Drug Pedigree Requirements for Pharmacies and Wholesalers

State Statutes

Arizona Revised Statutes Annotated
Title 32. Professions and Occupations
Chapter 18. Pharmacy
Article 3.1. Regulation of Full Service Wholesale Permittees
§ 32-1981. Definitions

In this article, unless the context otherwise requires:

1. "Chain pharmacy warehouse" means a physical location for prescription-only drugs that acts as a central warehouse and that performs intracompany sales or transfers of the prescription-only drugs to a group of pharmacies that are under common ownership or control. A chain pharmacy warehouse is not limited to the distribution of prescription-only drugs under this article.

2. "Company under common ownership" has the same meaning as affiliated group as defined in 26 United States code § 1504.

3. "Intracompany transaction" means any sale, transfer or trade between a division, subsidiary, parent or affiliated or related company under the common ownership of a person.

4. "Normal distribution channel" means the chain of custody for a prescription-only drug that begins with the delivery of the drug by a manufacturer to a wholesale distributor who then delivers the drug to a pharmacy or a practitioner for final receipt by a patient. Normal distribution channel includes the receipt of a prescription-only drug by a common carrier or other delivery service that delivers the drug at the direction of a manufacturer, full service wholesale permittee or pharmacy and that does not purchase, sell, trade or take title to any prescription-only drug.

5. "Pedigree" means a document or electronic file that contains information that records each wholesale distribution of any given prescription-only drug, from sale by a pharmaceutical manufacturer, through acquisition and sale by any wholesale distributor or repackager and until

final sale to a pharmacy or other person dispensing or administering the prescription-only drug.

6. "Third party logistics provider" means a person who receives prescription-only drugs only from the original manufacturer, who delivers the prescription-only drugs at the direction of that manufacturer and who does not purchase, sell, trade or take title to prescription-only drugs.

7. "Wholesale distribution" means distribution of a drug to a person other than a consumer or patient. Wholesale distribution does not include:

(a) Any transaction or transfer between any division, subsidiary, parent or affiliated or related company under common ownership and control of a corporate entity.

(b) Selling, purchasing, distributing, transferring or trading a drug or offering to sell, purchase, distribute, transfer or trade a drug for emergency medical reasons. For the purposes of this subdivision, "emergency medical reasons" includes transferring a prescription drug by a community pharmacy or hospital pharmacy to another community pharmacy or hospital pharmacy to alleviate a temporary shortage.

(c) Drug returns if conducted by a hospital, health care entity, retail pharmacy or charitable institution in accordance with 21 Code of Federal Regulations § 203.23.

(d) The sale of prescription drugs by a pharmacy, not to exceed five per cent of the pharmacy's gross sales, to practitioners for office use.

(e) Dispensing by a retail pharmacy of prescription drugs to a patient or patient's agent pursuant to the lawful order of a practitioner.

(f) Distributing a drug sample by a manufacturer's representative.

(g) Selling, purchasing or trading blood or blood components intended for transfusion.

Arizona Revised Statutes Annotated
Title 32. Professions and Occupations
Chapter 18. Pharmacy
Article 3.1. Regulation of Full Service Wholesale Permittees
§ 32-1984. Pedigrees; electronic files

A. Each full service wholesale permittee must establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription-only drugs, including pedigrees for all prescription-only drugs that leave the normal distribution channel.

B. A retail pharmacy or chain pharmacy warehouse must comply with this section if the pharmacy or chain pharmacy warehouse engages in the wholesale distribution of prescription-only drugs.

C. Subsection A does not apply to:

1. The original manufacturer of the finished form of the prescription-only drug.

2. The sale, trade or transfer of a prescription-only drug between pharmacies with a common ownership or as required by an emergency.

3. Intracompany transactions.

4. The sale, trade or transfer of a prescription-only drug by a full service wholesale permittee to an entity that assists in the administration of pharmacy benefits under contracts with insurers or to a company under common ownership with that entity.

5. The sale, trade or transfer of a prescription-only drug to a pharmacy or practitioner by an entity that assists in the administration of pharmacy benefits under contracts with insurers or by a company under common ownership with that entity.

D. Each person who is engaged in the wholesale distribution of a prescription-only drug, who is in the possession of a pedigree and who attempts to further distribute that prescription-only drug must verify before any distribution of that drug occurs that each transaction listed on the pedigree has occurred.

E. The pedigree must include:

1. The name of the prescription-only drug.

2. The dosage form and strength of the prescription-only drug.

3. The size of the container.

4. The number of containers.

5. The lot number of the prescription-only drug.

6. The name of the manufacturer of the finished dosage form.

7. All necessary identifying information concerning each sale in the chain of distribution of the

product from the manufacturer through acquisition and sale by any full service wholesale permittee and until final sale to a pharmacy or other person dispensing or administering the drug. At a minimum this information must include:

(a) The name, address, telephone number and, if available, the e-mail address of each owner of the prescription-only drug and each full service wholesale permittee that does not take title to the prescription-only drug.

(b) The name and address of each location from which the product was shipped, if different from the owner's.

(c) Transaction dates.

(d) Certification that each recipient has authenticated the pedigree.

8. Any other information required by the board.

F. Except as provided in subsection B, the purchaser and full service wholesale permittee must keep the information prescribed by this section for at least three years.

G. The information prescribed by this section shall be available to the board of pharmacy on request.

Annotated California Codes
Business and Professions Code
Division 2. Healing Arts
Chapter 9. Pharmacy
Article 2. Definitions
§ 4034. Pedigree defined; contents; dangerous drugs; contractual relationships; exemptions; notice to board of drugs that are counterfeit or subject of fraudulent transactions; interoperable electronic system

(a) "Pedigree" means a record, in electronic form, containing information regarding each transaction resulting in a change of ownership of a given dangerous drug, from sale by a manufacturer, through acquisition and sale by one or more wholesalers, manufacturers, or pharmacies, until final sale to a pharmacy or other person furnishing, administering, or dispensing the dangerous drug. The pedigree shall be created and maintained in an interoperable electronic system, ensuring compatibility throughout all stages of distribution.

(b) A pedigree shall include all of the following information:

(1) The source of the dangerous drug, including the name, the federal manufacturer's registration number or a state license number as determined by the board, and principal address of the source.

(2) The trade or generic name of the drug, the quantity of the dangerous drug, its dosage form and strength, the date of the transaction, the sales invoice number, the container size, the number of containers, the expiration dates, and the lot numbers.

(3) The business name, address, and the federal manufacturer's registration number or a state license number as determined by the board, of each owner of the dangerous drug, and the dangerous drug shipping information, including the name and address of each person certifying delivery or receipt of the dangerous drug.

(4) A certification under penalty of perjury from a responsible party of the source of the dangerous drug that the information contained in the pedigree is true and accurate.

(c) A single pedigree shall include every change of ownership of a given dangerous drug from its initial manufacture through to its final transaction to a pharmacy or other person for furnishing, administering, or dispensing the drug, regardless of repackaging or assignment of another National Drug Code (NDC) Directory number.

(d) A pedigree shall track each dangerous drug at the smallest package or immediate container distributed by the manufacturer, received and distributed by the wholesaler, and received by the pharmacy or another person furnishing, administering, or dispensing the dangerous drug.

(e) Any return of a dangerous drug to a wholesaler or manufacturer shall be documented on the same pedigree as the transaction that resulted in the receipt of the drug by the party returning it.

(f) If a licensed health care service plan, hospital organization, and one or more physician organizations have exclusive contractual relationships to provide health care services, drugs distributed between these persons shall be deemed not to have changed ownership.

(g) The following transactions are not required to be recorded on a pedigree:

(1) The provision of samples of dangerous drugs by a manufacturer's employee to an authorized prescriber, provided the samples are dispensed to a patient of the prescriber without charge.

(2) An injectable dangerous drug that is delivered by the manufacturer directly to an authorized prescriber or other entity directly responsible for administration of the injectable dangerous drug, only for an injectable dangerous drug that by law may only be administered under the

professional supervision of the prescriber or other entity directly responsible for administration of the drug. Injectable dangerous drugs exempted from the pedigree requirement by this paragraph may not be dispensed to a patient or a patient's agent for self-administration, and shall only be administered to the patient, as defined in Section 4016, by the prescriber or other authorized entity that received the drug directly from the manufacturer.

(3) The exemption in paragraph (2) shall expire and be inoperative on January 1, 2010, unless prior to that date the board receives, at a public hearing, evidence that entities involved in the distribution of the injectable dangerous drugs subject to that paragraph are not able to provide a pedigree in compliance with all of the provisions of California law, and the board votes to extend the expiration date for the exemption until January 1, 2011. The decision as to whether to extend the expiration date shall be within the sole discretion of the board, and shall not be subject to the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of the Government Code.

(h) If a manufacturer, wholesaler, or pharmacy has reasonable cause to believe that a dangerous drug in, or having been in, its possession is counterfeit or the subject of a fraudulent transaction, the manufacturer, wholesaler, or pharmacy shall notify the board within 72 hours of obtaining that knowledge. This subdivision shall apply to any dangerous drug that has been sold or distributed in or through this state.

(i) "Interoperable electronic system" as used in this chapter means an electronic track and trace system for dangerous drugs that uses a unique identification number, established at the point of manufacture, contained within a standardized nonproprietary data format and architecture, that is uniformly used by manufacturers, wholesalers, and pharmacies for the pedigree of a dangerous drug.

(j) The application of the pedigree requirement in pharmacies shall be subject to review during the board's sunset review to be conducted as described in subdivision (f) of Section 4001.

