

CHAPTER 330

PROFESSIONS AND OCCUPATIONS

SENATE BILL 06-230

BY SENATOR(S) Boyd, Fitz-Gerald, Shaffer, Tochtrop, Tupa, Williams, and Windels;
also REPRESENTATIVE(S) Benefield, Borodkin, Buescher, Cloer, Green, Jahn, Kerr A., Kerr J., Merrifield, Paccione, Riesberg,
Solano, Stafford, Todd, and Vigil.

AN ACT

CONCERNING THE REGULATION OF WHOLESALERS OF PRESCRIPTION DRUGS, AND MAKING AN APPROPRIATION THEREFOR.

Be it enacted by the General Assembly of the State of Colorado:

SECTION 1. Article 22 of title 12, Colorado Revised Statutes, is amended BY THE ADDITION OF A NEW PART to read:

**PART 8
WHOLESALERS**

12-22-801. Definitions. (1) AS USED IN THIS SECTION, UNLESS THE CONTEXT OTHERWISE REQUIRES:

(a) "AUTHENTICATION" MEANS THE PROCESS OF AFFIRMATIVELY VERIFYING THAT EACH TRANSACTION LISTED ON A PEDIGREE HAS OCCURRED BEFORE ANY WHOLESALE DISTRIBUTION OF A PRESCRIPTION DRUG OCCURS.

(b) "AUTHORIZED DISTRIBUTOR OF RECORD" MEANS A WHOLESALER WITH WHOM A MANUFACTURER HAS ESTABLISHED AN ONGOING RELATIONSHIP TO DISTRIBUTE THE MANUFACTURER'S PRESCRIPTION DRUG. AN ONGOING RELATIONSHIP IS DEEMED TO EXIST BETWEEN A WHOLESALER AND A MANUFACTURER WHEN THE WHOLESALER, INCLUDING ANY AFFILIATED GROUP OF THE WHOLESALER AS DEFINED IN SECTION 1504 OF THE FEDERAL "INTERNAL REVENUE CODE OF 1986", COMPLIES WITH EITHER OF THE FOLLOWING:

(I) THE WHOLESALER HAS A WRITTEN AGREEMENT CURRENTLY IN EFFECT WITH THE MANUFACTURER EVIDENCING SUCH ONGOING RELATIONSHIP; OR

Capital letters indicate new material added to existing statutes; dashes through words indicate deletions from existing statutes and such material not part of act.

(II) THE WHOLESALER IS LISTED ON THE MANUFACTURER'S CURRENT LIST OF AUTHORIZED DISTRIBUTORS OF RECORD, WHICH LIST IS UPDATED BY THE MANUFACTURER ON NO LESS THAN A MONTHLY BASIS.

(c) "BOARD" MEANS THE STATE BOARD OF PHARMACY.

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

(e) "DESIGNATED REPRESENTATIVE" MEANS A PERSON AUTHORIZED BY A LICENSED WHOLESALER TO ACT AS A REPRESENTATIVE FOR THE WHOLESALER.

(f) "DROP SHIPMENT" MEANS THE SALE, BY A MANUFACTURER OF THE MANUFACTURER'S PRESCRIPTION DRUG, THAT MANUFACTURER'S THIRD-PARTY LOGISTICS PROVIDER, OR THAT MANUFACTURER'S EXCLUSIVE DISTRIBUTOR, TO A WHOLESALER WHEREBY THE WHOLESALER TAKES TITLE TO, BUT NOT POSSESSION OF, SUCH PRESCRIPTION DRUG AND THE WHOLESALER INVOICES THE PHARMACY OR CHAIN PHARMACY WAREHOUSE AND THE PHARMACY OR CHAIN PHARMACY WAREHOUSE RECEIVES DELIVERY OF THE PRESCRIPTION DRUG DIRECTLY FROM THE MANUFACTURER OF SUCH DRUG, THAT MANUFACTURER'S THIRD-PARTY LOGISTICS PROVIDER, OR THAT MANUFACTURER'S EXCLUSIVE DISTRIBUTOR.

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

(h) "MANUFACTURER'S EXCLUSIVE DISTRIBUTOR" MEANS ANYONE WHO CONTRACTS WITH A MANUFACTURER TO PROVIDE OR COORDINATE WAREHOUSING, DISTRIBUTION, OR OTHER SERVICES ON BEHALF OF A MANUFACTURER AND WHO TAKES TITLE TO THE MANUFACTURER'S PRESCRIPTION DRUG, BUT WHO DOES NOT HAVE GENERAL RESPONSIBILITY TO DIRECT THE SALE OR DISPOSITION OF THE MANUFACTURER'S PRESCRIPTION DRUG. SUCH MANUFACTURER'S EXCLUSIVE DISTRIBUTOR MUST BE LICENSED AS A WHOLESALER UNDER THIS PART 8.

