Unofficial Copy 2004 Regular Session
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By: **Delegate Stern**
Introduced and read first time: February 13, 2004
Assigned to: Health and Government Operations

A BILL ENTITLED

AN ACT concerning

Prescription Drug Distribution Safety Act

FOR the purpose of requiring a wholesale prescription drug distributor to review certain records for the acquisition of prescription drugs in a certain manner; requiring a wholesale prescription drug distributor to establish and maintain certain inventories and records; requiring the records to meet certain specifications; requiring inventories and records to be made available for inspection and photocopying by certain officials and for a certain period of time; requiring a person who is engaged in the wholesale distribution of a prescription drug and who is not the manufacturer of that drug to provide, at a certain time, a pedigree paper to the person who receives the drug; establishing requirements for a pedigree paper; requiring a wholesale prescription drug distributor to provide the Department of Health and Mental Hygiene with a certain list; establishing requirements for changes to and confidentiality of the list; requiring a wholesale prescription drug distributor, prior to a certain purchase, to enter into a certain agreement, determine certain insurance coverage, obtain certain information, verify a certain permit, and inspect a certain establishment for a certain purpose; requiring the Department to conduct certain inspections; authorizing the Department to take certain actions with regard to the inspections; authorizing certain property owners to seek judicial relief after a seizure of prescription drugs; authorizing the Department to close a prescription drug wholesale establishment under certain circumstances; providing that a certain refusal constitutes an imminent danger to the public health; authorizing the Department to issue and serve a complaint upon a permittee under certain circumstances; providing for a certain hearing; authorizing the Department to issue a certain cease and desist order under certain circumstances; making certain actions unlawful; establishing certain penalties for certain violations; requiring the Department to adopt certain regulations; defining certain terms; altering certain definitions; and generally relating to distribution of prescription drugs.

BY repealing and reenacting, with amendments,
Article - Health - General
Section 21-201 and 21-216(c)
Annotated Code of Maryland

(2000 Replacement Volume and 2003 Supplement)

BY repealing and reenacting, without amendments,
Article - Health - General
Section 21-216(a) and (b)
Annotated Code of Maryland
(2000 Replacement Volume and 2003 Supplement)

BY adding to
Article - Health - General
Section 21-228, 21-229, 21-229.1, and 21-258.1
Annotated Code of Maryland
(2000 Replacement Volume and 2003 Supplement)

BY repealing and reenacting, with amendments,
Article - Health Occupations
Section 12-602(a), (c), and (h)
Annotated Code of Maryland
(2000 Replacement Volume and 2003 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.

(B) "AUTHENTICATE" MEANS TO AFFIRMATIVELY VERIFY BEFORE ANY DISTRIBUTION OF A LEGEND DRUG OCCURS THAT EACH TRANSACTION LISTED ON A PEDIGREE PAPER HAS OCCURRED.

(C) "CONTRABAND LEGEND DRUG" MEANS ANY ADULTERATED DRUG, ANY COUNTERFEIT DRUG, OR ANY LEGEND DRUG FOR WHICH A PEDIGREE PAPER DOES NOT EXIST, OR FOR WHICH THE PEDIGREE PAPER IN EXISTENCE HAS BEEN FORGED, COUNTERFEITED, FALSELY CREATED, OR CONTAINS ANY ALTERED, FALSE, OR MISREPRESENTED MATTER.

[(b)] (D) "Counterfeit drug" means a drug that:

(1) Bears, or the container or labeling of which bears, without authorization, the trademark, trade name, imprint, symbol, or any other identifying mark, or any likeness of any of these markings, of a manufacturer, processor, packer, or distributor other than the one who, in fact, manufactured, processed, packed, or distributed the drug; and

(2) By use of these markings falsely purports or is represented to be the product of, or to have been packed or distributed by, the other drug manufacturer, processor, packer, or distributor.

[(c)] (E) (1) "Established name" means, in regard to a drug or an ingredient of a drug:

(i) The name designated under the Federal Act;

(ii) If a name has not been designated under the Federal Act, but the drug or ingredient has been recognized in an official compendium, then the title used in the compendium; or

(iii) If a name cannot be determined under item (i) or (ii) of this paragraph, the common or usual name of the drug or ingredient.

(2) In applying the provisions of paragraph (1)(ii) of this subsection, if a drug or an ingredient of a drug is recognized in both the United States Pharmacopoeia and National Formulary and in the Homeopathic Pharmacopoeia of the United States under different official titles, the title used in the United States Pharmacopoeia and National Formulary is the established name, unless the drug is labeled and offered for sale as a homeopathic drug, in which event the official title used in the Homeopathic Pharmacopoeia of the United States is the established name.