(k) This section shall become operative on January 1, 2009. However, the board may extend the date for compliance with this section and Section 4163 until January 1, 2011, in accordance with Section 4163.5.

Annotated California Codes
Business and Professions Code
Division 2. Healing Arts
Chapter 9. Pharmacy
Article 2. Definitions
§ 4034. Pedigree defined; contents; dangerous drugs; contractual relationships; exemptions; notice to board of drugs that are counterfeit or subject of fraudulent transactions; interoperable electronic system

<Section operative January 1, 2015.>

(a) "Pedigree" means a record, in electronic form, containing information regarding each transaction resulting in a change of ownership of a given dangerous drug, from sale by a manufacturer, through acquisition and sale by one or more wholesalers, manufacturers, repackagers, or pharmacies, until final sale to a pharmacy or other person furnishing, administering, or dispensing the dangerous drug. The pedigree shall be created and maintained in an interoperable electronic system, ensuring compatibility throughout all stages of distribution.

(b) A pedigree shall include all of the following information:

(1) The source of the dangerous drug, including the name, the federal manufacturer's registration number or a state license number as determined by the board, and principal address of the source.

(2) The trade or generic name of the dangerous drug, the quantity of the dangerous drug, its dosage form and strength, the date of the transaction, the sales invoice number or, if not immediately available, a customer-specific shipping reference number linked to the sales invoice number, the container size, the number of containers, the expiration dates, and the lot numbers.

(3) The business name, address, and the federal manufacturer's registration number or a state

license number as determined by the board, of each owner of the dangerous drug, and the dangerous drug shipping information, including the name and address of each person certifying delivery or receipt of the dangerous drug.

(4) A certification under penalty of perjury from a responsible party of the source of the dangerous drug that the information contained in the pedigree is true and accurate.

(5) The unique identification number described in subdivision (i).

(c) A single pedigree shall include every change of ownership of a given dangerous drug from its initial manufacture through to its final transaction to a pharmacy or other person for furnishing, administering, or dispensing the drug, regardless of repackaging or assignment of another National Drug Code (NDC) Directory number. Dangerous drugs that are repackaged shall be serialized by the repackager and a pedigree shall be provided that references the pedigree of the original package or packages provided by the manufacturer.

(d) A pedigree shall track each dangerous drug at the smallest package or immediate container distributed by the manufacturer, received and distributed by the wholesaler or repackager, and received by the pharmacy or another person furnishing, administering, or dispensing the dangerous drug. For purposes of this section, the "smallest package or immediate container" of a dangerous drug shall include any dangerous drug package or container made available to a repackager, wholesaler, pharmacy, or other entity for repackaging or redistribution, as well as the smallest unit made by the manufacturer for sale to the pharmacy or other person furnishing, administering, or dispensing the drug.

(e) Any return of a dangerous drug to a wholesaler or manufacturer shall be documented on the same pedigree as the transaction that resulted in the receipt of the drug by the party returning it.

(f) If a licensed health care service plan, hospital organization, and one or more physician

organizations have exclusive contractual relationships to provide health care services, drugs distributed between these persons shall be deemed not to have changed ownership.

(g) The following transactions are exempt from the pedigree requirement created by this section:

(1) An intracompany sale or transfer of a dangerous drug. For purposes of this section, "intracompany sale or transfer" means any transaction for any valid business purpose between a division, subsidiary, parent, or affiliated or related company under the common ownership and control of the same corporate or legal entity.

(2) Dangerous drugs received by the state or a local government entity from a department or agency of the federal government or an agent of the federal government specifically authorized to deliver dangerous drugs to the state or local government entity.

(3) The provision of samples of dangerous drugs by a manufacturer's employee to an authorized prescriber, provided the samples are dispensed to a patient of the prescriber without charge.

(4)(A) A sale, trade, or transfer of a radioactive drug, as defined in Section 1708.3 of Title 16 of the California Code of Regulations, between any two entities licensed by the Radiologic Health Branch of the State Department of Public Health, the federal Nuclear Regulatory Commission, or an Agreement state.

(B) The exemption in this paragraph shall remain in effect unless the board, no earlier than the date that is two years after the compliance date for manufacturers set forth in subdivision (k) of Section 4034 or Section 4163.5, determines after consultation with the Radiologic Health Branch of the State Department of Public Health that the risk of counterfeiting or diversion of a radioactive drug is sufficient to require a pedigree. Two years following the date of any such determination, this paragraph shall become inoperative.

(5) The sale, trade, or transfer of a dangerous drug that is labeled by the manufacturer as "for veterinary use only."

(6) The sale, trade, or transfer of compressed medical gas. For purposes of this section, "compressed medical gas" means any substance in its gaseous or cryogenic liquid form that meets medical purity standards and has application in a medical or homecare environment, including, but not limited to, oxygen and nitrous oxide.

(7) The sale, trade, or transfer of solutions. For purposes of this section, "solutions" means any of the following:

(A) Those intravenous products that, by their formulation, are intended for the replenishment of fluids and electrolytes, such as sodium, chloride, and potassium, calories, such as dextrose and amino acids, or both.

(B) Those intravenous products used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions.

(C) Products that are intended for irrigation or reconstitution, as well as sterile water, whether intended for those purposes or for injection.

(8) Dangerous drugs that are placed in a sealed package with a medical device or medical supplies at the point of first shipment into commerce by the manufacturer and the package remains sealed until the drug and device are used, provided that the package is only used for surgical purposes.

(9) A product that meets either of the following criteria:

(A) A product comprised of two or more regulated components, such as a drug/device, biologic/device, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity.

(B) Two or more separate products packaged together in a single package or as a unit and comprised of drug and device products or device and biological products.

(h) If a manufacturer, wholesaler, or pharmacy has reasonable cause to believe that a dangerous drug in, or having been in, its possession is counterfeit or the subject of a fraudulent transaction, the manufacturer, wholesaler, or pharmacy shall notify the board within 72 hours of obtaining that knowledge. This subdivision shall apply to any dangerous drug that has been sold or distributed in or through this state.

(i) "Interoperable electronic system" as used in this chapter means an electronic track and trace system for dangerous drugs that uses a unique identification number, established at the point of manufacture and supplemented by a linked unique identification number in the event that drug is repackaged, contained within a standardized nonproprietary data format and architecture, that is uniformly used by manufacturers, wholesalers, repackagers, and pharmacies for the pedigree of a dangerous drug. No particular data carrier or other technology is mandated to accomplish the attachment of the unique identification number described in this subdivision.

(j) The application of the pedigree requirement shall be subject to review during the board's evaluation pursuant to Section 473.4.

(k) This section shall become operative on January 1, 2015.

Annotated California Codes

Business and Professions Code
Division 2. Healing Arts
Chapter 9. Pharmacy
Article 2. Definitions
§ 4045. Third-party logistics provider or reverse third-party logistic provider

"Third-party logistics provider" or "reverse third-party logistic provider" means an entity licensed as a wholesaler that contracts with a dangerous drug manufacturer to provide or coordinate warehousing, distribution, or other similar services on behalf of a manufacturer, but for which there is no change of ownership in the dangerous drugs. For purposes of Sections 4034, 4163, 4163.1, 4163.2, 4163.3, 4163.4, and 4163.5, a third-party logistics provider shall not be responsible for generating or updating pedigree documentation, but shall maintain copies of the pedigree. To be exempt from documentation for pedigrees, a reverse third-party logistic provider may only accept decommissioned drugs from pharmacies or wholesalers.

West's Annotated California Codes
Business and Professions Code
Division 2. Healing Arts
Chapter 9. Pharmacy
Article 11. Wholesalers and Manufacturers
§ 4163. Dangerous drugs or devices furnished to unauthorized persons; obligations of wholesalers, repackagers, or pharmacies

(a) A manufacturer, wholesaler, repackager, or pharmacy may not furnish a dangerous drug or dangerous device to an unauthorized person.

(b) Dangerous drugs or dangerous devices shall be acquired from a person authorized by law to possess or furnish dangerous drugs or dangerous devices. When the person acquiring the dangerous drugs or dangerous devices is a wholesaler, the obligation of the wholesaler shall be limited to obtaining confirmation of licensure of those sources from whom it has not previously acquired dangerous drugs or dangerous devices.

(c) Except as otherwise provided in Section 4163.5, commencing on July 1, 2016, a wholesaler or repackager may not sell, trade, or transfer a dangerous drug at wholesale without providing a pedigree.

(d) Except as otherwise provided in Section 4163.5, commencing on July 1, 2016, a wholesaler or repackager may not acquire a dangerous drug without receiving a pedigree.

(e) Except as otherwise provided in Section 4163.5, commencing on July 1, 2017, a pharmacy may not sell, trade, or transfer a dangerous drug at wholesale without providing a pedigree.

(f) Except as otherwise provided in Section 4163.5, commencing on July 1, 2017, a pharmacy may not acquire a dangerous drug without receiving a pedigree.

(g) Except as otherwise provided in Section 4163.5, commencing on July 1, 2017, a pharmacy warehouse may not acquire a dangerous drug without receiving a pedigree. For purposes of this section and Section 4034, a "pharmacy warehouse" means a physical location licensed as a wholesaler for prescription drugs that acts as a central warehouse and performs intracompany sales or transfers of those drugs to a group of pharmacies under common ownership and control.

