PHARMACY, PHARMACIST, OR PRACTITIONER SELLING, TRADING, TRANSFERRING, OR DISTRIBUTING A DRUG OR DEVICE TO A REVERSE DISTRIBUTOR, OR ANY OTHER TRANSACTION IN WHICH THE DRUG WILL NOT ULTIMATELY BE SOLD, TRADED, TRANSFERRED OR DISTRIBUTED TO A CONSUMER OR PATIENT.

(I) "WHOLESALE DISTRIBUTOR" MEANS ANY PERSON ENGAGED IN WHOLESALE DISTRIBUTION OF PRESCRIPTION DRUGS OR DEVICES, INCLUDING:

(1) MANUFACTURERS;

(2) REPACKERS;

(3) OWN-LABEL DISTRIBUTORS;

(4) PRIVATE-LABEL DISTRIBUTORS;

(5) JOBBERS;

(6) BROKERS;

(7) WAREHOUSES, INCLUDING:

(I) MANUFACTURERS' AND DISTRIBUTORS' WAREHOUSES; AND

(II) WHOLESALE DRUG WAREHOUSES;

(8) INDEPENDENT WHOLESALE DRUG TRADERS; AND

(9) RETAIL PHARMACIES OR CHAIN PHARMACY WAREHOUSES THAT CONDUCT WHOLESALE DISTRIBUTIONS.

12-6B-02.

THIS SUBTITLE APPLIES TO ANY PERSON ENGAGING IN THE WHOLESALE DISTRIBUTION OF PRESCRIPTION DRUGS OR DEVICES WITHIN THE STATE.

12-6B-03.

(A) THE PURPOSE OF THIS SUBTITLE IS TO ESTABLISH REQUIREMENTS FOR THE DISTRIBUTION OF PRESCRIPTION DRUGS OR DEVICES TO PROTECT THE DRUG AND DEVICE SUPPLY AND CONSUMER SAFETY.

(B) THIS SUBTITLE ESTABLISHES:

(1) LICENSING REQUIREMENTS FOR WHOLESALE DISTRIBUTORS; AND

(2) DUTIES AND ENFORCEMENT RESPONSIBILITIES OF THE BOARD.

(C) FOR THE PURPOSES OF DRUG OR DEVICE RETURNS UNDER § 19-6B-01(IX) OR (X) OF THIS SUBTITLE, A WHOLESALE DISTRIBUTOR SHALL RECEIVE PRESCRIPTION DRUG OR DEVICE RETURNS FROM A PHARMACY OR CHAIN PHARMACY WAREHOUSE IN ACCORDANCE WITH THE TERMS AND CONDITIONS OF THE AGREEMENT BETWEEN THE WHOLESALER AND THE PHARMACY OR CHAIN PHARMACY WAREHOUSE, AND THE RETURNS OR EXCHANGES ARE NOT SUBJECT TO THE STATEMENT OF RECORD REQUIREMENTS UNDER THIS SUBTITLE.

12-6B-04.

(A) ON OR AFTER JANUARY 1, 2007, A PERSON SHALL HOLD A WHOLESALE DISTRIBUTOR'S LICENSE ISSUED BY THE BOARD BEFORE THE PERSON MAY DISTRIBUTE PRESCRIPTION DRUGS OR DEVICES IN THE STATE.

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

12-6B-05.

(A) TO APPLY FOR A WHOLESALE DISTRIBUTOR'S LICENSE, AN APPLICANT SHALL:

(1) SUBMIT AN APPLICATION TO THE BOARD ON THE FORM AND IN THE MANNER THAT THE BOARD REQUIRES; AND

(2) PAY TO THE BOARD AN APPLICATION FEE SET BY THE BOARD.