[(d)] (F) "New drug" means any drug that:

(1) Among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, is not recognized generally as safe and effective for use under the conditions specified, recommended, or suggested in the labeling of the drug; or

(2) As a result of investigations to determine its safety and effectiveness for use, has become recognized by these experts as safe and effective under the conditions, but that, other than in the investigations, has not been used to a material extent or for a material time under the conditions.

(G) "PEDIGREE PAPER" MEANS A DOCUMENT APPROVED BY THE DEPARTMENT CONTAINING INFORMATION THAT RECORDS EACH DISTRIBUTION OF A LEGEND DRUG, FROM SALE BY A PHARMACEUTICAL MANUFACTURER, THROUGH ACQUISITION AND SALE BY A WHOLESALER OR REPACKAGER, UNTIL FINAL SALE TO A PHARMACY OR OTHER PERSON ADMINISTERING OR DISPENSING THE DRUG.

[(e)] (H) (1) "Prescription drug" means a drug that, under § 21-220 of this subtitle, may be dispensed only on the prescription of a health practitioner who is authorized by law to prescribe the drug.

(2) "PRESCRIPTION DRUG" INCLUDES A LEGEND DRUG.

(I) (1) "REPACKAGER" MEANS A PERSON WHO REPACKS OR OTHERWISE CHANGES THE CONTAINER, WRAPPER, OR LABELING TO FURTHER THE DISTRIBUTION OF A PRESCRIPTION DRUG.

(2) "REPACKAGER" DOES NOT INCLUDE A PHARMACY THAT IS OPERATING IN COMPLIANCE WITH PHARMACY PRACTICE STANDARDS UNDER TITLE 12 OF THE HEALTH OCCUPATIONS ARTICLE.

[(f)] (J) "State adopted federal rule or regulation" means any rule or regulation that is adopted by the federal government under the Federal Act and that becomes a rule or regulation by automatic adoption under the provisions of this subtitle.

21-216.

(a) For purposes of this subtitle, a drug or device is adulterated if the standards in this section apply.

(b) A drug or device is adulterated if:

(1) Any part of it is a filthy, putrid, or decomposed substance; or

(2) It was produced, prepared, packed, or held under unsanitary conditions that reasonably would be expected to have:

(i) Contaminated it with filth; or

(ii) Caused it to be injurious to health.

(c) In addition to the grounds specified in subsection (b) of this section, a drug is adulterated if:

(1) Any part of its container is composed of any poisonous or otherwise deleterious substance that reasonably would be expected to have caused the drug to be injurious to health;

(2) For purposes of coloring only, it is or it contains a color additive, the particular use of which has not been found safe as provided under § 21-239 of this subtitle;

(3) The mixing or packing of any substance with the drug has reduced the quality or strength of the drug;

(4) Any substance has been substituted for any part of the drug;

(5) The methods, facilities, or controls used in the manufacture, processing, packing, or holding of the drug do not conform to, or are not administered in conformity to, good practice to assure that the drug:

(i) Meets the requirements of this subtitle as to safety; and

(ii) Has the identity, strength, quality, and purity that it purports to have;

(6) It is purported to be a drug the name of which is recognized in an official compendium and:

(i) The strength of the drug differs from, or the quality or purity of the drug falls below, the standard set in the official compendium; and

(ii) The difference in strength, quality, or purity is not stated plainly on its label; [or]

(7) Although not purported to be a drug recognized in an official compendium, the strength of the drug differs from, or the quality or purity of the drug falls below that which the drug purports to possess; OR

(8) IT IS A LEGEND DRUG FOR WHICH THE REQUIRED PEDIGREE PAPER IS NONEXISTENT, FRAUDULENT, OR INCOMPLETE UNDER THE REQUIREMENTS OF THIS SUBTITLE, OR THAT HAS BEEN PURCHASED, HELD, SOLD, OR DISTRIBUTED AT ANY TIME BY A PERSON NOT AUTHORIZED UNDER FEDERAL OR STATE LAW TO DO SO.

21-228.

(A) THE DEPARTMENT SHALL ADOPT REGULATIONS FOR THE STORAGE AND HANDLING OF PRESCRIPTION DRUGS AND FOR THE ESTABLISHMENT AND MAINTENANCE OF PRESCRIPTION DRUG DISTRIBUTION RECORDS.

(B) (1) ON RECEIPT, A WHOLESALE PRESCRIPTION DRUG DISTRIBUTOR SHALL REVIEW RECORDS REQUIRED UNDER THIS SECTION FOR THE ACQUISITION OF PRESCRIPTION DRUGS FOR ACCURACY AND COMPLETENESS, CONSIDERING THE TOTAL FACTS AND CIRCUMSTANCES SURROUNDING THE TRANSACTIONS AND THE WHOLESALE DISTRIBUTORS INVOLVED.