Annotated California Codes

Business and Professions Code
Division 2. Healing Arts
Chapter 9. Pharmacy
Article 11. Wholesalers and Manufacturers
§ 4163.2. Dangerous drugs designated as not subject to pedigree requirements; written declaration

(a)(1) A manufacturer, wholesaler, or pharmacy lawfully possessing or owning dangerous drugs manufactured or distributed prior to the operative date of the pedigree requirements, specified in Sections 4034 and 4163, may designate these dangerous drugs as not subject to the pedigree requirements by preparing a written declaration made under penalty of perjury that lists those dangerous drugs.

(2) The written declaration shall include the National Drug Code Directory lot number for each dangerous drug designated. The written declaration shall be submitted to and received by the board no later than 30 days after the operative date of the pedigree requirements. The entity or person submitting the written declaration shall also retain for a period of three years and make available for inspection by the board a copy of each written declaration submitted.

(3) The board may, by regulation, further specify the requirements and procedures for the creation and submission of these written declarations. Information contained in these declarations shall be considered trade secrets and kept confidential by the board.

(b) Any dangerous drugs designated on a written declaration timely created and submitted to the board may be purchased, sold, acquired, returned, or otherwise transferred without meeting the pedigree requirements, if the transfer complies with the other requirements of this chapter.

Annotated California Codes
Business and Professions Code
Division 2. Healing Arts
Chapter 9. Pharmacy
Article 11. Wholesalers and Manufacturers
§ 4163.3. Legislative intent; maintaining integrity of pedigree system; use of inference

(a) It is the intent of the Legislature that participants in the distribution chain for dangerous drugs, including manufacturers, wholesalers, or pharmacies furnishing, administering, or dispensing dangerous drugs, distribute and receive electronic pedigrees, and verify and validate the delivery and receipt of dangerous drugs against those pedigrees at the unit level, in a manner that maintains the integrity of the pedigree system without an unacceptable increase in the risk of diversion or counterfeiting.

(b) To meet this goal, and to facilitate efficiency and safety in the distribution chain, the board shall, by regulation, define the circumstances under which participants in the distribution chain may infer the contents of a case, pallet, or other aggregate of individual units, packages, or containers of dangerous drugs, from a unique identifier associated with the case, pallet, or other aggregate, without opening each case, pallet, or other aggregate or otherwise individually validating each unit.

(c) Manufacturers, wholesalers, and pharmacies opting to employ the use of inference as authorized by the board to comply with the pedigree requirements shall document their processes and procedures in their standard operating procedures (SOPs) and shall make those SOPs available for board review.

(d) SOPs regarding inference shall include a process for statistically sampling the accuracy of information sent with inbound product.

(e) Liability associated with accuracy of product information and pedigree using inference shall be specified in the board's regulations.

Annotated California Codes
Business and Professions Code
Division 2. Healing Arts
Chapter 9. Pharmacy
Article 11. Wholesalers and Manufacturers
§ 4163.4. Exemption from pedigree requirements

(a) All units of dangerous drug in the possession of a wholesaler or pharmacy, for which the manufacturer does not hold legal title on the effective date of the pedigree requirement set forth in Section 4163.5, shall not be subject to the pedigree requirements set forth in Sections 4034 and 4163. However, if any units of those drugs are subsequently returned to the manufacturer, they shall be subject to the pedigree requirements if the manufacturer distributes those units in California.

(b) All units of dangerous drug manufactured in California but distributed outside the state for dispensing outside the state shall not be subject to the pedigree requirements set forth in Sections 4034 and 4163 at either the time of initial distribution or in the event that any of those units are subsequently returned to the manufacturer.

Annotated California Codes
Business and Professions Code
Division 2. Healing Arts
Chapter 9. Pharmacy
Article 11. Wholesalers and Manufacturers
§ 4163.5. Legislative findings and declarations; system benefits; compliance

(a) The Legislature hereby finds and declares that:

(1) The electronic pedigree system required by Sections 4034 and 4163 will provide tremendous benefits to the public and to all participants in the distribution chain. Those benefits should be made available as quickly as possible through the full cooperation of prescription drug supply chain participants. To this end, all drug manufacturers and repackagers are strongly encouraged to serialize drug products and initiate electronic pedigrees as soon as possible, and all participants in the supply chain are encouraged to immediately ready themselves to receive and pass electronic pedigrees.

(2) At the same time, it is recognized that the process of implementing serialized electronic pedigree for all prescription drugs in the entire chain of distribution is a complicated technological and logistical undertaking for manufacturers, wholesalers, repackagers, pharmacies, and other supply chain participants. The Legislature seeks to ensure continued availability of prescription drugs in California while participants implement these requirements.

(b) Before January 1, 2015, each manufacturer of a dangerous drug distributed in California shall designate those dangerous drugs representing a minimum of 50 percent of its drugs, generic or single source, distributed in California, for which it is listed as the manufacturer by the federal Food and Drug Administration, which shall be the subject of its initial phase of compliance with the January 1, 2015, deadline of the state's serialized electronic pedigree requirements set forth in Sections 4034 and 4163. Each manufacturer shall notify the Board of Pharmacy of the drugs so designated and the measure or measures used in designating its drugs to be serialized, and shall

include in the notification the technology to be used to meet the serialized electronic pedigree requirements. The notification process for these specific actions may be specified by the board.

(c) Before January 1, 2016, each manufacturer of a dangerous drug distributed in California shall designate the final 50 percent of its drugs, generic or single source, distributed in California for which it is listed as the manufacturer by the federal Food and Drug Administration that are subject to the state's serialized electronic pedigree requirements set forth in Sections 4034 and 4163, which shall comply with the state's serialized electronic pedigree requirement by January 1, 2016. Each manufacturer shall notify the Board of Pharmacy of the drugs so designated and the measure or measures used in designating its drugs to be serialized, and shall include in the notification the technology to be used to meet the serialized electronic pedigree requirements. The notification process for these specific actions may be specified by the board.

(d) For purposes of designating drugs to be serialized as required by subdivisions (b) and (c), manufacturers shall select from any of the following measures:

(1) Unit volume.

(2) Product package (SKU) type.

(3) Drug product family.

(e) Drugs not subject to compliance with the pedigree requirements set forth in Sections 4034 and 4163 under this section shall not be subject to the provisions of subdivisions (c), (d), (e), and (f) of Section 4163.

West's Annotated California Codes
Health and Safety Code
Division 116. Surplus Medication Collection and Distribution
§ 150204. County-established repository and distribution program

(a) A county may establish, by ordinance, a repository and distribution program for purposes of this division. Only pharmacies that are county-owned or that contract with the county pursuant to this division may participate in this program to dispense medication donated to the drug repository and distribution program.

(b) A county that elects to establish a repository and distribution program pursuant to this division shall establish procedures for, at a minimum, all of the following:

(1) Establishing eligibility for medically indigent patients who may participate in the program.

(2) Ensuring that patients eligible for the program shall not be charged for any medications provided under the program.

(3) Developing a formulary of medications appropriate for the repository and distribution program.

(4) Ensuring proper safety and management of any medications collected by and maintained under the authority of a county-owned or county-contracted, licensed pharmacy.

(5) Ensuring the privacy of individuals for whom the medication was originally prescribed.

(c) Any medication donated to the repository and distribution program shall comply with the requirements specified in this division. Medication donated to the repository and distribution program shall meet all of the following criteria:

(1) The medication shall not be a controlled substance.

(2) The medication shall not have been adulterated, misbranded, or stored under conditions contrary to standards set by the United States Pharmacopoeia (USP) or the product manufacturer.

(3) The medication shall not have been in the possession of a patient or any individual member of the public, and in the case of medications donated by a skilled nursing facility, shall have been under the control of staff of the skilled nursing facility.

(d) Only medication that is donated in unopened, tamper-evident packaging or modified unit dose containers that meet USP standards is eligible for donation to the repository and distribution program, provided lot numbers and expiration dates are affixed. Medication donated in opened containers shall not be dispensed by the repository and distribution program.

(e) A pharmacist shall use his or her professional judgment in determining whether donated medication meets the standards of this division before accepting or dispensing any medication under the repository and distribution program.

(f) A pharmacist shall adhere to standard pharmacy practices, as required by state and federal law, when dispensing all medications.

(g) Medication that is donated to the repository and distribution program shall be handled in any of the following ways:

(1) Dispensed to an eligible patient.

(2) Destroyed.

(3) Returned to a reverse distributor.

(h) Medication that is donated to the repository and distribution program that does not meet the requirements of this division shall not be distributed under this program and shall be either destroyed or returned to a reverse distributor. This medication shall not be sold, dispensed, or otherwise transferred to any other entity.

(i) Medication donated to the repository and distribution program shall be maintained in the donated packaging units until dispensed to an eligible patient under this program, who presents a valid prescription. When dispensed to an eligible patient under this program, the medication shall be in a new and properly labeled container, specific to the eligible patient and ensuring the privacy of the individuals for whom the medication was initially dispensed. Expired medication shall not be dispensed.

(j) Medication donated to the repository and distribution program shall be segregated from the pharmacy's other drug stock by physical means, for purposes including, but not limited to, inventory, accounting, and inspection.

(k) The pharmacy shall keep complete records of the acquisition and disposition of medication donated to and dispensed under the repository and distribution program. These records shall be kept separate from the pharmacy's other acquisition and disposition records and shall conform to the Pharmacy Law (Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code), including being readily retrievable.

(l) Local and county protocols established pursuant to this division shall conform to the Pharmacy Law regarding packaging, transporting, storing, and dispensing all medications.