(B) AN APPLICATION FOR A LICENSE SHALL INCLUDE:

(1) THE NAME, FULL BUSINESS ADDRESS, AND TELEPHONE NUMBER OF THE APPLICANT;

(2) ALL TRADE OR BUSINESS NAMES USED BY THE APPLICANT, INCLUDING ALL AFFILIATED BUSINESSES;

(3) THE NAME, ADDRESS, AND TELEPHONE NUMBER OF A CONTACT PERSON FOR EACH FACILITY USED BY THE APPLICANT FOR THE STORAGE, HANDLING, AND DISTRIBUTION OF PRESCRIPTION DRUGS;

(4) THE TYPE OF OWNERSHIP OR OPERATION, SUCH AS A PARTNERSHIP, CORPORATION, OR SOLE PROPRIETORSHIP;

(5) THE NAMES OF THE OWNER OR OWNERS AND THE OPERATOR OF THE WHOLESALE DISTRIBUTOR, INCLUDING:

(I) IF THE OWNER OR OPERATOR IS AN INDIVIDUAL, THE NAME OF THE INDIVIDUAL;

(II) IF THE OWNER OR OPERATOR IS A PARTNERSHIP, THE NAME OF EACH PARTNER AND THE NAME OF THE PARTNERSHIP;

(III) IF THE OWNER OR OPERATOR IS A CORPORATION:

1. THE NAME, ADDRESS, AND TITLE OF EACH CORPORATE OFFICER AND DIRECTOR;

2. THE NAME AND ADDRESS OF THE CORPORATION, THE NAME AND ADDRESS OF THE RESIDENT AGENT OF THE CORPORATION, AND THE STATE IN WHICH THE CORPORATION IS INCORPORATED; AND

3. IF THE CORPORATION IS NOT PUBLICLY HELD, THE NAME AND ADDRESS OF EACH SHAREHOLDER THAT OWNS 10% OR MORE OF THE OUTSTANDING STOCK OF THE CORPORATION; AND

(IV) IF THE OWNER OR OPERATOR IS A LIMITED LIABILITY COMPANY:

1. THE NAME AND ADDRESS OF EACH PRINCIPAL;

2. THE NAME AND ADDRESS OF EACH MANAGER; AND

3. THE NAME AND ADDRESS OF THE LIMITED LIABILITY COMPANY, THE NAME AND ADDRESS OF THE RESIDENT AGENT OF THE LIMITED LIABILITY COMPANY, AND THE NAME OF THE STATE IN WHICH THE LIMITED LIABILITY COMPANY IS ORGANIZED;

(6) A LIST OF ALL STATE LICENSES, REGISTRATIONS, OR PERMITS, INCLUDING THE LICENSE, REGISTRATION, OR PERMIT NUMBERS, ISSUED TO THE APPLICANT BY REGULATORY AUTHORITIES IN OTHER STATES THAT AUTHORIZE THE APPLICANT TO PURCHASE, POSSESS, AND DISTRIBUTE PRESCRIPTION DRUGS;

(7) IF THE APPLICANT IS DISTRIBUTING OR HAS PREVIOUSLY DISTRIBUTED DRUGS IN THIS STATE UNDER A PERMIT ISSUED BY THE BOARD, THE PERMIT NUMBER;

(8) A LIST OF ALL DISCIPLINARY ACTIONS BY STATE OR FEDERAL AGENCIES AGAINST THE COMPANY, AS WELL AS ANY SUCH ACTIONS AGAINST PRINCIPALS, OWNERS, DIRECTORS, OR OFFICERS OVER THE LAST 7 YEARS;

(9) THE NUMBER OF EMPLOYEES AT EACH FACILITY AND SCREENING PROCEDURES FOR HIRING;

(10) THE MINIMUM LIABILITY INSURANCE LIMITS THE COMPANY MAINTAINS, INCLUDING GENERAL AS WELL AS PRODUCT LIABILITY INSURANCE;

(11) A DESCRIPTION OF EACH FACILITY AND WAREHOUSE UTILIZED FOR PRESCRIPTION DRUG OR DEVICE STORAGE OR DISTRIBUTION, INCLUDING:

(I) SQUARE FOOTAGE;

(II) SECURITY AND ALARM SYSTEM;

(III) TERMS OF LEASE OR OWNERSHIP;

(IV) ADDRESS; AND

(V) TEMPERATURE AND HUMIDITY CONTROLS;