(2) THE WHOLESALE PRESCRIPTION DRUG DISTRIBUTOR'S REVIEW SHALL INCLUDE AUTHENTICATING EACH TRANSACTION LISTED ON A PEDIGREE PAPER.

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

(2) THE RECORDS SHALL:

(I) PROVIDE A COMPLETE AUDIT TRAIL FROM RECEIPT TO SALE OR OTHER DISPOSITION;

(II) BE READILY RETRIEVABLE FOR INSPECTION; AND

(III) INCLUDE, AT A MINIMUM, THE FOLLOWING INFORMATION:

1. THE SOURCE OF THE DRUGS, INCLUDING THE NAME AND PRINCIPAL ADDRESS OF THE SELLER OR TRANSFEROR, AND THE ADDRESS OF THE LOCATION FROM WHICH THE DRUGS WERE SHIPPED;

2. THE NAME, PRINCIPAL ADDRESS, AND STATE LICENSE, PERMIT, OR REGISTRATION NUMBER OF THE PERSON AUTHORIZED TO PURCHASE PRESCRIPTION DRUGS;

3. THE NAME, STRENGTH, DOSAGE FORM, AND QUANTITY OF THE DRUGS RECEIVED AND DISTRIBUTED OR DISPOSED OF;

4. THE DATES OF RECEIPT AND DISTRIBUTION OR OTHER DISPOSITION OF THE DRUGS; AND

5. ANY FINANCIAL DOCUMENTATION SUPPORTING THE TRANSACTION.

(D) INVENTORIES AND RECORDS SHALL BE MADE AVAILABLE FOR INSPECTION AND PHOTOCOPYING BY AUTHORIZED FEDERAL, STATE, OR LOCAL OFFICIALS FOR A PERIOD OF 3 YEARS FOLLOWING DISPOSITION OF THE DRUGS OR 3 YEARS AFTER THE CREATION OF THE RECORDS, WHICHEVER PERIOD IS LONGER.

(E) (1) RECORDS DESCRIBED IN THIS SECTION THAT ARE KEPT AT THE INSPECTION SITE OR THAT CAN BE IMMEDIATELY RETRIEVED BY COMPUTER OR OTHER ELECTRONIC MEANS SHALL BE READILY AVAILABLE FOR AUTHORIZED INSPECTION DURING THE RETENTION PERIOD PROVIDED IN SUBSECTION (D) OF THIS SECTION.

(2) RECORDS THAT ARE KEPT AT A CENTRAL LOCATION OUTSIDE OF THIS STATE AND THAT ARE NOT ELECTRONICALLY RETRIEVABLE SHALL BE MADE AVAILABLE FOR INSPECTION WITHIN 2 WORKING DAYS AFTER A REQUEST BY AN AUTHORIZED OFFICIAL OF A FEDERAL, STATE, OR LOCAL LAW ENFORCEMENT AGENCY.

(3) RECORDS THAT ARE MAINTAINED AT A CENTRAL LOCATION WITHIN THE STATE MUST BE READILY AVAILABLE.

(F) (1) (I) EFFECTIVE JULY 1, 2006, AND EXCEPT AS PROVIDED IN PARAGRAPH (3) OF THIS SUBSECTION, A PERSON WHO IS ENGAGED IN THE WHOLESALE DISTRIBUTION OF A PRESCRIPTION DRUG AND WHO IS NOT THE MANUFACTURER OF THAT DRUG SHALL, BEFORE EACH WHOLESALE DISTRIBUTION OF THE DRUG, PROVIDE TO THE PERSON THAT RECEIVES THE DRUG A PEDIGREE PAPER FOR THE PRESCRIPTION DRUG.

(II) THE PEDIGREE PAPER SHALL INCLUDE AT LEAST THE FOLLOWING INFORMATION FOR THE PRESCRIPTION DRUG:

1. THE AMOUNT;

2. THE DOSAGE FORM AND STRENGTH;

3. THE LOT NUMBERS;

4. THE NAME, SIGNATURE, AND ADDRESS OF EACH OWNER;

5. SHIPPING INFORMATION, INCLUDING THE NAME AND ADDRESS OF EACH PERSON CERTIFYING DELIVERY OR RECEIPT OF THE PRESCRIPTION DRUG;

6. CERTIFICATION THAT THE RECIPIENT HAS AUTHENTICATED THE PEDIGREE PAPERS; AND

7. THE NAME, ADDRESS, TELEPHONE NUMBER, AND, IF AVAILABLE, ELECTRONIC MAIL CONTACT INFORMATION OF EACH WHOLESALE PRESCRIPTION DRUG DISTRIBUTOR INVOLVED IN THE CHAIN OF CUSTODY FOR THE PRESCRIPTION DRUG.