(m) County protocols established for packaging, transporting, storing, and dispensing medications that require refrigeration, including, but not limited to, any biological product as defined in Section 351 of the Public Health and Service Act (42 U.S.C. Sec. 262), an intravenously injected drug, or an infused drug, include specific procedures to ensure that these medications are packaged, transported, stored, and dispensed at their appropriate temperatures and in accordance with USP standards and the Pharmacy Law.

(n) Notwithstanding any other provision of law, a participating county-owned or county-contracted pharmacy shall follow the same procedural drug pedigree requirements for donated drugs as it would follow for drugs purchased from a wholesaler or directly from a drug manufacturer.

Colorado Revised Statutes Annotated

Title 12. Professions and Occupations
General
Article 22. Pharmaceuticals and Pharmacists
Part 8. Wholesalers
§ 12-22-801. Definitions--exemption from licensing requirements

(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" [FN1], complies with the following:

(I) The wholesaler has a written agreement currently in effect with the manufacturer evidencing such ongoing relationship; and

(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.

(c.5) "Board-registered outlet" means a prescription drug outlet, an entity licensed pursuant to

section 12-22-304, an other outlet, a nonresident prescription drug outlet, a wholesaler, or a manufacturer.

(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. Notwithstanding any other provision of this part 8, a chain pharmacy warehouse receiving distributions on behalf of, or making distributions to, an intracompany pharmacy is not required to be an authorized distributor of record to be considered part of the normal distribution channel.

(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 board-registered outlet or practitioner authorized by law to prescribe the prescription drug and the board-registered outlet or the practitioner authorized by law to prescribe the prescription drug 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 shall be licensed as a wholesaler under this part 8 and, to be

considered part of the normal distribution channel, shall also be an authorized distributor of record.

(i) "Normal distribution channel" means a chain of custody for a prescription drug that goes directly or by drop shipment 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; or 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 in this paragraph (o). 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 shall be licensed as a wholesale distributor under this part 8.

(q) "Wholesaler" 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 wholesalers 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) Deleted by Laws 2007, Ch. 293, § 1, eff. Aug. 3, 2007.

(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" [FN2], 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.

Colorado Revised Statutes Annotated

Title 12. Professions and Occupations
General
Article 22. Pharmaceuticals and Pharmacists
Part 8. Wholesalers
§ 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 of expired, damaged, recalled, or otherwise unsaleable pharmaceutical product shall be distributed by the receiving wholesale distributor only to either the original manufacturer or to a third-party returns processor. The returns or exchanges of prescription drugs, saleable or unsaleable, including any redistribution by a receiving wholesaler, shall not be subject to the pedigree requirements of section 12- 22-805, so long as the drugs are exempt from the pedigree requirement of the federal food and drug administration's currently applicable "Prescription Drug Marketing Act of 1987" guidance. 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 ensure 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 board-registered outlet or practitioner authorized by law to prescribe the drugs. Before furnishing prescription drugs to a person or entity not known to the manufacturer or wholesaler, the manufacturer or wholesaler shall affirmatively verify that the person or entity is legally authorized to receive the prescription drugs by contacting the board.

(3) Deleted by Laws 2007, Ch. 293, § 4, eff. Aug. 3, 2007.

(4) Prescription drugs may be furnished to a hospital pharmacy receiving area if 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.

Colorado Revised Statutes Annotated

Title 12. Professions and Occupations
General
Article 22. Pharmaceuticals and Pharmacists
Part 8. Wholesalers
§ 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 or the first authorized distributor of record 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 after 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 or an authorized agent of the board.

(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.

Connecticut General Statutes Annotated

Title 21A. Consumer Protection
Chapter 417. General Provisions. Pure Food and Drugs
§ 21a-70c. Prescription drug pedigree program. Working group convened

(a) The Commissioner of Consumer Protection shall convene a working group comprised of the Commissioners of Consumer Protection and Emergency Management and Homeland Security, or their designees, a member of the Commission of Pharmacy, the chairpersons of the joint standing committee of the General Assembly having cognizance of matters relating to public health, or their designees, and representatives of retail drug establishments, independent pharmacies and pharmaceutical manufacturers. The working group shall be responsible for submitting recommendations to the Governor and to the joint standing committee of the General Assembly having cognizance of matters relating to public health concerning the development and implementation of a program to authenticate the pedigree of prescription drugs distributed in this state.

(b) For purposes of this section, (1) "authenticate" means to affirmatively verify, before any distribution of a prescription drug occurs, that each transaction listed on the pedigree has occurred; (2) "pedigree" means a document or electronic file containing information that records each distribution of any given prescription drug, from sale by a pharmaceutical manufacturer, through acquisition and sale by any wholesale distributor or repackager, until final sale to a pharmacy or other person dispensing or administering the prescription drug; and (3) "prescription drug" means any drug, including any biological product, except for blood and blood components intended for transfusion or biological products that are also medical devices required by federal law or regulations, 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.

Title XXXIII. Regulation of Trade, Commerce, Investments, and Solicitations (Chapters 494-560)
Chapter 499. Drug, Cosmetic, and Household Products
Part I. Drugs; Devices; Cosmetics; Household Products
499.003. Definitions of terms used in this part

As used in this part, the term:

(1) "Advertisement" means any representation disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase of drugs, devices, or cosmetics.

(2) "Affiliated group" means an affiliated group as defined by s. 1504 of the Internal Revenue Code of 1986, as amended, which is composed of chain drug entities, including at least 50 retail pharmacies, warehouses, or repackagers, which are members of the same affiliated group. The affiliated group must disclose the names of all its members to the department.

(3) "Affiliated party" means:

(a) A director, officer, trustee, partner, or committee member of a permittee or applicant or a subsidiary or service corporation of the permittee or applicant;

(b) A person who, directly or indirectly, manages, controls, or oversees the operation of a permittee or applicant, regardless of whether such person is a partner, shareholder, manager, member, officer, director, independent contractor, or employee of the permittee or applicant;

(c) A person who has filed or is required to file a personal information statement pursuant to s. 499.012(9) or is required to be identified in an application for a permit or to renew a permit pursuant to s. 499.012(8); or

(d) The five largest natural shareholders that own at least 5 percent of the permittee or applicant.

(4) "Applicant" means a person applying for a permit or certification under this part.

(5) "Authenticate" means to affirmatively verify upon receipt of a prescription drug that each transaction listed on the pedigree paper has occurred.

(a) A wholesale distributor is not required to open a sealed, medical convenience kit to authenticate a pedigree paper for a prescription drug contained within the kit.

(b) Authentication of a prescription drug included in a sealed, medical convenience kit shall be limited to verifying the transaction and pedigree information received.

(6) "Certificate of free sale" means a document prepared by the department which certifies a drug, device, or cosmetic, that is registered with the department, as one that can be legally sold in the state.

(7) "Chain pharmacy warehouse" means a wholesale distributor permitted pursuant to s. 499.01 that maintains a physical location for prescription drugs that functions solely as a central warehouse to perform intracompany transfers of such drugs to a member of its affiliated group.

(8) "Closed pharmacy" means a pharmacy that is licensed under chapter 465 and purchases prescription drugs for use by a limited patient population and not for wholesale distribution or

sale to the public. The term does not include retail pharmacies.

(9) "Color" includes black, white, and intermediate grays.

(10) "Color additive" means, with the exception of any material that has been or hereafter is exempt under the federal act, a material that:

(a) Is a dye pigment, or other substance, made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity from a vegetable, animal, mineral, or other source; or

(b) When added or applied to a drug or cosmetic or to the human body, or any part thereof, is capable alone, or through reaction with other substances, of imparting color thereto.

(11) "Compressed medical gas" means any liquefied or vaporized gas that is a prescription drug, whether it is alone or in combination with other gases.

(12) "Contraband prescription drug" means any adulterated drug, as defined in s. 499.006, any counterfeit drug, as defined in this section, and also means any prescription 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.

(13) "Cosmetic" means an article, with the exception of soap, that is:

(a) Intended to be rubbed, poured, sprinkled, or sprayed on; introduced into; or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance; or

(b) Intended for use as a component of any such article.

(14) "Counterfeit drug," "counterfeit device," or "counterfeit cosmetic" means a drug, device, or cosmetic which, or the container, seal, or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug, device, or cosmetic manufacturer, processor, packer, or distributor other than the person that in fact manufactured, processed, packed, or distributed that drug, device, or cosmetic and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, that other drug, device, or cosmetic manufacturer, processor, packer, or distributor.

(15) "Department" means the Department of Health.

(16) "Device" means any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including its components, parts, or accessories, which is:

(a) Recognized in the current edition of the United States Pharmacopoeia and National Formulary, or any supplement thereof,

(b) Intended for use in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans or other animals, or

(c) Intended to affect the structure or any function of the body of humans or other animals,

and that does not achieve any of its principal intended purposes through chemical action within

or on the body of humans or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

(17) "Distribute " or "distribution" means to sell; offer to sell; give away; transfer, whether by passage of title, physical movement, or both; deliver; or offer to deliver. The term does not mean to administer or dispense.

(18) "Drop shipment" means the sale of a prescription drug from a manufacturer to a wholesale distributor, where the wholesale distributor takes title to, but not possession of, the prescription drug, and the manufacturer of the prescription drug ships the prescription drug directly to a chain pharmacy warehouse or a person authorized by law to purchase prescription drugs for the purpose of administering or dispensing the drug, as defined in s. 465.003.