(12) THE TAX YEAR OF THE APPLICANT;

(13) (I) IF THE PROPERTY IS OWNED BY THE APPLICANT, A COPY OF THE DEED FOR THE PROPERTY ON WHICH THE APPLICANT'S FACILITY OR WAREHOUSE IS LOCATED; OR

(II) IF THE PROPERTY IS LEASED BY THE APPLICANT, A COPY OF THE APPLICANT'S LEASE FOR THE PROPERTY ON WHICH THE APPLICANT'S FACILITY OR WAREHOUSE IS LOCATED; AND

(14) A DESCRIPTION OF THE APPLICANT'S PRESCRIPTION DRUG IMPORT AND EXPORT ACTIVITIES.

(C) INFORMATION SUBMITTED UNDER THIS SECTION IS PROPRIETARY AND CONFIDENTIAL COMMERCIAL INFORMATION UNDER § 10-617(D) OF THE STATE GOVERNMENT ARTICLE AND MAY NOT BE DISCLOSED, EXCEPT AS OTHERWISE REQUIRED BY LAW.

(D) A WHOLESALE DISTRIBUTOR'S LICENSE EXPIRES ON THE DECEMBER 31 AFTER ITS EFFECTIVE DATE, UNLESS THE LICENSE IS RENEWED FOR A 1-YEAR TERM AS PROVIDED IN THIS SECTION.

(E) AT LEAST 1 MONTH BEFORE A WHOLESALE DISTRIBUTOR'S LICENSE EXPIRES, THE BOARD SHALL SEND TO THE LICENSE HOLDER, BY FIRST-CLASS MAIL

TO THE LAST KNOWN ADDRESS OF THE LICENSE HOLDER, A RENEWAL NOTICE THAT CONTAINS A STATEMENT OF:

(1) THE DATE ON WHICH THE CURRENT WHOLESALE DISTRIBUTOR'S LICENSE EXPIRES;

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

(3) THE AMOUNT OF THE RENEWAL FEE.

(F) BEFORE A WHOLESALE DISTRIBUTOR'S LICENSE EXPIRES, A LICENSE HOLDER MAY RENEW IT FOR AN ADDITIONAL 1-YEAR TERM, IF THE LICENSE HOLDER:

(1) OTHERWISE IS ENTITLED TO A WHOLESALE DISTRIBUTOR'S LICENSE;

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

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

(G) THE BOARD SHALL RENEW THE WHOLESALE DISTRIBUTOR'S LICENSE OF EACH LICENSE HOLDER THAT MEETS THE REQUIREMENTS OF THIS SUBTITLE AND ANY REGULATIONS ADOPTED UNDER THIS SUBTITLE.

(H) A WHOLESALE DISTRIBUTOR'S LICENSE SHALL BE DISPLAYED CONSPICUOUSLY IN THE PLACE FOR WHICH IT IS ISSUED.

(I) A WHOLESALE DISTRIBUTOR'S LICENSE IS NOT TRANSFERABLE.

(J) (1) THE BOARD SHALL SET REASONABLE FEES FOR THE ISSUANCE AND RENEWAL OF LICENSES.

(2) THE FEES CHARGED SHALL BE SET TO PRODUCE FUNDS SO AS TO APPROXIMATE THE COST OF THE LICENSING, INSPECTION, AND ENFORCEMENT REQUIREMENTS UNDER THIS SUBTITLE.

(3) FUNDS TO COVER THE EXPENSES OF THE PRESCRIPTION DRUG AND DEVICE WHOLESALER ADVISORY COUNCIL MEMBERS SHALL BE GENERATED BY FEES SET UNDER THIS SUBSECTION.

12-6B-06.

(A) A MANUFACTURER OF A PRESCRIPTION DRUG OR DEVICE SOLD IN THE STATE SHALL:

(1) FILE WITH THE BOARD A WRITTEN LIST OF ALL OF THE MANUFACTURER'S AUTHORIZED DISTRIBUTORS OF RECORD; AND

(2) NOTIFY THE BOARD NO LATER THAN 10 DAYS AFTER ANY CHANGE TO THE LIST.