(i) "NORMAL DISTRIBUTION CHANNEL" MEANS A CHAIN OF CUSTODY FOR A PRESCRIPTION DRUG THAT GOES FROM A MANUFACTURER OF THE PRESCRIPTION DRUG TO:

(I) A WHOLESALER TO A PHARMACY TO A PATIENT OR OTHER DESIGNATED PERSONS AUTHORIZED BY LAW TO DISPENSE OR ADMINISTER SUCH DRUG TO A PATIENT; A WHOLESALER TO A CHAIN PHARMACY WAREHOUSE TO THEIR INTRACOMPANY PHARMACIES TO A PATIENT; A CHAIN PHARMACY WAREHOUSE TO THEIR INTRACOMPANY PHARMACIES TO A PATIENT, A PHARMACY TO A PATIENT; OR

(II) A MANUFACTURER'S COLICENSED PARTNER, THIRD-PARTY LOGISTICS PROVIDER, OR EXCLUSIVE DISTRIBUTOR TO A WHOLESALER TO A PHARMACY TO A PATIENT OR OTHER DESIGNATED PERSONS AUTHORIZED BY LAW TO DISPENSE OR ADMINISTER SUCH DRUG TO A PATIENT; OR

(III) A MANUFACTURER'S COLICENSED PARTNER OR THAT MANUFACTURER'S THIRD-PARTY LOGISTICS PROVIDER OR EXCLUSIVE DISTRIBUTOR TO A WHOLESALER TO A CHAIN PHARMACY WAREHOUSE TO THAT CHAIN PHARMACY WAREHOUSE'S INTRACOMPANY PHARMACY TO A PATIENT OR OTHER DESIGNATED PERSONS AUTHORIZED BY LAW TO DISPENSE OR ADMINISTER SUCH DRUG TO A PATIENT; OR

(IV) A SPECIALTY WHOLESALER TO A PHARMACY, PHYSICIAN, OR HOSPITAL; OR

(V) A WHOLESALER TO A PHARMACY BUYING COOPERATIVE WAREHOUSE TO A PHARMACY THAT IS A MEMBER OR MEMBER OWNER OF SUCH COOPERATIVE TO A PATIENT OR OTHER DESIGNATED PERSON AUTHORIZED BY LAW TO DISPENSE OR ADMINISTER THE PRESCRIPTION DRUG TO A PATIENT.

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

(k) "PHARMACY BUYING COOPERATIVE WAREHOUSE" MEANS A PERMANENT PHYSICAL LOCATION THAT ACTS AS A CENTRAL WAREHOUSE FOR PRESCRIPTION DRUGS AND FROM WHICH SALES OF SUCH DRUGS ARE MADE TO AN EXCLUSIVE GROUP OF PHARMACIES THAT ARE MEMBERS OR MEMBER OWNERS OF THE BUYING COOPERATIVE OPERATING THE WAREHOUSE THAT SHALL BE LICENSED AS A WHOLESALER.

(l) "PRESCRIPTION DRUG" MEANS ANY DRUG, INCLUDING ANY BIOLOGICAL PRODUCT, EXCEPT FOR BLOOD AND BLOOD COMPONENTS, INCLUDING FACTOR, INTENDED FOR TRANSFUSION OR BIOLOGICAL PRODUCTS THAT ARE ALSO MEDICAL DEVICES, REQUIRED BY FEDERAL LAW OR REGULATION TO BE DISPENSED ONLY BY A PRESCRIPTION, INCLUDING FINISHED DOSAGE FORMS AND BULK DRUG SUBSTANCES SUBJECT TO SECTION 503(b) OF THE FEDERAL "FOOD, DRUG, AND COSMETIC ACT".

(m) "REPACKAGE" MEANS REPACKAGING OR OTHERWISE CHANGING THE CONTAINER, WRAPPER, OR LABELING TO FURTHER THE DISTRIBUTION OF A PRESCRIPTION DRUG, EXCLUDING THAT COMPLETED BY THE PHARMACIST RESPONSIBLE FOR DISPENSING PRODUCT TO THE PATIENT.

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

(o) "SPECIALTY WHOLESALER" MEANS A PERSON WHO EXCLUSIVELY DISTRIBUTES A PRESCRIPTION DRUG TO A SPECIFIC GROUP OF SPECIALTY PHARMACIES OR LICENSED PRACTITIONERS AND WHO HAS CERTIFIED TO THE BOARD THAT THE DISTRIBUTION OF SUCH PRODUCTS WILL ONLY OCCUR IN THE LIMITED SITUATIONS DESCRIBED HEREIN. SUCH SPECIALTY WHOLESALE DISTRIBUTORS SHALL BE SEPARATELY LICENSED AND DESIGNATED AS SPECIALTY WHOLESALE DISTRIBUTORS BY THE BOARD.