(19) "Drug" means an article that is:

(a) Recognized in the current edition of the United States Pharmacopoeia and National Formulary, official Homeopathic Pharmacopoeia of the United States, or any supplement to any of those publications;

(b) Intended for use in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans or other animals;

(c) Intended to affect the structure or any function of the body of humans or other animals; or

(d) Intended for use as a component of any article specified in paragraph (a), paragraph (b), or paragraph (c), but does not include devices or their components, parts, or accessories.

(20) "Establishment" means a place of business at one general physical location.

(21) "Federal act" means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.

(22) "Freight forwarder" means a person who receives prescription drugs which are owned by another person and designated by that person for export, and exports those prescription drugs.

(23) "Health care entity" means a closed pharmacy or any person, organization, or business entity that provides diagnostic, medical, surgical, or dental treatment or care, or chronic or rehabilitative care, but does not include any wholesale distributor or retail pharmacy licensed under state law to deal in prescription drugs.

(24) "Health care facility" means a health care facility licensed under chapter 395.

(25) "Hospice" means a corporation licensed under part IV of chapter 400.

(26) "Hospital" means a facility as defined in s. 395.002 and licensed under chapter 395.

(27) "Immediate container" does not include package liners.

(28) "Label" means a display of written, printed, or graphic matter upon the immediate container of any drug, device, or cosmetic. A requirement made by or under authority of this part or rules adopted under this part that any word, statement, or other information appear on the label is not complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any, of the retail package of such drug, device, or cosmetic or is easily legible through the outside container or wrapper.

(29) "Labeling" means all labels and other written, printed, or graphic matters:

(a) Upon a drug, device, or cosmetic, or any of its containers or wrappers; or

(b) Accompanying or related to such drug, device, or cosmetic.

(30) "Manufacture" means the preparation, deriving, compounding, propagation, processing, producing, or fabrication of any drug, device, or cosmetic.

(31) "Manufacturer" means:

(a) A person who prepares, derives, manufactures, or produces a drug, device, or cosmetic;

(b) The holder or holders of a New Drug Application (NDA), an Abbreviated New Drug Application (ANDA), a Biologics License Application (BLA), or a New Animal Drug Application (NADA), provided such application has become effective or is otherwise approved consistent with s. 499.023;

(c) A private label distributor for whom the private label distributor's prescription drugs are originally manufactured and labeled for the distributor and have not been repackaged;

(d) A person registered under the federal act as a manufacturer of a prescription drug, who is described in paragraph (a), paragraph (b), or paragraph (c), who has entered into a written agreement with another prescription drug manufacturer that authorizes either manufacturer to distribute the prescription drug identified in the agreement as the manufacturer of that drug

consistent with the federal act and its implementing regulations;

(e) A member of an affiliated group that includes, but is not limited to, persons described in paragraph (a), paragraph (b), paragraph (c), or paragraph (d), which member distributes prescription drugs, whether or not obtaining title to the drugs, only for the manufacturer of the drugs who is also a member of the affiliated group. As used in this paragraph, the term "affiliated group" means an affiliated group as defined in s. 1504 of the Internal Revenue Code of 1986, as amended. The manufacturer must disclose the names of all of its affiliated group members to the department; or

(f) A person permitted as a third party logistics provider, only while providing warehousing, distribution, or other logistics services on behalf of a person described in paragraph (a), paragraph (b), paragraph (c), paragraph (d), or paragraph (e).

The term does not include a pharmacy that is operating in compliance with pharmacy practice standards as defined in chapter 465 and rules adopted under that chapter.

(32) "New drug" means:

(a) Any drug the composition of which is such that the drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling of that drug; or

(b) Any drug the composition of which is such that the drug, as a result of investigations to determine its safety and effectiveness for use under certain conditions, has been recognized for use under such conditions, but which drug has not, other than in those investigations, been used to a material extent or for a material time under such conditions.

(33) "Normal distribution chain" means a wholesale distribution of a prescription drug in which the wholesale distributor or its wholly owned subsidiary purchases and receives the specific unit of the prescription drug directly from the manufacturer and distributes the prescription drug directly, or through up to two intracompany transfers, to a chain pharmacy warehouse or a person authorized by law to purchase prescription drugs for the purpose of administering or dispensing the drug, as defined in s. 465.003. For purposes of this subsection, the term "intracompany" means any transaction or transfer between any parent, division, or subsidiary wholly owned by a corporate entity.

(34) "Nursing home" means a facility licensed under part II of chapter 400.

(35) "Official compendium" means the current edition of the official United States Pharmacopoeia and National Formulary, or any supplement thereto.

(36) "Pedigree paper" means a document in written or electronic form approved by the department which contains information required by s. 499.01212 regarding the sale and distribution of any given prescription drug.

(37) "Permittee" means any person holding a permit issued pursuant to s. 499.012.

(38) "Person" means any individual, child, joint venture, syndicate, fiduciary, partnership, corporation, division of a corporation, firm, trust, business trust, company, estate, public or private institution, association, organization, group, city, county, city and county, political subdivision of this state, other governmental agency within this state, and any representative, agent, or agency of any of the foregoing, or any other group or combination of the foregoing.

(39) "Pharmacist" means a person licensed under chapter 465.

(40) "Pharmacy" means an entity licensed under chapter 465.

(41) "Prepackaged drug product" means a drug that originally was in finished packaged form sealed by a manufacturer and that is placed in a properly labeled container by a pharmacy or practitioner authorized to dispense pursuant to chapter 465 for the purpose of dispensing in the establishment in which the prepackaging occurred.

(42) "Prescription drug" means a prescription, medicinal, or legend drug, including, but not limited to, finished dosage forms or active ingredients subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act or s. 465.003(8), s. 499.007(13), or subsection (11), subsection (45), or subsection (52).

(43) "Prescription drug label" means any display of written, printed, or graphic matter upon the immediate container of any prescription drug prior to its dispensing to an individual patient pursuant to a prescription of a practitioner authorized by law to prescribe.

(44) "Prescription label" means any display of written, printed, or graphic matter upon the immediate container of any prescription drug dispensed pursuant to a prescription of a practitioner authorized by law to prescribe.

(45) "Prescription medical oxygen" means oxygen USP which is a drug that can only be sold on the order or prescription of a practitioner authorized by law to prescribe. The label of prescription medical oxygen must comply with current labeling requirements for oxygen under the Federal Food, Drug, and Cosmetic Act.

(46) "Primary wholesale distributor " means any wholesale distributor that:

(a) Purchased 90 percent or more of the total dollar volume of its purchases of prescription drugs directly from manufacturers in the previous year; and

(b) 1. Directly purchased prescription drugs from not fewer than 50 different prescription drug manufacturers in the previous year; or

2. Has, or the affiliated group, as defined in s. 1504 of the Internal Revenue Code, of which the wholesale distributor is a member has, not fewer than 250 employees.

(c) For purposes of this subsection, "directly from manufacturers " means:

1. Purchases made by the wholesale distributor directly from the manufacturer of prescription drugs; and

2. Transfers from a member of an affiliated group, as defined in s. 1504 of the Internal Revenue Code, of which the wholesale distributor is a member, if:

a. The affiliated group purchases 90 percent or more of the total dollar volume of its purchases of prescription drugs from the manufacturer in the previous year; and

b. The wholesale distributor discloses to the department the names of all members of the affiliated group of which the wholesale distributor is a member and the affiliated group agrees in writing to provide records on prescription drug purchases by the members of the affiliated group not later than 48 hours after the department requests access to such records, regardless of the location where the records are stored.

(47) "Proprietary drug," or "OTC drug," means a patent or over-the-counter drug in its unbroken,

original package, which drug is sold to the public by, or under the authority of, the manufacturer or primary distributor thereof, is not misbranded under the provisions of this part, and can be purchased without a prescription.

(48) "Repackage" includes repacking or otherwise changing the container, wrapper, or labeling to further the distribution of the drug, device, or cosmetic.

(49) "Repackager" means a person who repackages. The term excludes pharmacies that are operating in compliance with pharmacy practice standards as defined in chapter 465 and rules adopted under that chapter.

(50) "Retail pharmacy" means a community pharmacy licensed under chapter 465 that purchases prescription drugs at fair market prices and provides prescription services to the public.

(51) "Secondary wholesale distributor " means a wholesale distributor that is not a primary wholesale distributor.

(52) "Veterinary prescription drug" means a prescription drug intended solely for veterinary use. The label of the drug must bear the statement, "Caution: Federal law restricts this drug to sale by or on the order of a licensed veterinarian."

(53) "Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

(a) Any of the following activities, which is not a violation of s. 499.005(21) if such activity is conducted in accordance with s. 499.01(2)(g):

1. The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a prescription drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of that organization.

2. The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug by a charitable organization described in s. 501(c)(3) of the Internal Revenue Code of 1986, as amended and revised, to a nonprofit affiliate of the organization to the extent otherwise permitted by law.

3. The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug among hospitals or other health care entities that are under common control. For purposes of this subparagraph, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, by voting rights, by contract, or otherwise.