(B) (1) THE BOARD SHALL PUBLISH A LIST OF ALL AUTHORIZED DISTRIBUTORS OF RECORD ON ITS WEBSITE.

(2) THE BOARD SHALL UPDATE THE LIST ON AT LEAST A MONTHLY BASIS.

12-6B-07.

(A) (1) BEFORE ISSUING AN INITIAL LICENSE, AND PERIODICALLY THEREAFTER ON A SCHEDULE TO BE DETERMINED BY THE BOARD, THE BOARD SHALL CONDUCT A CRIMINAL AND FINANCIAL BACKGROUND CHECK OF EACH WHOLESALE DISTRIBUTOR APPLICANT.

(2) THE BACKGROUND CHECK SHALL INCLUDE:

(I) A CRIMINAL BACKGROUND AND CRIMINAL AND CIVIL LITIGATION CHECK OF ALL COMPANY OFFICERS, KEY MANAGEMENT, PRINCIPALS, AND OWNERS WITH 10% OR GREATER INTEREST IN THE COMPANY;

(II) A DRIVER'S LICENSE AND SOCIAL SECURITY VERIFICATION OF ALL COMPANY OFFICERS, KEY MANAGEMENT, PRINCIPALS, AND OWNERS;

(III) A CREDIT HISTORY OF THE COMPANY AND ITS KEY OFFICERS MAINTAINED BY AN INDEPENDENT THIRD PARTY CREDIT EVALUATION ORGANIZATION;

(IV) A CHECK TO DETERMINE IF ANY CIVIL OR CRIMINAL LITIGATION EXISTS AGAINST THE COMPANY; AND

(V) VERIFICATION, AS APPLICABLE, OF THE DATE OF INCORPORATION, YEARS IN BUSINESS, PLACE OF INCORPORATION, AND BUSINESS FORM OF THE APPLICANT.

(3) INFORMATION PROVIDED UNDER THIS SUBSECTION IS PROPRIETARY AND CONFIDENTIAL COMMERCIAL INFORMATION UNDER § 10-617(D) OF THE STATE GOVERNMENT ARTICLE AND MAY NOT BE DISCLOSED, EXCEPT AS OTHERWISE REQUIRED BY LAW.

(B) (1) THE BOARD SHALL CONDUCT A PHYSICAL INSPECTION OF EACH IN-STATE FACILITY OR WAREHOUSE OF THE APPLICANT BEFORE ISSUING A LICENSE.

(2) AT LEAST EVERY 3 YEARS AFTER THE INITIAL INSPECTION, THE BOARD SHALL CONDUCT A PHYSICAL REINSPECTION.

(3) (I) IN CONDUCTING ITS INSPECTIONS, THE BOARD SHALL USE A QUALIFIED INSPECTOR, WHO IS SPECIFICALLY TRAINED TO CONDUCT INSPECTIONS OF WHOLESALE DISTRIBUTORS.

(II) THE BOARD SHALL REQUIRE AN INSPECTOR TO MAINTAIN CURRENT TRAINING AND KNOWLEDGE REGARDING THE WHOLESALE DRUG AND DEVICE DISTRIBUTION INDUSTRY.

12-6B-08.

(A) AN APPLICANT FOR A WHOLESALE DISTRIBUTOR LICENSE SHALL SUBMIT TO THE BOARD:

(1) A SURETY BOND OF $100,000; OR

(2) EVIDENCE OF OTHER EQUIVALENT MEANS OF SECURITY ACCEPTABLE TO THE BOARD, SUCH AS:

(I) INSURANCE;

(II) AN IRREVOCABLE LETTER OF CREDIT; OR

(III) FUNDS DEPOSITED IN A TRUST ACCOUNT OR FINANCIAL INSTITUTION.

(B) A SEPARATE SURETY BOND OR OTHER EQUIVALENT MEANS OF SECURITY IS NOT REQUIRED FOR EACH COMPANY'S SEPARATE LOCATIONS OR FOR AFFILIATED COMPANIES OR GROUPS.