(p) "THIRD-PARTY LOGISTICS PROVIDER" MEANS ANYONE WHO CONTRACTS WITH A MANUFACTURER TO PROVIDE OR COORDINATE WAREHOUSING, DISTRIBUTION, OR OTHER SERVICES ON BEHALF OF A MANUFACTURER, BUT DOES NOT TAKE TITLE TO A PRESCRIPTION DRUG OR HAVE GENERAL RESPONSIBILITY TO DIRECT THE PRESCRIPTION DRUG'S SALE OR DISPOSITION. A THIRD-PARTY LOGISTICS PROVIDER MUST BE LICENSED AS A WHOLESALE DISTRIBUTOR UNDER THIS PART 8.

(q) "WHOLESALE" MEANS ANY PERSON ENGAGED IN THE WHOLESALE DISTRIBUTION OF PRESCRIPTION DRUGS, INCLUDING, BUT NOT LIMITED TO, REPACKAGERS; OWN-LABEL DISTRIBUTORS; PRIVATE-LABEL DISTRIBUTORS; JOBBERS; BROKERS; WAREHOUSES, INCLUDING MANUFACTURERS' AND DISTRIBUTORS' WAREHOUSES; MANUFACTURERS' EXCLUSIVE DISTRIBUTORS; AUTHORIZED DISTRIBUTORS OF RECORD; DRUG WHOLESALE OR DISTRIBUTORS; INDEPENDENT WHOLESALE DRUG TRADERS; SPECIALTY WHOLESALE DISTRIBUTORS; PHARMACY BUYING COOPERATIVE WAREHOUSES; RETAIL PHARMACIES THAT CONDUCT WHOLESALE DISTRIBUTION; AND CHAIN PHARMACY WAREHOUSES THAT CONDUCT WHOLESALE DISTRIBUTION.

(2) FOR THE PURPOSES OF THIS PART 8, "WHOLESALE DISTRIBUTION" MEANS DISTRIBUTION OF PRESCRIPTION DRUGS TO PERSONS OR ENTITIES OTHER THAN A CONSUMER OR PATIENT. "WHOLESALE DISTRIBUTION" DOES NOT INCLUDE:

(a) INTRACOMPANY SALES OR TRANSFERS OF PRESCRIPTION DRUGS, INCLUDING A TRANSACTION OR TRANSFER BETWEEN A DIVISION, SUBSIDIARY, PARENT, OR AFFILIATED OR RELATED COMPANY UNDER COMMON OWNERSHIP OR CONTROL OF AN ENTITY;

(b) THE SALE, PURCHASE, DISTRIBUTION, TRADE, OR TRANSFER OF A PRESCRIPTION DRUG OR OFFER TO SELL, PURCHASE, DISTRIBUTE, TRADE, OR TRANSFER A PRESCRIPTION DRUG FOR EMERGENCY MEDICAL REASONS OR DURING A STATE OR NATIONAL DECLARATION OF EMERGENCY;

(c) THE SALE OR TRANSFER OF A DRUG FOR MEDICAL REASONS BY A RETAIL PHARMACY TO ANOTHER RETAIL PHARMACY TO ALLEVIATE A TEMPORARY SHORTAGE PURSUANT TO COLORADO LAW;

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

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

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

(g) A RETAIL PHARMACY'S DELIVERY OF PRESCRIPTION DRUGS TO A PATIENT OR PATIENT'S AGENT PURSUANT TO THE LAWFUL ORDER OF A LICENSED PRACTITIONER;

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

(i) THE DIRECT SALE, PURCHASE, DISTRIBUTION, TRADE, OR TRANSFER OF A PRESCRIPTION DRUG FROM A MANUFACTURER TO AN AUTHORIZED DISTRIBUTOR OF RECORD TO ONE ADDITIONAL AUTHORIZED DISTRIBUTOR OF RECORD, BUT ONLY IF AN AUTHORIZED DISTRIBUTOR OF RECORD THAT PURCHASES A PRESCRIPTION DRUG FROM AN AUTHORIZED DISTRIBUTOR OF RECORD THAT PURCHASED THE

PRESCRIPTION DRUG DIRECTLY FROM THE MANUFACTURER:

(I) PROVIDES THE SUPPLYING AUTHORIZED DISTRIBUTOR OF RECORD WITH A VERIFIABLE STATEMENT THAT THE PRODUCT IS UNAVAILABLE FROM THE MANUFACTURER; AND

(II) RECEIVES A VERIFIABLE STATEMENT FROM THE SUPPLYING AUTHORIZED DISTRIBUTOR OF RECORD THAT THE PRODUCT WAS PURCHASED DIRECTLY FROM THE MANUFACTURER.