(III) THE DEPARTMENT SHALL ADOPT REGULATIONS, INCLUDING A FORM, FOR THE PEDIGREE PAPER.

(2) A REPACKAGER SHALL COMPLY WITH THIS SUBSECTION.

(3) THE PEDIGREE PAPER REQUIREMENTS IN THIS SUBSECTION DO NOT APPLY TO COMPRESSED MEDICAL GASES OR VETERINARY LEGEND DRUGS.

(4) A WHOLESALE PRESCRIPTION DRUG DISTRIBUTOR SHALL MAINTAIN SEPARATE AND DISTINCT FROM OTHER REQUIRED RECORDS ALL STATEMENTS THAT ARE REQUIRED UNDER PARAGRAPH (1) OF THIS SUBSECTION.

(G) (1) EXCEPT FOR A MANUFACTURER, A WHOLESALE PRESCRIPTION DRUG DISTRIBUTOR SHALL ANNUALLY PROVIDE THE DEPARTMENT WITH A WRITTEN LIST OF ALL WHOLESALE DISTRIBUTORS AND MANUFACTURERS FROM WHOM THE WHOLESALE DISTRIBUTOR PURCHASES PRESCRIPTION DRUGS.

(2) EXCEPT FOR A MANUFACTURER, A WHOLESALE PRESCRIPTION DRUG DISTRIBUTOR SHALL NOTIFY THE DEPARTMENT NOT LATER THAN 10 DAYS AFTER ANY CHANGE TO EITHER LIST.

(3) THE DEPARTMENT SHALL KEEP CONFIDENTIAL THOSE PORTIONS OF THE INFORMATION REQUIRED UNDER THIS PARAGRAPH THAT ARE A TRADE SECRET.

(H) (1) PRIOR TO PURCHASING ANY PRESCRIPTION DRUGS FROM ANOTHER WHOLESALE PRESCRIPTION DRUG DISTRIBUTOR, A WHOLESALE PRESCRIPTION DRUG DISTRIBUTOR SHALL:

(I) ENTER INTO AN AGREEMENT WITH THE SELLING WHOLESALE PRESCRIPTION DRUG DISTRIBUTOR BY WHICH THE SELLING WHOLESALE PRESCRIPTION DRUG DISTRIBUTOR WILL INDEMNIFY THE PURCHASING WHOLESALE PRESCRIPTION DRUG DISTRIBUTOR FOR ANY LOSS TO THE PURCHASING WHOLESALE PRESCRIPTION DRUG DISTRIBUTOR RELATED TO THE PURCHASE OF DRUGS FROM THE SELLING WHOLESALE PRESCRIPTION DRUG DISTRIBUTOR THAT

ARE DETERMINED TO BE COUNTERFEIT OR TO HAVE BEEN DISTRIBUTED IN VIOLATION OF ANY FEDERAL OR STATE LAW GOVERNING THE DISTRIBUTION OF DRUGS;

(II) DETERMINE THAT THE SELLING WHOLESALE PRESCRIPTION DRUG DISTRIBUTOR HAS INSURANCE COVERAGE OF NOT LESS THAN THE GREATER OF 1% OF THE AMOUNT OF ITS TOTAL DOLLAR VOLUME OF PRESCRIPTION DRUG SALES OR $500,000, PROVIDED THAT THE COVERAGE NEED NOT EXCEED $2,000,000;

(III) OBTAIN INFORMATION FROM THE SELLING WHOLESALE PRESCRIPTION DRUG DISTRIBUTOR, INCLUDING:

1. THE LENGTH OF TIME THE SELLING WHOLESALE PRESCRIPTION DRUG DISTRIBUTOR HAS BEEN LICENSED IN THE STATE;

2. A COPY OF THE SELLING WHOLESALE PRESCRIPTION DRUG DISTRIBUTOR'S LICENSES OR PERMITS; AND

3. BACKGROUND INFORMATION CONCERNING THE OWNERSHIP OF THE SELLING WHOLESALE PRESCRIPTION DRUG DISTRIBUTOR, INCLUDING THE EXPERIENCE OF THE WHOLESALE PRESCRIPTION DRUG DISTRIBUTOR IN THE WHOLESALE DISTRIBUTION OF PRESCRIPTION DRUGS;

(IV) VERIFY THAT THE PERMIT ISSUED BY THE STATE TO THE SELLING WHOLESALE PRESCRIPTION DRUG DISTRIBUTOR IS VALID; AND

(V) INSPECT THE SELLING WHOLESALE PRESCRIPTION DRUG DISTRIBUTOR'S ESTABLISHMENT TO DOCUMENT THAT IT HAS A POLICIES AND PROCEDURES MANUAL RELATING TO THE DISTRIBUTION OF DRUGS, THE APPROPRIATE TEMPERATURE-CONTROLLED ENVIRONMENT FOR DRUGS REQUIRING TEMPERATURE CONTROL, AN ALARM SYSTEM, APPROPRIATE ACCESS RESTRICTIONS, AND PROCEDURES TO ENSURE THAT RECORDS RELATED TO THE WHOLESALE DISTRIBUTION OF PRESCRIPTION DRUGS ARE MAINTAINED AS REQUIRED BY LAW AND REGULATION.