(C) THE BOARD MAY MAKE A CLAIM AGAINST A SURETY BOND OR OTHER EQUIVALENT MEANS OF SECURITY TO SECURE PAYMENT OF ANY ADMINISTRATIVE PENALTIES IMPOSED BY THE BOARD IF THE WHOLESALE DISTRIBUTOR FAILS TO PAY WITHIN 30 DAYS AFTER A PENALTY IS IMPOSED.

(D) THE BOARD MAY MAKE A CLAIM AGAINST A SURETY BOND OR OTHER EQUIVALENT MEANS OF SECURITY UNTIL THE LATER OF:

(1) ONE YEAR AFTER THE WHOLESALE DISTRIBUTOR'S LICENSE CEASES TO BE VALID; OR

(2) 60 DAYS AFTER ANY ADMINISTRATIVE OR LEGAL PROCEEDING AS AUTHORIZED UNDER THIS SUBTITLE OR UNDER § 21-1215 OF THE HEALTH - GENERAL ARTICLE WHICH INVOLVES THE LICENSE HOLDER IS CONCLUDED.

(E) THE SURETY BOND OR OTHER EQUIVALENT MEANS OF SECURITY SHALL REMAIN IN PLACE UNTIL THE LATER OF:

(1) ONE YEAR AFTER THE WHOLESALE DISTRIBUTOR'S LICENSE CEASES TO BE VALID; OR

(2) 60 DAYS AFTER ANY ADMINISTRATIVE OR LEGAL PROCEEDING AS AUTHORIZED UNDER THIS SUBTITLE OR UNDER § 21-1215 OF THE HEALTH - GENERAL ARTICLE WHICH INVOLVES THE LICENSE HOLDER IS CONCLUDED.

(F) THE SURETY BOND REQUIREMENT MAY BE WAIVED, AT THE DISCRETION OF THE BOARD, IF THE WHOLESALE DISTRIBUTOR PREVIOUSLY HAS OBTAINED A COMPARABLE SURETY BOND OR OTHER EQUIVALENT MEANS OF SECURITY FOR THE PURPOSE OF LICENSURE IN ANOTHER STATE WHERE THE WHOLESALE DISTRIBUTOR POSSESSES A VALID LICENSE IN GOOD STANDING.

(G) THE BOARD MAY ACCEPT A SURETY BOND OF $25,000 IF THE ANNUAL GROSS RECEIPTS OF THE PREVIOUS TAX YEAR FOR THE WHOLESALE DISTRIBUTOR IS $10,000,000 OR LESS.

12-6B-09.

(A) A WHOLESALE DISTRIBUTOR LICENSED BY THE BOARD SHALL IDENTIFY A DESIGNATED REPRESENTATIVE WHO IS RESPONSIBLE FOR THE WHOLESALE DISTRIBUTOR'S COMPLIANCE WITH APPLICABLE STATE AND FEDERAL LAWS.

(B) A DESIGNATED REPRESENTATIVE:

(1) MAY BE A CORPORATE EMPLOYEE OR OFFICER, OUTSIDE COUNSEL, OR OUTSIDE CONSULTING SPECIALIST WITH AUTHORITY TO HELP ENSURE COMPLIANCE;

(2) IS NOT REQUIRED TO BE PHYSICALLY PRESENT AT THE FACILITY; AND

(3) MAY HAVE RESPONSIBILITY FOR MULTIPLE LICENSED FACILITIES.

(C) (1) A WHOLESALE DISTRIBUTOR MAY NOT OPERATE UNDER A WHOLESALE DISTRIBUTOR'S LICENSE FOR MORE THAN 30 WORKING DAYS WITHOUT A DESIGNATED REPRESENTATIVE.

(2) A WHOLESALE DISTRIBUTOR SHALL:

(I) APPOINT A REPLACEMENT FOR A DESIGNATED REPRESENTATIVE WITHIN 30 WORKING DAYS; AND

(II) NOTIFY THE BOARD WITHIN 10 WORKING DAYS OF CHANGING ITS DESIGNATED REPRESENTATIVE.