(j) DROP SHIPMENTS OF A PRESCRIPTION DRUG FROM A MANUFACTURER, THAT MANUFACTURER'S THIRD-PARTY LOGISTICS PROVIDER, OR THAT MANUFACTURER'S EXCLUSIVE DISTRIBUTOR TO A PHARMACY OR CHAIN PHARMACY WAREHOUSE;

(k) 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, WHERE THE COMMON CARRIER DOES NOT STORE, WAREHOUSE, OR TAKE LEGAL OWNERSHIP OF THE PRESCRIPTION DRUG;

(l) THE SALE OR TRANSFER FROM A RETAIL PHARMACY OR CHAIN PHARMACY WAREHOUSE OF EXPIRED, DAMAGED, RETURNED, OR RECALLED PRESCRIPTION DRUGS TO THE ORIGINAL MANUFACTURER OR TO A THIRD-PARTY RETURNS PROCESSOR;

(m) THE SALE OR TRANSFER OF COMPOUNDED DRUGS COMPOUNDED BY A RETAIL PHARMACY AS DEFINED IN SECTION 12-22-102 (6) AND AS AUTHORIZED BY SECTION 12-22-121 (6) (b).

(3) (a) THE BOARD SHALL HAVE THE AUTHORITY TO EXEMPT A PHARMACY BENEFITS ENTITY FROM THE REQUIREMENTS OF SECTIONS 12-22-802 AND 12-22-803 IF SUCH ENTITY'S PURCHASES ARE SOLELY FROM A MANUFACTURER OR A WHOLESALE DISTRIBUTOR IN THE NORMAL DISTRIBUTION CHANNEL, AND ANY SUBSEQUENT SALES OR FURTHER DISTRIBUTIONS ARE TO ENTITIES OTHER THAN A WHOLESALER WITHIN THE NORMAL DISTRIBUTION CHANNEL. FOR THE PURPOSES OF THIS SUBSECTION (3), "PHARMACY BENEFITS ENTITY" MEANS AN ENTITY THAT IS NOT ENGAGED IN THE ACTIVITIES DESCRIBED IN PARAGRAPH (d) OF SUBSECTION (1) OF THIS SECTION BUT THAT ASSISTS IN THE ADMINISTRATION OF PHARMACY BENEFITS UNDER CONTRACTS WITH INSURERS OR TO A COMPANY UNDER COMMON OWNERSHIP WITH THAT ENTITY.

(b) THE BOARD SHALL HAVE THE AUTHORITY TO EXEMPT A WHOLESALER FROM ANY OF THE REQUIREMENTS OF THIS PART 8 IF THE WHOLESALER EXCLUSIVELY DISTRIBUTES ANIMAL HEALTH MEDICINES.

(c) THE BOARD SHALL EXEMPT FROM THE REQUIREMENTS OF SECTIONS 12-22-802 AND 12-22-803 A LICENSED WHOLESALER OPERATED BY A NONPROFIT ORGANIZATION EXEMPT FROM TAXATION UNDER SECTION 501 (c) (3) OF THE FEDERAL "INTERNAL REVENUE CODE OF 1986", AS AMENDED, THAT ENGAGES ONLY IN INTRACOMPANY SALES OR TRANSFERS OF PRESCRIPTION DRUGS TO LICENSED OTHER OUTLETS OR PHARMACIES THAT ARE CONTROLLED BY, OR UNDER COMMON OWNERSHIP OR CONTROL WITH, THE WHOLESALER AND THAT PURCHASE DRUGS DIRECTLY FROM THE MANUFACTURER OR THE MANUFACTURER'S AUTHORIZED

DISTRIBUTOR OF RECORD FOR DISTRIBUTION OR TRANSFER TO THE WHOLESALER'S LICENSED OTHER OUTLETS, PHARMACIES, OR OTHER AREAS AUTHORIZED BY STATE LAW. THE BOARD SHALL EXEMPT A LICENSED WHOLESALER OPERATED BY A HOSPITAL, A STATE AGENCY, OR A POLITICAL SUBDIVISION FROM THE REQUIREMENTS OF SECTIONS 12-22-802 AND 12-22-803 IF SUCH ENTITY PURCHASES DRUGS DIRECTLY FROM A MANUFACTURER OR A MANUFACTURER'S AUTHORIZED DISTRIBUTOR OF RECORD AND IF ANY FURTHER DISTRIBUTION IS TO AUTHORIZED, LICENSED ENTITIES WITHIN ITS OWN NETWORK.

12-22-802. Wholesaler license requirements. (1) A WHOLESALER THAT RESIDES IN THIS STATE SHALL BE LICENSED BY THE BOARD. A WHOLESALER THAT DOES NOT RESIDE IN THIS STATE SHALL BE LICENSED IN THIS STATE PRIOR TO ENGAGING IN THE WHOLESALE DISTRIBUTION OF PRESCRIPTION DRUGS IN THIS STATE. THE BOARD SHALL EXEMPT A MANUFACTURER AND THAT MANUFACTURER'S THIRD-PARTY LOGISTICS PROVIDERS TO THE EXTENT INVOLVING THAT MANUFACTURER'S DRUGS UNDER CONTRACT, FROM ANY LICENSING AND OTHER REQUIREMENTS OF THIS SECTION TO THE EXTENT THE REQUIREMENTS ARE NOT REQUIRED BY FEDERAL LAW OR REGULATION, UNLESS THE PARTICULAR REQUIREMENTS ARE DEEMED NECESSARY AND APPROPRIATE FOLLOWING RULEMAKING BY THE BOARD.