4. The sale, purchase, trade, or other transfer of a prescription drug from or for any federal, state, or local government agency or any entity eligible to purchase prescription drugs at public health services prices pursuant to Pub. L. No. 102-585, s. 602 to a contract provider or its subcontractor for eligible patients of the agency or entity under the following conditions:

a. The agency or entity must obtain written authorization for the sale, purchase, trade, or other transfer of a prescription drug under this subparagraph from the State Surgeon General or his or her designee.

b. The contract provider or subcontractor must be authorized by law to administer or dispense prescription drugs.

c. In the case of a subcontractor, the agency or entity must be a party to and execute the subcontract.

d. A contract provider or subcontractor must maintain separate and apart from other prescription drug inventory any prescription drugs of the agency or entity in its possession.

e. The contract provider and subcontractor must maintain and produce immediately for inspection all records of movement or transfer of all the prescription drugs belonging to the agency or entity, including, but not limited to, the records of receipt and disposition of prescription drugs. Each contractor and subcontractor dispensing or administering these drugs must maintain and produce records documenting the dispensing or administration. Records that are required to be maintained include, but are not limited to, a perpetual inventory itemizing drugs received and drugs dispensed by prescription number or administered by patient identifier, which must be submitted to the agency or entity quarterly.

f. The contract provider or subcontractor may administer or dispense the prescription drugs only to the eligible patients of the agency or entity or must return the prescription drugs for or to the agency or entity. The contract provider or subcontractor must require proof from each person seeking to fill a prescription or obtain treatment that the person is an eligible patient of the agency or entity and must, at a minimum, maintain a copy of this proof as part of the records of the contractor or subcontractor required under sub-subparagraph e.

g. In addition to the departmental inspection authority set forth in s. 499.051, the establishment of the contract provider and subcontractor and all records pertaining to prescription drugs subject to this subparagraph shall be subject to inspection by the agency or entity. All records relating to prescription drugs of a manufacturer under this subparagraph shall be subject to audit by the manufacturer of those drugs, without identifying individual patient information.

(b) Any of the following activities, which is not a violation of s. 499.005(21) if such activity is conducted in accordance with rules established by the department:

1. The sale, purchase, or trade of a prescription drug among federal, state, or local government health care entities that are under common control and are authorized to purchase such prescription drug.

2. The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug for emergency medical reasons. For purposes of this subparagraph, the term "emergency medical reasons" includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage.

3. The transfer of a prescription drug acquired by a medical director on behalf of a licensed emergency medical services provider to that emergency medical services provider and its transport vehicles for use in accordance with the provider's license under chapter 401.

4. The revocation of a sale or the return of a prescription drug to the person's prescription drug wholesale supplier.

5. The donation of a prescription drug by a health care entity to a charitable organization that has been granted an exemption under s. 501(c)(3) of the Internal Revenue Code of 1986, [FN2] as amended, and that is authorized to possess prescription drugs.

6. The transfer of a prescription drug by a person authorized to purchase or receive prescription drugs to a person licensed or permitted to handle reverse distributions or destruction under the laws of the jurisdiction in which the person handling the reverse distribution or destruction receives the drug.

7. The transfer of a prescription drug by a hospital or other health care entity to a person licensed under this part to repackage prescription drugs for the purpose of repackaging the prescription drug for use by that hospital, or other health care entity and other health care entities that are under common control, if ownership of the prescription drugs remains with the hospital or other

health care entity at all times. In addition to the recordkeeping requirements of s. 499.0121(6), the hospital or health care entity that transfers prescription drugs pursuant to this subparagraph must reconcile all drugs transferred and returned and resolve any discrepancies in a timely manner.

(c) The distribution of prescription drug samples by manufacturers' representatives or distributors' representatives conducted in accordance with s. 499.028.

(d) The sale, purchase, or trade of blood and blood components intended for transfusion. As used in this paragraph, the term "blood" means whole blood collected from a single donor and processed for transfusion or further manufacturing, and the term "blood components" means that part of the blood separated by physical or mechanical means.

(e) The lawful dispensing of a prescription drug in accordance with chapter 465.

(f) The sale, purchase, or trade of a prescription drug between pharmacies as a result of a sale, transfer, merger, or consolidation of all or part of the business of the pharmacies from or with another pharmacy, whether accomplished as a purchase and sale of stock or of business assets.

(54) "Wholesale distributor" means any person engaged in wholesale distribution of prescription drugs in or into this state, including, but not limited to, manufacturers; repackagers; own-label distributors; jobbers; private-label distributors; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; exporters; retail pharmacies; and the agents thereof that conduct wholesale distributions.

Florida Statutes Annotated

Title XXXIII. Regulation of Trade, Commerce, Investments, and Solicitations (Chapters 494-560)
Chapter 499. Drug, Cosmetic, and Household Products
Part I. Drugs; Devices; Cosmetics; Household Products
499.005. Prohibited acts

It is unlawful for a person to perform or cause the performance of any of the following acts in this state:

(1) The manufacture, repackaging, sale, delivery, or holding or offering for sale of any drug, device, or cosmetic that is adulterated or misbranded or has otherwise been rendered unfit for human or animal use.

(2) The adulteration or misbranding of any drug, device, or cosmetic.

(3) The receipt of any drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery of such drug, device, or cosmetic, for pay or otherwise.

(4) The sale, distribution, purchase, trade, holding, or offering of any drug, device, or cosmetic in violation of this part.

(5) The dissemination of any false or misleading advertisement of a drug, device, or cosmetic.

(6) The refusal or constructive refusal:

(a) To allow the department to enter or inspect an establishment in which drugs, devices, or

cosmetics are manufactured, processed, repackaged, sold, brokered, or held;

(b) To allow inspection of any record of that establishment;

(c) To allow the department to enter and inspect any vehicle that is being used to transport drugs, devices, or cosmetics; or

(d) To allow the department to take samples of any drug, device, or cosmetic.

(7) The purchase or sale of prescription drugs for wholesale distribution in exchange for currency, as defined in s. 560.103.

(8) Committing any act that causes a drug, device, or cosmetic to be a counterfeit drug, device, or cosmetic; or selling, dispensing, or holding for sale a counterfeit drug, device, or cosmetic.

(9) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of a drug, device, or cosmetic, or the doing of any other act with respect to a drug, device, or cosmetic, if the act is done while the drug, device, or cosmetic is held for sale and the act results in the drug, device, or cosmetic being misbranded.

(10) Forging; counterfeiting; simulating; falsely representing any drug, device, or cosmetic; or, without the authority of the manufacturer, using any mark, stamp, tag, label, or other identification device authorized or required by rules adopted under this part.

(11) The use, on the labeling of any drug or in any advertisement relating to such drug, of any representation or suggestion that an application of the drug is effective when it is not or that the drug complies with this part when it does not.

(12) The possession of any drug in violation of this part.

(13) The sale, delivery, holding, or offering for sale of any self-testing kits designed to tell persons their status concerning human immunodeficiency virus or acquired immune deficiency syndrome or related disorders or conditions. This prohibition shall not apply to home access HIV test kits approved for distribution and sale by the United States Food and Drug Administration.

(14) The purchase or receipt of a prescription drug from a person that is not authorized under this chapter to distribute prescription drugs to that purchaser or recipient.

(15) The sale or transfer of a prescription drug to a person that is not authorized under the law of the jurisdiction in which the person receives the drug to purchase or possess prescription drugs from the person selling or transferring the prescription drug.

(16) The purchase or receipt of a compressed medical gas from a person that is not authorized under this chapter to distribute compressed medical gases.

(17) The sale, purchase, or trade, or the offer to sell, purchase, or trade, a drug sample as defined in s. 499.028; the distribution of a drug sample in violation of s. 499.028; or the failure to otherwise comply with s. 499.028.

(18) Failure to maintain records as required by this part and rules adopted under this part.

(19) Providing the department with false or fraudulent records, or making false or fraudulent statements, regarding any matter within the provisions of this part.

(20) The importation of a prescription drug except as provided by s. 801(d) of the Federal Food, Drug, and Cosmetic Act.

(21) The wholesale distribution of any prescription drug that was:

(a) Purchased by a public or private hospital or other health care entity; or

(b) Donated or supplied at a reduced price to a charitable organization.

(22) Failure to obtain a permit or registration, or operating without a valid permit when a permit or registration is required by this part for that activity.

(23) Obtaining or attempting to obtain a prescription drug or device by fraud, deceit, misrepresentation or subterfuge, or engaging in misrepresentation or fraud in the distribution of a drug or device.

(24) The distribution of a prescription device to the patient or ultimate consumer without a prescription or order from a practitioner licensed by law to use or prescribe the device.

(25) Charging a dispensing fee for dispensing, administering, or distributing a prescription drug sample.

(26) Removing a pharmacy's dispensing label from a dispensed prescription drug with the intent to further distribute the prescription drug.

(27) Distributing a prescription drug that was previously dispensed by a licensed pharmacy, unless such distribution was authorized in chapter 465 or the rules adopted under chapter 465.

(28) Failure to acquire or deliver a pedigree paper as required under this part.

(29) The receipt of a prescription drug pursuant to a wholesale distribution without having previously received or simultaneously receiving a pedigree paper that was attested to as accurate and complete by the wholesale distributor as required under this part.