12-6B-10.

(A) THERE IS A PRESCRIPTION DRUG AND DEVICE WHOLESALER ADVISORY COUNCIL WITHIN THE BOARD.

(B) THE COUNCIL CONSISTS OF THE FOLLOWING MEMBERS, APPOINTED BY THE BOARD TO A 4-YEAR TERM:

(1) THREE INDIVIDUALS EMPLOYED BY DIFFERENT LICENSED WHOLESALE DISTRIBUTORS THAT ARE NOT DRUG MANUFACTURERS;

(2) ONE INDIVIDUAL EMPLOYED BY A DRUG MANUFACTURER;

(3) ONE INDIVIDUAL EMPLOYED BY A CHAIN PHARMACY WAREHOUSE; AND

(4) ONE LICENSED PHARMACIST.

(C) THE COUNCIL SHALL ELECT A CHAIRMAN AND A VICE CHAIRMAN ANNUALLY.

(D) THE COUNCIL SHALL MEET AT LEAST ONCE EACH CALENDAR QUARTER.

(E) THE BOARD SHALL PROVIDE STAFF FOR THE COUNCIL.

(F) A MEMBER OF THE COUNCIL:

(1) MAY NOT RECEIVE COMPENSATION; BUT

(2) IS ENTITLED TO REIMBURSEMENT FOR EXPENSES UNDER THE STANDARD STATE TRAVEL REGULATIONS, AS PROVIDED IN THE STATE BUDGET.

(G) THE COUNCIL SHALL:

(1) PROVIDE INPUT TO THE BOARD REGARDING PROPOSED REGULATIONS THAT WOULD AFFECT THE DISTRIBUTION OF PRESCRIPTION DRUGS OR DEVICES; AND

(2) MAKE RECOMMENDATIONS TO THE BOARD REGARDING MEASURES OR PROCEDURES TO IMPROVE THE INTEGRITY OF THE PRESCRIPTION DRUG AND DEVICE DISTRIBUTION SYSTEM AND PROTECT PUBLIC HEALTH.

12-6B-11.

(A) SUBJECT TO SUBSECTIONS (B) AND (C) OF THIS SECTION, A WHOLESALE DISTRIBUTOR OF A DRUG OR DEVICE THAT IS NOT THE MANUFACTURER OR AUTHORIZED DISTRIBUTOR OF RECORD FOR THE DRUG OR DEVICE SHALL PROVIDE TO EACH WHOLESALE DISTRIBUTOR OF THE DRUG OR DEVICE, BEFORE THE SALE IS MADE TO THE WHOLESALE DISTRIBUTOR, A STATEMENT OR RECORD THAT IDENTIFIES:

(1) BY DATE, EACH PREVIOUS SALE OF THE DRUG OR DEVICE, STARTING WITH THE LAST AUTHORIZED DISTRIBUTOR OF RECORD, OR THE MANUFACTURER IF THE DRUG OR DEVICE HAS NOT BEEN PURCHASED PREVIOUSLY BY AN AUTHORIZED DISTRIBUTOR OF RECORD;

(2) THE PROPRIETARY AND ESTABLISHED NAME OF THE DRUG OR DEVICE;

(3) DOSAGE;

(4) CONTAINER SIZE;

(5) NUMBER OF CONTAINERS; AND

(6) THE BUSINESS NAME AND ADDRESS OF ALL ENTITIES IDENTIFIED IN THE STATEMENT OR RECORD.

(B) A REPACKAGER OR A MANUFACTURER THAT REPACKAGES A DRUG AND THAT IS NOT AN AUTHORIZED DISTRIBUTOR OF RECORD IS SUBJECT TO THE REQUIREMENTS OF THIS SECTION.