(2)(a) THE BOARD MAY ADOPT RULES TO APPROVE AN ACCREDITATION BODY TO EVALUATE A WHOLESALER'S OPERATIONS TO DETERMINE COMPLIANCE WITH PROFESSIONAL STANDARDS AND ANY OTHER APPLICABLE LAWS, AND TO PERFORM INSPECTIONS OF EACH FACILITY AND LOCATION WHERE WHOLESALE DISTRIBUTION OPERATIONS ARE CONDUCTED BY THE WHOLESALER.

(b) AN APPLICANT FOR A LICENSE SHALL PAY ANY REASONABLE FEE REQUIRED BY THE ACCREDITATION BODY OR THE BOARD AND COMPLY WITH ANY RULES PROMULGATED BY THE BOARD.

(c) THE BOARD SHALL NOT ISSUE OR RENEW A LICENSE TO A WHOLESALER WHO DOES NOT COMPLY WITH THIS PART 8.

(3)(a) AN APPLICANT FOR A WHOLESALER LICENSE SHALL PROVIDE TO THE BOARD THE FOLLOWING INFORMATION, AND ANY OTHER INFORMATION DEEMED APPROPRIATE BY THE BOARD, ON A FORM PROVIDED BY THE BOARD AT THE TIME OF APPLICATION AND EACH CALENDAR YEAR THEREAFTER:

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

(II) THE TRADE AND BUSINESS NAMES USED BY THE APPLICANT;

(III) THE ADDRESSES, TELEPHONE NUMBERS, AND THE NAMES OF THE CONTACT PERSONS FOR ALL FACILITIES USED BY THE APPLICANT FOR THE STORAGE, HANDLING, AND DISTRIBUTION OF PRESCRIPTION DRUGS;

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

(V) THE NAMES OF THE OWNER AND THE OPERATOR OF THE APPLICANT,

INCLUDING THE NAME OF EACH PARTNER IF THE APPLICANT IS A PARTNERSHIP; THE NAME AND TITLE OF EACH OFFICER AND DIRECTOR, THE NAME OF THE CORPORATION, AND THE STATE OF INCORPORATION, IF THE APPLICANT IS A CORPORATION; THE NAME OF THE LIMITED LIABILITY COMPANY, IF THE APPLICANT IS A LIMITED LIABILITY COMPANY, AND THE NAME OF THE PARENT COMPANY, IF ANY, AND STATE OF INCORPORATION OF BOTH; AND THE NAME OF THE SOLE PROPRIETOR AND THE BUSINESS ENTITY IF THE APPLICANT IS A SOLE PROPRIETORSHIP;

(VI) A LIST OF THE LICENSES AND PERMITS ISSUED TO THE APPLICANT BY ANY OTHER STATE THAT AUTHORIZES THE APPLICANT TO PURCHASE OR POSSESS PRESCRIPTION DRUGS; AND

(VII) THE NAME OF THE APPLICANT'S DESIGNATED REPRESENTATIVE FOR THE FACILITY, THE FINGERPRINTS OF THE DESIGNATED REPRESENTATIVE, AND A PERSONAL INFORMATION STATEMENT FOR THE DESIGNATED REPRESENTATIVE THAT INCLUDES INFORMATION AS REQUIRED BY THE BOARD, INCLUDING BUT NOT LIMITED TO THE INFORMATION IN SUBSECTION (5) OF THIS SECTION.

(b) A LICENSEE SHALL COMPLETE AND RETURN THE FORM PROVIDED BY THE BOARD EACH CALENDAR YEAR WITHIN THIRTY DAYS AFTER THE RECEIPT OF THE FORM. THE BOARD MAY SUSPEND OR REVOKE THE LICENSE OF A WHOLESALER IF THE BOARD DETERMINES THAT THE WHOLESALER NO LONGER QUALIFIES FOR A LICENSE.

(4) PRIOR TO ISSUING A WHOLESALER LICENSE TO AN APPLICANT, THE BOARD, STATE BOARD OF PHARMACY, OR BOARD-APPROVED ACCREDITATION BODY SHALL CONDUCT A PHYSICAL INSPECTION OF THE FACILITY AT THE BUSINESS ADDRESS PROVIDED BY THE APPLICANT. NOTHING IN THIS SUBSECTION (4) SHALL PRECLUDE THE BOARD FROM INSPECTING A WHOLESALER.