Florida Statutes Annotated

Title XXXIII. Regulation of Trade, Commerce, Investments, and Solicitations (Chapters 494-560)
Chapter 499. Drug, Cosmetic, and Household Products
Part I. Drugs; Devices; Cosmetics; Household Products
499.0051. Criminal acts

(1) Failure to maintain or deliver pedigree papers.--

(a) A person, other than a manufacturer, engaged in the wholesale distribution of prescription drugs who fails to deliver to another person complete and accurate pedigree papers concerning a prescription drug or contraband prescription drug prior to, or simultaneous with, the transfer of the prescription drug or contraband prescription drug to another person commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(b) A person engaged in the wholesale distribution of prescription drugs who fails to acquire complete and accurate pedigree papers concerning a prescription drug or contraband prescription drug prior to, or simultaneous with, the receipt of the prescription drug or contraband prescription drug from another person commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(c) Any person who knowingly destroys, alters, conceals, or fails to maintain complete and accurate pedigree papers concerning any prescription drug or contraband prescription drug in his or her possession commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(2) Failure to authenticate pedigree papers.--Effective July 1, 2006:

(a) A person engaged in the wholesale distribution of prescription drugs who is in possession of

pedigree papers concerning prescription drugs or contraband prescription drugs and who fails to authenticate the matters contained in the pedigree papers and who nevertheless attempts to further distribute prescription drugs or contraband prescription drugs commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(b) A person in possession of pedigree papers concerning prescription drugs or contraband prescription drugs who falsely swears or certifies that he or she has authenticated the matters contained in the pedigree papers commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(3) Knowing forgery of pedigree papers.--A person who knowingly forges, counterfeits, or falsely creates any pedigree paper; who falsely represents any factual matter contained on any pedigree paper; or who knowingly omits to record material information required to be recorded in a pedigree paper, commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(4) Knowing purchase or receipt of prescription drug from unauthorized person.--A person who knowingly purchases or receives from a person not authorized to distribute prescription drugs under this chapter a prescription drug in a wholesale distribution transaction commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(5) Knowing sale or transfer of prescription drug to unauthorized person.--A person who knowingly sells or transfers to a person not authorized to purchase or possess prescription drugs, under the law of the jurisdiction in which the person receives the drug, a prescription drug in a wholesale distribution transaction commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(6) Knowing sale or delivery, or possession with intent to sell, contraband prescription drugs.--A person who is knowingly in actual or constructive possession of any amount of contraband prescription drugs, who knowingly sells or delivers, or who possesses with intent to sell or

deliver any amount of contraband prescription drugs, commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(7) Knowing trafficking in contraband prescription drugs.--A person who knowingly sells, purchases, manufactures, delivers, or brings into this state, or who is knowingly in actual or constructive possession of any amount of contraband prescription drugs valued at $25,000 or more commits a felony of the first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(a) Upon conviction, each defendant shall be ordered to pay a mandatory fine according to the following schedule:

1. If the value of contraband prescription drugs involved is $25,000 or more, but less than $100,000, the defendant shall pay a mandatory fine of $25,000. If the defendant is a corporation or other person that is not a natural person, it shall pay a mandatory fine of $75,000.

2. If the value of contraband prescription drugs involved is $100,000 or more, but less than $250,000, the defendant shall pay a mandatory fine of $100,000. If the defendant is a corporation or other person that is not a natural person, it shall pay a mandatory fine of $300,000.

3. If the value of contraband prescription drugs involved is $250,000 or more, the defendant shall pay a mandatory fine of $200,000. If the defendant is a corporation or other person that is not a natural person, it shall pay a mandatory fine of $600,000.

(b) As used in this subsection, the term "value" means the market value of the property at the time and place of the offense or, if such cannot be satisfactorily ascertained, the cost of replacement of the property within a reasonable time after the offense. Amounts of value of separate contraband prescription drugs involved in distinct transactions for the distribution of the contraband prescription drugs committed pursuant to one scheme or course of conduct, whether

involving the same person or several persons, may be aggregated in determining the punishment of the offense.

(8) Knowing forgery of prescription or prescription drug labels.--A person who knowingly forges, counterfeits, or falsely creates any prescription label or prescription drug label, or who falsely represents any factual matter contained on any prescription label or prescription drug label, commits a felony of the first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(9) Knowing sale or purchase of contraband prescription drugs resulting in great bodily harm.--A person who knowingly sells, purchases, manufactures, delivers, or brings into this state, or who is knowingly in actual or constructive possession of any amount of contraband prescription drugs, and whose acts in violation of this subsection result in great bodily harm to a person, commits a felony of the first degree, as provided in s. 775.082, s. 775.083, or s. 775.084.

(10) Knowing sale or purchase of contraband prescription drugs resulting in death.--A person who knowingly manufactures, sells, purchases, delivers, or brings into this state, or who is knowingly in actual or constructive possession of any amount of contraband prescription drugs, and whose acts in violation of this subsection result in the death of a person, commits a felony of the first degree, punishable by a term of years not exceeding life, as provided in s. 775.082, s. 775.083, or s. 775.084.

(11) Violations of s. 499.005 related to devices and cosmetics; dissemination of false advertisement.--

(a) Any person who violates any of the provisions of s. 499.005 with respect to a device or cosmetic commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083; but, if the violation is committed after a conviction of such person under this subsection has become final, such person is guilty of a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083 or as otherwise provided in this part, except

that any person who violates s. 499.005(8) or (10) with respect to a device or cosmetic commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, or as otherwise provided in this part.

(b) A publisher, radio broadcast licensee, or agency or medium for the dissemination of an advertisement, except the manufacturer, wholesaler, or seller of the article to which a false advertisement relates, is not liable under this subsection by reason of the dissemination by him or her of such false advertisement, unless he or she has refused, on the request of the department, to furnish to the department the name and post office address of the manufacturer, wholesaler, seller, or advertising agency that asked him or her to disseminate such advertisement.

(12) Adulterated and misbranded drugs; false advertisement; failure to maintain records relating to drugs.--Any person who violates any of the following provisions commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083; but, if the violation is committed after a conviction of such person under this subsection has become final, such person commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083, or as otherwise provided in this part:

(a) The manufacture, repackaging, sale, delivery, or holding or offering for sale of any drug that is adulterated or misbranded or has otherwise been rendered unfit for human or animal use.

(b) The adulteration or misbranding of any drug intended for further distribution.

(c) The receipt of any drug that is adulterated or misbranded, and the delivery or proffered delivery of such drug, for pay or otherwise.

(d) The dissemination of any false or misleading advertisement of a drug.

(e) The use, on the labeling of any drug or in any advertisement relating to such drug, of any representation or suggestion that an application of the drug is effective when it is not or that the drug complies with this part when it does not.

(f) The purchase or receipt of a compressed medical gas from a person that is not authorized under this chapter to distribute compressed medical gases.

(g) Charging a dispensing fee for dispensing, administering, or distributing a prescription drug sample.

(h) The failure to maintain records related to a drug as required by this part and rules adopted under this part, except for pedigree papers, invoices, or shipping documents related to prescription drugs.

(i) The possession of any drug in violation of this part, except if the violation relates to a deficiency in pedigree papers.

(13) Refusal to allow inspection; selling, purchasing, or trading drug samples; failure to maintain records relating to prescription drugs.-- Any person who violates any of the following provisions commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, or as otherwise provided in this part:

(a) The refusal or constructive refusal to allow:

1. The department to enter or inspect an establishment in which drugs are manufactured, processed, repackaged, sold, brokered, or held;

2. Inspection of any record of that establishment;

3. The department to enter and inspect any vehicle that is being used to transport drugs; or

4. The department to take samples of any drug.

(b) The sale, purchase, or trade, or the offer to sell, purchase, or trade, a drug sample as defined in s. 499.028; the distribution of a drug sample in violation of s. 499.028; or the failure to otherwise comply with s. 499.028.

(c) Providing the department with false or fraudulent records, or making false or fraudulent statements, regarding any matter within the provisions of this part related to a drug.

(d) The failure to receive, maintain, or provide invoices and shipping documents, other than pedigree papers, if applicable, related to the distribution of a prescription drug.

(e) The importation of a prescription drug for wholesale distribution, except as provided by s. 801(d) of the Federal Food, Drug, and Cosmetic Act.

(f) The wholesale distribution of a prescription drug that was:

1. Purchased by a public or private hospital or other health care entity; or

2. Donated or supplied at a reduced price to a charitable organization.

(g) The failure to obtain a permit as a prescription drug wholesale distributor when a permit is required by this part for that activity.

(h) Knowingly possessing any adulterated or misbranded prescription drug outside of a designated quarantine area.

(i) The purchase or sale of a prescription drug for wholesale distribution in exchange for currency, as defined in s. 560.103.

(14) Other violations.--Any person who violates any of the following provisions commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, or as otherwise provided in this part:

(a) Knowingly manufacturing, repackaging, selling, delivering, or holding or offering for sale any drug that is adulterated or misbranded or has otherwise been rendered unfit for human or animal use.

(b) Knowingly adulterating a drug that is intended for further distribution.

(c) Knowingly receiving a drug that is adulterated and delivering or proffering delivery of such drug for pay or otherwise.

(d) Committing any act that causes a drug to be a counterfeit drug, or selling, dispensing, or knowingly holding for sale a counterfeit drug.

(e) Forging, counterfeiting, simulating, or falsely representing any drug, or, without the authority of the manufacturer, using any mark, stamp, tag, label, or other identification device authorized

or required by rules adopted under this part.

(f) Knowingly obtaining or attempting to obtain a prescription drug for wholesale distribution by fraud, deceit, misrepresentation, or subterfuge, or engaging in misrepresentation or fraud in the distribution of a drug.

(g) Removing a pharmacy's dispensing label from a dispensed prescription drug with the intent to further distribute the prescription drug.

(h) Knowingly distributing a prescription drug that was previously dispensed by a licensed pharmacy, unless such distribution was authorized in chapter 465 or the rules adopted under chapter 465.

(15) False advertisement.--A publisher, radio broadcast licensee, or agency or medium for the dissemination of an advertisement, except the manufacturer, repackager, wholesale distributor, or seller of the article to which a false advertisement relates, is not liable under subsection (12), subsection (13), or subsection (14) by reason of the dissemination by him or her of such false advertisement, unless he or she has refused, on the request of the department, to furnish to the department the name and post office address of the manufacturer, repackager, wholesale distributor, seller, or advertising agency that asked him or her to disseminate such advertisement.