(C) A WHOLESALE DISTRIBUTOR OF A SPECIFIED DRUG THAT DID NOT PURCHASE THE SPECIFIED DRUG DIRECTLY FROM THE MANUFACTURER SHALL PROVIDE TO EACH WHOLESALE DISTRIBUTOR OF THE SPECIFIED DRUG A STATEMENT OR RECORD THAT IDENTIFIES:

(1) BY DATE, EACH PREVIOUS SALE OF THE SPECIFIC UNIT OF THE SPECIFIED DRUG BACK TO THE MANUFACTURER OF THE SPECIFIED DRUG;

(2) THE PROPRIETARY AND ESTABLISHED NAME OF THE SPECIFIED DRUG;

(3) DOSAGE;

(4) CONTAINER SIZE;

(5) NUMBER OF CONTAINERS; AND

(6) THE BUSINESS NAME AND ADDRESS OF ALL ENTITIES IDENTIFIED IN THE STATEMENT OR RECORD.

(D) (1) ON OR BEFORE DECEMBER 31, 2010, THE BOARD SHALL ESTABLISH AN EFFECTIVE, UNIQUE ELECTRONIC PRODUCT IDENTIFICATION TRACKING SYSTEM FOR DRUGS OR DEVICES TO BE IMPLEMENTED BY MANUFACTURERS, REPACKAGERS, PHARMACIES, AND WHOLESALE DISTRIBUTORS.

(2) THE ELECTRONIC PRODUCT IDENTIFICATION TRACKING SYSTEM SHALL:

(I) BE DESIGNED TO DETER AND DETECT COUNTERFEITING AND PROVIDE A MEANS FOR PRESCRIPTION DRUG AND DEVICE MANUFACTURERS, REPACKAGERS, DISTRIBUTORS, AND PHARMACIES TO AUTHENTICATE THE DRUGS AND DEVICES; AND

(II) BE PART OF A STANDARDIZED SYSTEM CAPABLE OF BEING USED ACROSS THE HEALTH CARE INDUSTRY, INCLUDING MANUFACTURERS, WHOLESALE DISTRIBUTORS, AND PHARMACIES.

(3) ON OR BEFORE JANUARY 1, 2007, AND ON OR BEFORE EACH JANUARY 1 THEREAFTER, THE BOARD SHALL REPORT TO THE GOVERNOR AND, IN ACCORDANCE WITH § 2-1246 OF THE STATE GOVERNMENT ARTICLE, THE GENERAL ASSEMBLY, ON ITS PROGRESS IN ESTABLISHING THE ELECTRONIC PRODUCT IDENTIFICATION TRACKING SYSTEM REQUIRED UNDER THIS SUBSECTION.

12-6B-12.

BEFORE PURCHASING A PRESCRIPTION DRUG OR DEVICE FROM ANOTHER WHOLESALE DISTRIBUTOR, THE PURCHASING WHOLESALE DISTRIBUTOR SHALL OBTAIN FROM THE SELLING WHOLESALE DISTRIBUTOR:

(1) (I) THE STATE IN WHICH THE SELLING WHOLESALE DISTRIBUTOR IS DOMICILED AND A LISTING OF THE STATES INTO WHICH THE SELLING WHOLESALE DISTRIBUTOR IS SHIPPING; AND

(II) COPIES OF ALL CURRENT STATE AND FEDERAL LICENSES, REGISTRATIONS, AND PERMITS THAT AUTHORIZE THE SELLING WHOLESALER TO PURCHASE, POSSESS, AND DISTRIBUTE PRESCRIPTION DRUGS;

(2) THE MOST RECENT FACILITY INSPECTION REPORT PREPARED BY THE BOARD;

(3) INFORMATION REGARDING GENERAL AND PRODUCT LIABILITY INSURANCE THE SELLING WHOLESALE DISTRIBUTOR MAINTAINS;

(4) A LIST OF ALL CORPORATE OFFICERS;

(5) UNLESS THE SELLING WHOLESALE DISTRIBUTOR IS A PUBLICLY HELD COMPANY, A LIST OF ALL OWNERS OF GREATER THAN 10% OF THE COMPANY;

(6) IF THE SELLING WHOLESALE DISTRIBUTOR CLAIMS TO BE AN AUTHORIZED DISTRIBUTOR OF RECORD, A WRITTEN STATEMENT FROM THE SELLING WHOLESALE DISTRIBUTOR STATING THAT IT IS AN AUTHORIZED DISTRIBUTOR OF RECORD AND THE BASIS ON WHICH THIS STATUS WAS GIVEN;