(5) THE DESIGNATED REPRESENTATIVE OF AN APPLICANT FOR A WHOLESALER LICENSE SHALL:

(a) BE AT LEAST TWENTY-ONE YEARS OF AGE;

(b) HAVE AT LEAST THREE YEARS OF FULL-TIME EMPLOYMENT HISTORY WITH A PHARMACY OR A WHOLESALER IN A CAPACITY RELATED TO THE DISPENSING AND DISTRIBUTION OF AND THE RECORD KEEPING RELATED TO PRESCRIPTION DRUGS;

(c) BE EMPLOYED BY THE APPLICANT IN A FULL-TIME MANAGERIAL POSITION;

(d) BE ACTIVELY INVOLVED IN AND AWARE OF THE ACTUAL DAILY OPERATION OF THE WHOLESALER;

(e) BE PHYSICALLY PRESENT AT THE FACILITY OF THE APPLICANT DURING REGULAR BUSINESS HOURS, EXCEPT WHEN THE ABSENCE OF THE DESIGNATED REPRESENTATIVE IS AUTHORIZED, INCLUDING, BUT NOT LIMITED TO, SICK LEAVE AND VACATION LEAVE;

(f) SERVE IN THE CAPACITY OF A DESIGNATED REPRESENTATIVE FOR ONLY ONE APPLICANT OR WHOLESALER AT A TIME, EXCEPT WHERE MORE THAN ONE LICENSED WHOLESALER IS CO-LOCATED IN THE SAME FACILITY AND THE WHOLESALERS ARE

MEMBERS OF AN AFFILIATED GROUP AS DEFINED BY SECTION 1504 OF THE FEDERAL "INTERNAL REVENUE CODE OF 1986";

(g) NOT HAVE ANY CONVICTIONS UNDER FEDERAL, STATE, OR LOCAL LAW RELATING TO WHOLESALE OR RETAIL PRESCRIPTION DRUG DISTRIBUTION OR A CONTROLLED SUBSTANCE;

(h) NOT HAVE ANY FELONY CONVICTIONS PURSUANT TO FEDERAL, STATE, OR LOCAL LAW; AND

(i) UPDATE ALL OF THE INFORMATION REQUIRED IN THIS PART 8 WHENEVER CHANGES OCCUR.

(6) A WHOLESALER SHALL OBTAIN A LICENSE FOR EACH FACILITY IT USES FOR THE DISTRIBUTION OF PRESCRIPTION DRUGS.

12-22-803. Criminal history record check. PRIOR TO SUBMISSION OF AN APPLICATION, EACH APPLICANT SHALL HAVE HIS OR HER FINGERPRINTS TAKEN BY A LOCAL LAW ENFORCEMENT AGENCY FOR THE PURPOSE OF OBTAINING A FINGERPRINT-BASED CRIMINAL HISTORY RECORD CHECK. THE APPLICANT IS REQUIRED TO SUBMIT PAYMENT BY CERTIFIED CHECK OR MONEY ORDER FOR THE FINGERPRINTS AND FOR THE ACTUAL COSTS OF SAID RECORD CHECK AT THE TIME THE FINGERPRINTS ARE SUBMITTED TO THE COLORADO BUREAU OF INVESTIGATION. UPON RECEIPT OF FINGERPRINTS AND RECEIPT OF THE PAYMENT FOR COSTS, THE COLORADO BUREAU OF INVESTIGATION SHALL CONDUCT A STATE AND NATIONAL FINGERPRINT-BASED CRIMINAL HISTORY RECORD CHECK UTILIZING RECORDS OF THE COLORADO BUREAU OF INVESTIGATION AND THE FEDERAL BUREAU OF INVESTIGATION.

12-22-804. Restrictions on transactions. (1) A WHOLESALER SHALL RECEIVE PRESCRIPTION DRUG RETURNS OR EXCHANGES FROM A PHARMACY OR A CHAIN PHARMACY WAREHOUSE PURSUANT TO THE TERMS AND CONDITIONS OF THE AGREEMENT BETWEEN THE WHOLESALE DISTRIBUTOR AND THE PHARMACY OR CHAIN PHARMACY WAREHOUSE. THE RETURNS OR EXCHANGES SHALL INCLUDE THE RETURNS OF EXPIRED, DAMAGED, AND RECALLED PHARMACEUTICAL PRODUCT TO EITHER THE ORIGINAL MANUFACTURER OR TO A THIRD-PARTY RETURNS PROCESSOR, AND SUCH RETURNS OR EXCHANGES SHALL NOT BE SUBJECT TO THE PEDIGREE REQUIREMENTS OF SECTION 12-22-805. THE PHARMACIES, CHAIN PHARMACY WAREHOUSES, AND COOPERATIVE PHARMACY WAREHOUSES SHALL BE RESPONSIBLE FOR ENSURING THAT THE PRESCRIPTION DRUGS RETURNED ARE WHAT THEY PURPORT TO BE AND SHALL ENSURE THAT THOSE RETURNED PRESCRIPTION DRUGS WERE STORED UNDER PROPER CONDITIONS SINCE THEIR RECEIPT. WHOLESALERS SHALL BE HELD ACCOUNTABLE FOR POLICING THEIR RETURNS PROCESS AND HELPING TO INSURE THAT THEIR OPERATIONS ARE SECURE AND DO NOT PERMIT THE ENTRY OF ADULTERATED OR COUNTERFEIT PRODUCT. A PHARMACIST SHALL NOT KNOWINGLY RETURN A MEDICATION THAT IS NOT WHAT IT PURPORTS TO BE.