(2) THE INSPECTION REQUIRED UNDER PARAGRAPH (1)(V) OF THIS SUBSECTION SHALL BE MADE OR CAUSED TO BE MADE BY THE PURCHASING PRESCRIPTION DRUG DISTRIBUTOR:

(I) BEFORE THE PURCHASING PRESCRIPTION DRUG DISTRIBUTOR PURCHASES ANY DRUG FROM THE SELLING WHOLESALE PRESCRIPTION DRUG DISTRIBUTOR; AND

(II) AT LEAST ONCE EACH YEAR, EITHER BY THE PURCHASING WHOLESALE PRESCRIPTION DRUG DISTRIBUTOR CONDUCTING A PHYSICAL INSPECTION OR OBTAINING A COMPLETE COPY OF THE MOST RECENT INSPECTION REPORT FOR THE ESTABLISHMENT PREPARED BY THE DEPARTMENT OR THE REGULATORY AUTHORITY RESPONSIBLE FOR WHOLESALE PRESCRIPTION DRUG DISTRIBUTORS IN THE STATE IN WHICH THE ESTABLISHMENT IS LOCATED.

21-229.

(A) (1) THE DEPARTMENT SHALL INSPECT EACH WHOLESALE PRESCRIPTION DRUG ESTABLISHMENT, PRESCRIPTION DRUG REPACKAGER ESTABLISHMENT, AND RETAIL PHARMACY DRUG ESTABLISHMENT THAT IS REQUIRED TO HOLD A PERMIT UNDER TITLE 12 OF THE HEALTH OCCUPATIONS ARTICLE AS OFTEN AS NECESSARY TO ENSURE COMPLIANCE WITH APPLICABLE LAWS AND RULES.

(2) THE DEPARTMENT SHALL HAVE THE RIGHT OF ENTRY AND ACCESS TO THE FACILITIES UNDER PARAGRAPH (1) OF THIS SUBSECTION AT ANY REASONABLE TIME.

(B) (1) TO PROTECT THE PUBLIC FROM PRESCRIPTION DRUGS THAT ARE ADULTERATED OR OTHERWISE UNFIT FOR HUMAN CONSUMPTION, THE DEPARTMENT MAY EXAMINE, SAMPLE, SEIZE, AND STOP THE SALE OR USE OF PRESCRIPTION DRUGS TO DETERMINE THE CONDITION OF THOSE DRUGS.

(2) THE DEPARTMENT MAY IMMEDIATELY SEIZE AND REMOVE ANY PRESCRIPTION DRUGS IF THE SECRETARY OR THE SECRETARY'S DESIGNEE DETERMINES THAT THE PRESCRIPTION DRUGS REPRESENT A THREAT TO THE PUBLIC HEALTH.

(3) THE OWNER OF ANY PROPERTY SEIZED UNDER THIS SECTION MAY, WITHIN 10 DAYS AFTER THE SEIZURE, APPLY TO A COURT OF COMPETENT JURISDICTION FOR WHATEVER RELIEF IS APPROPRIATE.

(4) AT ANY TIME AFTER 10 DAYS, THE DEPARTMENT MAY DESTROY THE DRUGS AS CONTRABAND.

(C) (1) THE DEPARTMENT MAY DETERMINE THAT A PRESCRIPTION DRUG WHOLESALE ESTABLISHMENT, PRESCRIPTION DRUG REPACKAGER ESTABLISHMENT, OR RETAIL PHARMACY DRUG ESTABLISHMENT THAT IS REQUIRED TO HAVE A PERMIT UNDER TITLE 12 OF THE HEALTH OCCUPATIONS ARTICLE IS AN IMMINENT DANGER TO THE PUBLIC HEALTH AND REQUIRE ITS IMMEDIATE CLOSURE IF THE ESTABLISHMENT:

(I) FAILS TO COMPLY WITH APPLICABLE LAWS AND REGULATIONS; AND

(II) AS A RESULT OF THAT FAILURE, PRESENTS AN IMMINENT THREAT TO THE PUBLIC'S HEALTH, SAFETY, OR WELFARE.

(2) AN ESTABLISHMENT CLOSED UNDER PARAGRAPH (1) OF THIS SUBSECTION SHALL REMAIN CLOSED UNTIL ALLOWED BY THE DEPARTMENT OR BY JUDICIAL ORDER TO REOPEN.