(7) A LIST OF ALL DISCIPLINARY ACTIONS BY STATE AND FEDERAL AGENCIES AGAINST THE SELLING WHOLESALE DISTRIBUTOR, AS WELL AS AGAINST PRINCIPALS, OWNERS, OR OFFICERS OVER THE LAST 7 YEARS;

(8) A DESCRIPTION, INCLUDING THE ADDRESS, DIMENSIONS, AND OTHER RELEVANT INFORMATION, OF EACH FACILITY OR WAREHOUSE THE SELLING WHOLESALE DISTRIBUTOR USES FOR DRUG AND DEVICE STORAGE AND DISTRIBUTION;

(9) A DESCRIPTION AND LISTING OF ALL DRUG AND DEVICE IMPORT AND EXPORT ACTIVITIES OF THE SELLING WHOLESALE DISTRIBUTOR;

(10) A DESCRIPTION OF THE PROCESS THE SELLING WHOLESALE DISTRIBUTOR USES TO VALIDATE AND CERTIFY ITS SUPPLIERS AND PURCHASES,

INCLUDING THE SUPPLIER'S STATUS AS AN AUTHORIZED DISTRIBUTOR OF RECORD; AND

(11) A DESCRIPTION OF THE SELLING WHOLESALE DISTRIBUTOR'S SYSTEMS AND PROCEDURES FOR PROMPT REPORTING TO STATE AND FEDERAL AUTHORITIES AND MANUFACTURERS ANY SUSPECTED:

(I) COUNTERFEIT, STOLEN, OR OTHERWISE UNLAWFUL PRESCRIPTION DRUGS OR DEVICES; OR

(II) BUYERS OR SELLERS OF COUNTERFEIT, STOLEN, OR OTHERWISE UNLAWFUL PRESCRIPTION DRUGS OR DEVICES.

12-6B-13.

(A) SUBJECT TO ANY OTHER RESTRICTION PROVIDED BY LAW, A PERSON MAY NOT PURCHASE OR OBTAIN PRESCRIPTION DRUGS OR DEVICES UNLESS THE PRESCRIPTION DRUG OR DEVICE IS OBTAINED FROM THE WHOLESALE DISTRIBUTOR LICENSE HOLDER, A LICENSED PHARMACIST, A LICENSED PHARMACY, A CHAIN PHARMACY WAREHOUSE, OR AN AUTHORIZED PRESCRIBER.

(B) A PERSON MAY NOT VIOLATE:

(1) THIS SUBTITLE; OR

(2) A REGULATION ADOPTED BY THE BOARD UNDER THIS SUBTITLE.

(C) SUBJECT TO THE HEARING PROVISIONS OF § 12-315 OF THIS TITLE, FOR A VIOLATION OF THIS SUBTITLE OR ANY REGULATION ADOPTED UNDER THIS SUBTITLE, THE BOARD MAY:

(1) DENY A LICENSE TO AN APPLICANT;

(2) REPRIMAND A LICENSE HOLDER;

(3) PLACE A LICENSE HOLDER ON PROBATION; OR

(4) SUSPEND OR REVOKE A LICENSE.

(D) A PERSON AGGRIEVED BY A FINAL ACTION OF THE BOARD UNDER THIS SUBTITLE 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.

(E) THE BOARD SHALL NOTIFY A WHOLESALE DISTRIBUTOR OF THE ACTION TAKEN AGAINST THE WHOLESALE DISTRIBUTOR'S LICENSE WITHIN 3 WORKING DAYS OF THE ACTION AND MAKE SUCH ACTIONS PUBLICLY AVAILABLE ON THE BOARD'S WEBSITE WITHIN 5 WORKING DAYS OF THE ACTION.

12-6B-14.

THE BOARD SHALL ADOPT REGULATIONS TO IMPLEMENT THE REQUIREMENTS OF THIS SUBTITLE.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2005.