(2) A MANUFACTURER OR WHOLESALER SHALL FURNISH PRESCRIPTION DRUGS ONLY TO A PERSON LICENSED BY THE BOARD. BEFORE FURNISHING PRESCRIPTION DRUGS TO A PERSON NOT KNOWN TO THE MANUFACTURER OR WHOLESALER, THE MANUFACTURER OR WHOLESALER SHALL AFFIRMATIVELY VERIFY THAT THE PERSON

IS LEGALLY AUTHORIZED TO RECEIVE THE PRESCRIPTION DRUGS BY CONTACTING THE BOARD.

(3) PRESCRIPTION DRUGS FURNISHED BY A MANUFACTURER OR WHOLESALER SHALL BE DELIVERED ONLY TO THE PREMISES LISTED ON THE LICENSE. THE MANUFACTURER OR WHOLESALER MAY FURNISH PRESCRIPTION DRUGS TO AN AUTHORIZED PERSON OR AGENT OF THE PERSON LISTED ON THE LICENSE IF THE IDENTITY AND AUTHORIZATION OF THE RECIPIENT IS PROPERLY ESTABLISHED AND THE METHOD OF RECEIPT IS EMPLOYED ONLY TO MEET THE IMMEDIATE NEEDS OF A PARTICULAR PATIENT OF THE AUTHORIZED PERSON OR AGENT.

(4) PRESCRIPTION DRUGS MAY BE FURNISHED TO A HOSPITAL PHARMACY RECEIVING AREA PROVIDED THAT A PHARMACIST OR AUTHORIZED RECEIVING AGENT SIGNS, AT THE TIME OF DELIVERY, A RECEIPT SHOWING THE TYPE AND QUANTITY OF THE PRESCRIPTION DRUG RECEIVED. ANY DISCREPANCY BETWEEN THE RECEIPT AND THE TYPE AND QUANTITY OF THE PRESCRIPTION DRUG ACTUALLY RECEIVED SHALL BE REPORTED TO THE DELIVERING MANUFACTURER OR WHOLESALER BY THE NEXT BUSINESS DAY AFTER THE DELIVERY TO THE PHARMACY RECEIVING AREA.

(5) A MANUFACTURER OR WHOLESALER SHALL NOT ACCEPT PAYMENT FOR, OR ALLOW THE USE OF, A PERSON'S OR ENTITY'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 OF A PERSON OR ENTITY LEGALLY AUTHORIZED TO RECEIVE PRESCRIPTION DRUGS. AN ACCOUNT ESTABLISHED FOR THE PURCHASE OF PRESCRIPTION DRUGS MUST BEAR THE NAME OF THE LICENSEE. THIS SUBSECTION (5) SHALL NOT APPLY TO STANDARD ORDERING AND PURCHASING BUSINESS PRACTICES BETWEEN A CHAIN PHARMACY WAREHOUSE, A WHOLESALER, AND A MANUFACTURER.

12-22-805. Records - study - authentication - pedigree. (1) A WHOLESALER SHALL ESTABLISH AND MAINTAIN INVENTORIES AND RECORDS OF ALL TRANSACTIONS REGARDING THE RECEIPT AND DISTRIBUTION OR OTHER DISPOSITION OF PRESCRIPTION DRUGS. THE RECORDS SHALL INCLUDE THE PEDIGREE FOR EACH WHOLESALE DISTRIBUTION OF A PRESCRIPTION DRUG THAT OCCURS OUTSIDE THE NORMAL DISTRIBUTION CHANNEL.

(2) ON OR BEFORE JUNE 1, 2007, THE BOARD SHALL DETERMINE AND ESTABLISH AN IMPLEMENTATION DATE FOR THE USE OF ELECTRONIC PEDIGREES. THE IMPLEMENTATION DATE SHALL BE ON OR AFTER DECEMBER 31, 2007. IN MAKING ITS DETERMINATION, THE BOARD SHALL CONSULT WITH MANUFACTURERS, WHOLESALERS, AND PHARMACIES RESPONSIBLE FOR THE SALE AND DISTRIBUTION OF PRESCRIPTION DRUGS IN THIS STATE.

(3) A WHOLESALER IN THE POSSESSION OF A PEDIGREE FOR A PRESCRIPTION DRUG SHALL VERIFY THAT EACH TRANSACTION ON THE PEDIGREE HAS OCCURRED PRIOR TO DISTRIBUTING THE PRESCRIPTION DRUG.