(D) A REFUSAL TO ALLOW ENTRY TO THE DEPARTMENT FOR INSPECTION AT REASONABLE TIMES OR A FAILURE OR REFUSAL TO PROVIDE THE DEPARTMENT

WITH REQUIRED DOCUMENTATION FOR PURPOSES OF INSPECTION CONSTITUTES AN IMMINENT DANGER TO THE PUBLIC HEALTH.

21-229.1.

(A) IN THIS SECTION, "PERMITTEE" MEANS ANY PERSON HOLDING A WHOLESALE DISTRIBUTION PERMIT ISSUED UNDER § 12-602 OF THE HEALTH OCCUPATIONS ARTICLE.

(B) (1) IN ADDITION TO ANY AUTHORITY OTHERWISE PROVIDED IN THIS SUBTITLE, THE DEPARTMENT MAY ISSUE AND SERVE A COMPLAINT STATING CHARGES UPON ANY PERMITTEE WHENEVER THE DEPARTMENT HAS REASONABLE CAUSE TO BELIEVE THAT THE PERMITTEE IS ENGAGING IN OR HAS ENGAGED IN CONDUCT THAT IS:

(I) 1. AN ACT THAT DEMONSTRATES A LACK OF FITNESS OR TRUSTWORTHINESS TO ENGAGE IN THE BUSINESS AUTHORIZED UNDER THE PERSON'S PERMIT;

2. HAZARDOUS TO THE PUBLIC HEALTH; OR

3. A BUSINESS OPERATION THAT IS A DETRIMENT TO THE PUBLIC HEALTH;

(II) A VIOLATION OF ANY PROVISION OF THIS SUBTITLE;

(III) A VIOLATION OF ANY REGULATION OF THE DEPARTMENT;

(IV) A VIOLATION OF ANY ORDER OF THE DEPARTMENT; OR

(V) A BREACH OF ANY WRITTEN AGREEMENT WITH THE DEPARTMENT.

(2) THE COMPLAINT SHALL CONTAIN A STATEMENT OF FACTS AND NOTICE OF THE OPPORTUNITY FOR A HEARING IN ACCORDANCE WITH TITLE 10 OF THE STATE GOVERNMENT ARTICLE.

(3) IF A HEARING IS NOT REQUESTED WITHIN THE TIME ALLOWED UNDER TITLE 10 OF THE STATE GOVERNMENT ARTICLE, OR IF A HEARING IS HELD AND THE DEPARTMENT FINDS THAT ANY OF THE CHARGES ARE PROVEN, THE DEPARTMENT MAY ENTER AN ORDER DIRECTING THE PERMITTEE NAMED IN THE COMPLAINT TO CEASE AND DESIST FROM ENGAGING IN THE CONDUCT IN THE COMPLAINT AND TAKE CORRECTIVE ACTION TO REMEDY THE EFFECTS OF PAST IMPROPER CONDUCT AND ASSURE FUTURE COMPLIANCE.

(4) (I) A CONTESTED OR DEFAULT CEASE AND DESIST ORDER IS EFFECTIVE WHEN SERVED ON THE PERMITTEE.

(II) AN UNCONTESTED CEASE AND DESIST ORDER IS EFFECTIVE AS AGREED BETWEEN THE PERMITTEE AND THE DEPARTMENT.

(5) (I) WHENEVER THE DEPARTMENT FINDS THAT CONDUCT DESCRIBED IN PARAGRAPH (1) OF THIS SUBSECTION IS LIKELY TO CAUSE AN IMMEDIATE THREAT TO THE PUBLIC HEALTH, THE DEPARTMENT MAY ISSUE AN EMERGENCY CEASE AND DESIST ORDER REQUIRING THE PERMITTEE TO IMMEDIATELY CEASE AND DESIST FROM ENGAGING IN THE CONDUCT IN THE COMPLAINT AND TO TAKE CORRECTIVE AND REMEDIAL ACTION.

(II) THE EMERGENCY ORDER IS EFFECTIVE IMMEDIATELY ON SERVICE OF A COPY OF THE ORDER ON THE PERMITTEE AND REMAINS EFFECTIVE FOR 90 DAYS.

(III) IF THE DEPARTMENT BEGINS NONEMERGENCY CEASE AND DESIST PROCEEDINGS UNDER THIS SUBSECTION, THE EMERGENCY ORDER REMAINS EFFECTIVE UNTIL THE CONCLUSION OF THE PROCEEDINGS UNDER TITLE 10 OF THE STATE GOVERNMENT ARTICLE.

21-258.1.

(A) IT IS UNLAWFUL FOR A PERSON:

(1) (I) TO PURCHASE OR SELL PRESCRIPTION DRUGS FOR WHOLESALE DISTRIBUTION IN EXCHANGE FOR CURRENCY;

(II) OTHER THAN A MANUFACTURER, ENGAGED IN THE WHOLESALE DISTRIBUTION OF LEGEND DRUGS, TO FAIL TO DELIVER TO ANOTHER PERSON COMPLETE AND ACCURATE PEDIGREE PAPERS CONCERNING A LEGEND DRUG OR CONTRABAND LEGEND DRUG PRIOR TO TRANSFERRING THE LEGEND DRUG OR CONTRABAND LEGEND DRUG TO ANOTHER PERSON;

(III) ENGAGED IN THE WHOLESALE DISTRIBUTION OF LEGEND DRUGS TO FAIL TO ACQUIRE COMPLETE AND ACCURATE PEDIGREE PAPERS CONCERNING A LEGEND DRUG OR CONTRABAND LEGEND DRUG PRIOR TO OBTAINING THE LEGEND DRUG OR CONTRABAND LEGEND DRUG FROM ANOTHER PERSON; OR

(IV) TO KNOWINGLY DESTROY, ALTER, CONCEAL, OR FAIL TO MAINTAIN COMPLETE AND ACCURATE PEDIGREE PAPERS CONCERNING ANY LEGEND DRUG OR CONTRABAND LEGEND DRUG IN THE PERSON'S POSSESSION; OR

(2) ON OR AFTER JULY 1, 2007:

(I) ENGAGED IN THE WHOLESALE DISTRIBUTION OF LEGEND DRUGS WHO IS IN POSSESSION OF PEDIGREE PAPERS CONCERNING LEGEND DRUGS OR CONTRABAND LEGEND DRUGS, TO FAIL TO AUTHENTICATE THE MATTERS CONTAINED IN THE PEDIGREE PAPERS AND TO NEVERTHELESS ATTEMPT TO FURTHER DISTRIBUTE LEGEND DRUGS OR CONTRABAND LEGEND DRUGS; OR

(II) IN POSSESSION OF PEDIGREE PAPERS CONCERNING LEGEND DRUGS OR CONTRABAND LEGEND DRUGS, TO FALSELY SWEAR OR CERTIFY THAT THE PERSON HAS AUTHENTICATED THE MATTERS CONTAINED IN THE PEDIGREE PAPERS.

(B) A PERSON WHO VIOLATES ANY PROVISION OF SUBSECTION (A) OF THIS SECTION IS GUILTY OF A FELONY AND ON CONVICTION IS SUBJECT TO:

(1) A FINE NOT EXCEEDING $10,000 OR IMPRISONMENT NOT EXCEEDING 3 YEARS OR BOTH; OR

(2) IF THE PERSON HAS BEEN CONVICTED ONCE OF VIOLATING SUBSECTION (B) OF THIS SECTION, A FINE NOT EXCEEDING $25,000 OR IMPRISONMENT NOT EXCEEDING 5 YEARS OR BOTH.

(C) IT IS UNLAWFUL FOR A PERSON TO:

(1) REMOVE A PHARMACY'S DISPENSING LABEL FROM A DISPENSED PRESCRIPTION DRUG WITH THE INTENT TO FURTHER DISTRIBUTE THE PRESCRIPTION DRUG;

(2) DISTRIBUTE A PRESCRIPTION DRUG THAT WAS PREVIOUSLY DISPENSED BY A LICENSED PHARMACY, UNLESS SUCH DISTRIBUTION WAS AUTHORIZED BY LAW;

(3) KNOWINGLY FORGE, COUNTERFEIT, OR FALSELY CREATE ANY PEDIGREE PAPER, FALSELY REPRESENT ANY FACTUAL MATTER CONTAINED ON ANY PEDIGREE PAPER, OR KNOWINGLY OMIT TO RECORD MATERIAL INFORMATION REQUIRED TO BE RECORDED IN A PEDIGREE PAPER;

(4) KNOWINGLY PURCHASE OR RECEIVE A LEGEND DRUG IN A WHOLESALE DISTRIBUTION TRANSACTION FROM A PERSON NOT AUTHORIZED TO DISTRIBUTE LEGEND DRUGS UNDER TITLE 12 OF THE HEALTH OCCUPATIONS ARTICLE;

(5) KNOWINGLY SELL OR TRANSFER A LEGEND DRUG IN A WHOLESALE DISTRIBUTION TRANSACTION TO A PERSON NOT AUTHORIZED TO PURCHASE OR POSSESS LEGEND DRUGS UNDER THE LAW OF THE JURISDICTION IN WHICH THE PERSON RECEIVES THE DRUG;

(6) BE KNOWINGLY IN ACTUAL OR CONSTRUCTIVE POSSESSION OF ANY AMOUNT OF CONTRABAND LEGEND DRUGS, KNOWINGLY SELL OR DELIVER, OR POSSESS WITH INTENT TO SELL OR DELIVER ANY AMOUNT OF CONTRABAND LEGEND DRUGS; OR

(7) KNOWINGLY FORGE, COUNTERFEIT, OR FALSELY CREATE ANY PRESCRIPTION LABEL OR LEGEND DRUG LABEL, OR FALSELY REPRESENT ANY FACTUAL MATTER CONTAINED ON ANY PRESCRIPTION LABEL OR LEGEND DRUG LABEL.