(4) A PEDIGREE SHALL INCLUDE ALL NECESSARY IDENTIFYING INFORMATION CONCERNING EACH SALE IN THE CHAIN OF DISTRIBUTION OF THE PRODUCT FROM THE MANUFACTURER THROUGH THE ACQUISITION AND SALE BY A WHOLESALER UNTIL

FINAL SALE TO A PHARMACY OR OTHER PERSON DISPENSING OR ADMINISTERING THE PRESCRIPTION DRUG. THE PEDIGREE SHALL INCLUDE, AT A MINIMUM:

(a) THE NAME, ADDRESS, TELEPHONE NUMBER, AND, IF AVAILABLE, THE ELECTRONIC MAIL ADDRESS OF EACH OWNER OF THE PRESCRIPTION DRUG AND EACH WHOLESALER OF THE DRUG;

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

(c) THE TRANSACTION DATES;

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

(e) THE NAME OF THE PRESCRIPTION DRUG;

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

(g) THE SIZE AND NUMBER OF CONTAINERS;

(h) THE LOT NUMBER OF THE PRESCRIPTION DRUG; AND

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

(5) A PURCHASER OR WHOLESALER SHALL MAINTAIN EACH PEDIGREE FOR THREE YEARS FROM THE DATE OF THE SALE OR TRANSFER OF THE PRESCRIPTION DRUG AND SHALL MAKE THE PEDIGREE AVAILABLE FOR INSPECTION OR USE WITHIN FIVE BUSINESS DAYS UPON THE REQUEST OF AN AUTHORIZED LAW ENFORCEMENT OFFICER.

(6) THIS SECTION SHALL NOT APPLY TO A RETAIL PHARMACY OR CHAIN PHARMACY WAREHOUSE IF THE RETAIL PHARMACY OR CHAIN PHARMACY WAREHOUSE DOES NOT ENGAGE IN THE WHOLESALE DISTRIBUTION OF PRESCRIPTION DRUGS.

(7) THE BOARD SHALL ADOPT RULES AS NECESSARY FOR THE IMPLEMENTATION OF THIS PART 8.

12-22-806. Penalty. (1) A PERSON WHO ENGAGES IN THE WHOLESALE DISTRIBUTION OF PRESCRIPTION DRUGS IN VIOLATION OF THIS PART 8 SHALL BE SUBJECT TO A PENALTY OF UP TO FIFTY THOUSAND DOLLARS.

(2) A PERSON WHO KNOWINGLY ENGAGES IN THE WHOLESALE DISTRIBUTION OF PRESCRIPTION DRUGS IN VIOLATION OF THIS PART 8 SHALL BE SUBJECT TO A PENALTY OF UP TO FIVE HUNDRED THOUSAND DOLLARS.

SECTION 2. Appropriation. (1) In addition to any other appropriation, there is hereby appropriated, out of any moneys in the division of registrations cash fund created in section 24-34-105 (2) (b) (I), Colorado Revised Statutes, not otherwise appropriated, to the department of regulatory agencies, for allocation to the executive director's office, for legal services, for the fiscal year beginning July 1,

2006, the sum of twenty-eight thousand eight hundred seventy-four dollars (\$28,874), or so much thereof as may be necessary, for the implementation of this act.

(2) In addition to any other appropriation, there is hereby appropriated, out of any moneys in the division of registrations cash fund created in section 24-34-105 (2) (b) (I), Colorado Revised Statutes, not otherwise appropriated, to the department of regulatory agencies, for allocation to the division of registrations, for the fiscal year beginning July 1, 2006, the sum of one hundred ninety-one thousand forty-one dollars (\$191,041) and 3.3 FTE, or so much thereof as may be necessary, for the implementation of this act.

(3) In addition to any other appropriation, there is hereby appropriated to the department of law, for the fiscal year beginning July 1, 2006, the sum of twenty-eight thousand eight hundred seventy-four dollars (\$28,874), and 0.2 FTE, or so much thereof as may be necessary, for the provision of legal services to the department of regulatory agencies related to the implementation of this act. Said sum shall be from cash funds exempt received from the department of regulatory agencies, executive director's office, out of the appropriation made in subsection (1) of this section.

(4) In addition to any other appropriation, there is hereby appropriated, to the department of public safety, for allocation to the Colorado bureau of investigation, for processing of fingerprint-based criminal history checks required by this act, for the fiscal year beginning July 1, 2006, the sum of thirty-one thousand one hundred eighty-three dollars (\$31,183) and 0.3 FTE, or so much thereof as may be necessary, for the implementation of this act. Said sum shall be from fingerprint processing fees collected by the Colorado bureau of investigation.

(5) In addition to any other appropriation, there is hereby appropriated to the department of public safety, for the fiscal year beginning July 1, 2006, the sum of thirty-nine thousand six hundred dollars (\$39,600), or so much thereof as may be necessary, for pass through to the federal bureau of investigation for fingerprint-based national criminal history checks required by this act. Said sum shall be from cash funds exempt fingerprint processing fees collected by the Colorado bureau of investigation.

SECTION 3. Safety clause. The general assembly hereby finds, determines, and declares that this act is necessary for the immediate preservation of the public peace, health, and safety.

Approved: June 2, 2006