(D) A PERSON WHO VIOLATES ANY PROVISION OF SUBSECTION (C) OF THIS SECTION IS GUILTY OF A FELONY AND ON CONVICTION IS SUBJECT TO:

(1) A FINE NOT EXCEEDING $10,000 OR IMPRISONMENT NOT EXCEEDING 5 YEARS OR BOTH; OR

(2) IF THE PERSON HAS BEEN CONVICTED ONCE OF VIOLATING SUBSECTION (D) OF THIS SECTION, A FINE NOT EXCEEDING $25,000 OR IMPRISONMENT NOT EXCEEDING 10 YEARS OR BOTH.

(E) (1) IT IS UNLAWFUL FOR A PERSON TO KNOWINGLY SELL, PURCHASE, MANUFACTURE, DELIVER, OR BRING INTO THE STATE, OR BE KNOWINGLY IN POSSESSION OF ANY AMOUNT OF CONTRABAND LEGEND DRUGS VALUED AT $25,000 OR MORE.

(2) A PERSON WHO VIOLATES ANY PROVISION OF PARAGRAPH (1) OF THIS SUBSECTION IS GUILTY OF A FELONY AND, ON CONVICTION, SHALL PAY A MANDATORY FINE ACCORDING TO THE FOLLOWING SCHEDULE:

(I) IF THE VALUE OF CONTRABAND LEGEND DRUGS INVOLVED IS AT LEAST $25,000 BUT LESS THAN $100,000, THE PERSON SHALL PAY A MANDATORY FINE OF $25,000;

(II) IF THE VALUE OF CONTRABAND LEGEND DRUGS INVOLVED IS AT LEAST $100,000 BUT LESS THAN $250,000, THE PERSON SHALL PAY A MANDATORY FINE OF $100,000; OR

(III) IF THE VALUE OF CONTRABAND LEGEND DRUGS INVOLVED IS $250,000 OR MORE, THE PERSON SHALL PAY A MANDATORY FINE OF $200,000.

(F) A PERSON WHO KNOWINGLY SELLS, PURCHASES, MANUFACTURES, DELIVERS, OR BRINGS INTO THE STATE, OR WHO IS KNOWINGLY IN POSSESSION OF ANY AMOUNT OF CONTRABAND LEGEND DRUGS, AND WHOSE ACTS IN VIOLATION OF THIS SECTION RESULT IN GREAT BODILY HARM TO A PERSON, IS GUILTY OF A FELONY AND, ON CONVICTION, IS SUBJECT TO IMPRISONMENT NOT EXCEEDING 30 YEARS.

(G) A PERSON WHO KNOWINGLY SELLS, PURCHASES, MANUFACTURES, DELIVERS, OR BRINGS INTO THE STATE, OR WHO IS KNOWINGLY IN POSSESSION OF ANY AMOUNT OF CONTRABAND LEGEND DRUGS, AND WHOSE ACTS IN VIOLATION OF THIS SECTION RESULT IN THE DEATH OF A PERSON IS GUILTY OF A FELONY AND, ON CONVICTION, IS SUBJECT TO IMPRISONMENT FOR A TERM OF YEARS NOT EXCEEDING LIFE.

Article - Health Occupations

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:

(I) [distribute] DISTRIBUTE prescription drugs or devices into, out of, or within the State as a distributor, jobber, manufacturer, or wholesaler, wherever located; OR

(II) REPACKAGE PRESCRIPTION DRUGS OR DEVICES.

(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.

(c) A person shall hold a distribution permit issued by the Board before the person may:

(1) [distribute] DISTRIBUTE prescription drugs or devices as a distributor, jobber, manufacturer, or wholesaler; OR

(2) REPACKAGE PRESCRIPTION DRUGS OR DEVICES.

(h) A distribution permit issued under this section authorizes, WHILE THE DISTRIBUTION PERMIT IS EFFECTIVE, the distribution permit holder to:

(1) [distribute] DISTRIBUTE prescription drugs or devices as a distributor, jobber, manufacturer, or wholesaler [while the distribution permit is effective]; OR

(2) REPACKAGE PRESCRIPTION DRUGS OR DEVICES.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2004.