Florida Statutes Annotated

Title XXXIII. Regulation of Trade, Commerce, Investments, and Solicitations (Chapters 494-560)
Chapter 499. Drug, Cosmetic, and Household Products
Part I. Drugs; Devices; Cosmetics; Household Products
499.01. Permits

(1) Prior to operating, a permit is required for each person and establishment that intends to operate as:

(a) A prescription drug manufacturer;

(b) A prescription drug repackager;

(c) A nonresident prescription drug manufacturer;

(d) A prescription drug wholesale distributor;

(e) An out-of-state prescription drug wholesale distributor;

(f) A retail pharmacy drug wholesale distributor;

(g) A restricted prescription drug distributor;

(h) A complimentary drug distributor;

(i) A freight forwarder;

(j) A veterinary prescription drug retail establishment;

(k) A veterinary prescription drug wholesale distributor;

(*l*) A limited prescription drug veterinary wholesale distributor;

(m) A medical oxygen retail establishment;

(n) A compressed medical gas wholesale distributor;

(*o*) A compressed medical gas manufacturer;

(p) An over-the-counter drug manufacturer;

(q) A device manufacturer;

(r) A cosmetic manufacturer;

(s) A third party logistics provider; or

(t) A health care clinic establishment.

(2) The following permits are established:

(a) *Prescription drug manufacturer permit.*--A prescription drug manufacturer permit is required for any person that is a manufacturer of a prescription drug and that manufactures or distributes such prescription drugs in this state.

1. A person that operates an establishment permitted as a prescription drug manufacturer may engage in wholesale distribution of prescription drugs manufactured at that establishment and must comply with all of the provisions of this part, except s. 499.01212, and the rules adopted under this part, except s. 499.01212, that apply to a wholesale distributor.

2. A prescription drug manufacturer must comply with all appropriate state and federal good manufacturing practices.

(b) *Prescription drug repackager permit*.--A prescription drug repackager permit is required for any person that repackages a prescription drug in this state.

1. A person that operates an establishment permitted as a prescription drug repackager may engage in wholesale distribution of prescription drugs repackaged at that establishment and must comply with all the provisions of this part and the rules adopted under this part that apply to a wholesale distributor.

2. A prescription drug repackager must comply with all appropriate state and federal good manufacturing practices.

(c) *Nonresident prescription drug manufacturer permit.*--A nonresident prescription drug manufacturer permit is required for any person that is a manufacturer of prescription drugs, unless permitted as a third party logistics provider, located outside of this state or outside the United States and that engages in the wholesale distribution in this state of such prescription drugs. Each such manufacturer must be permitted by the department and comply with all of the provisions required of a wholesale distributor under this part, except s. 499.01212.

1. A person that distributes prescription drugs for which the person is not the manufacturer must also obtain an out-of-state prescription drug wholesale distributor permit or third party logistics provider permit pursuant to this section to engage in the wholesale distribution of such prescription drugs. This subparagraph does not apply to a manufacturer as defined in s. 499.003(31)(e).

2. Any such person must comply with the licensing or permitting requirements of the jurisdiction in which the establishment is located and the federal act, and any product wholesaled into this state must comply with this part. If a person intends to import prescription drugs from a foreign country into this state, the nonresident prescription drug manufacturer must provide to the department a list identifying each prescription drug it intends to import and document approval by the United States Food and Drug Administration for such importation.

3. A nonresident prescription drug manufacturer permit is not required for a manufacturer to distribute a prescription drug active pharmaceutical ingredient that it manufactures to a prescription drug manufacturer permitted in this state in limited quantities intended for research and development and not for resale, or human use other than lawful clinical trials and biostudies authorized and regulated by federal law. A manufacturer claiming to be exempt from the permit requirements of this subparagraph and the prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient shall comply with the recordkeeping requirements of s. 499.0121(6), but not the requirements of s. 499.01212. The prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient shall maintain on file a record of the FDA registration number; the out-of-state license, permit, or registration number; and, if available, a copy of the most current FDA inspection report, for all manufacturers from whom they purchase active pharmaceutical ingredients under this section. The department shall specify

by rule the allowable number of transactions within a given period of time and the amount of active pharmaceutical ingredients that qualify as limited quantities for purposes of this exemption. The failure to comply with the requirements of this subparagraph, or rules adopted by the department to administer this subparagraph, for the purchase of prescription drug active pharmaceutical ingredients is a violation of s. 499.005(14).

(d) *Prescription drug wholesale distributor permit*.--A prescription drug wholesale distributor is a wholesale distributor that may engage in the wholesale distribution of prescription drugs. A prescription drug wholesale distributor that applies to the department for a new permit or the renewal of a permit must submit a bond of $100,000, or other equivalent means of security acceptable to the department, such as an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to the Florida Drug, Device, and Cosmetic Trust Fund. The purpose of the bond is to secure payment of any administrative penalties imposed by the department and any fees and costs incurred by the department regarding that permit which are authorized under state law and which the permittee fails to pay 30 days after the fine or costs become final. The department may make a claim against such bond or security until 1 year after the permittee's license ceases to be valid or until 60 days after any administrative or legal proceeding authorized in this part which involves the permittee is concluded, including any appeal, whichever occurs later. The department may adopt rules for issuing a prescription drug wholesale distributor-broker permit to a person who engages in the wholesale distribution of prescription drugs and does not take physical possession of any prescription drugs.

(e) *Out-of-state prescription drug wholesale distributor permit*.--An out-of- state prescription drug wholesale distributor is a wholesale distributor located outside this state which engages in the wholesale distribution of prescription drugs into this state and which must be permitted by the department and comply with all the provisions required of a wholesale distributor under this part . An out-of-state prescription drug wholesale distributor that applies to the department for a new permit or the renewal of a permit must submit a bond of $100,000, or other equivalent means of security acceptable to the department, such as an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to the Florida Drug, Device, and Cosmetic Trust Fund. The purpose of the bond is to secure payment of any administrative penalties imposed by the department and any fees and costs incurred by the department regarding that permit which are authorized under state law and which the permittee fails to pay 30 days after

the fine or costs become final. The department may make a claim against such bond or security until 1 year after the permittee's license ceases to be valid or until 60 days after any administrative or legal proceeding authorized in this part which involves the permittee is concluded, including any appeal, whichever occurs later.

1. The out-of-state prescription drug wholesale distributor must maintain at all times a license or permit to engage in the wholesale distribution of prescription drugs in compliance with laws of the state in which it is a resident.

2. An out-of-state prescription drug wholesale distributor permit is not required for an intracompany sale or transfer of a prescription drug from an out-of-state establishment that is duly licensed as a prescription drug wholesale distributor, in its state of residence, to a licensed prescription drug wholesale distributor in this state, if both wholesale distributors conduct wholesale distributions of prescription drugs under the same business name. The recordkeeping requirements of ss. 499.0121(6) and 499.01212 must be followed for this transaction.

(f) *Retail pharmacy drug wholesale distributor permit*.--A retail pharmacy drug wholesale distributor is a retail pharmacy engaged in wholesale distribution of prescription drugs within this state under the following conditions:

1. The pharmacy must obtain a retail pharmacy drug wholesale distributor permit pursuant to this part and the rules adopted under this part.

2. The wholesale distribution activity does not exceed 30 percent of the total annual purchases of prescription drugs. If the wholesale distribution activity exceeds the 30-percent maximum, the pharmacy must obtain a prescription drug wholesale distributor permit.

3. The transfer of prescription drugs that appear in any schedule contained in chapter 893 is subject to chapter 893 and the federal Comprehensive Drug Abuse Prevention and Control Act of

1970.

4. The transfer is between a retail pharmacy and another retail pharmacy, or a Modified Class II institutional pharmacy, or a health care practitioner licensed in this state and authorized by law to dispense or prescribe prescription drugs.

5. All records of sales of prescription drugs subject to this section must be maintained separate and distinct from other records and comply with the recordkeeping requirements of this part.

(g) *Restricted prescription drug distributor permit*.--A restricted prescription drug distributor permit is required for any person that engages in the distribution of a prescription drug, which distribution is not considered "wholesale distribution" under s. 499.003(53)(a).

1. A person who engages in the receipt or distribution of a prescription drug in this state for the purpose of processing its return or its destruction must obtain a permit as a restricted prescription drug distributor if such person is not the person initiating the return, the prescription drug wholesale supplier of the person initiating the return, or the manufacturer of the drug.

2. Storage, handling, and recordkeeping of these distributions must comply with the requirements for wholesale distributors under s. 499.0121, but not those set forth in s. 499.01212.

3. A person who applies for a permit as a restricted prescription drug distributor, or for the renewal of such a permit, must provide to the department the information required under s. 499.012.

4. The department may adopt rules regarding the distribution of prescription drugs by hospitals, health care entities, charitable organizations, or other persons not involved in wholesale distribution, which rules are necessary for the protection of the public health, safety, and welfare.

(h) *Complimentary drug distributor permit*.--A complimentary drug distributor permit is required for any person that engages in the distribution of a complimentary drug, subject to the requirements of s. 499.028.

(i) *Freight forwarder permit*.--A freight forwarder permit is required for any person that engages in the distribution of a prescription drug as a freight forwarder unless the person is a common carrier. The storage, handling, and recordkeeping of such distributions must comply with the requirements for wholesale distributors under s. 499.0121, but not those set forth in s. 499.01212. A freight forwarder must provide the source of the prescription drugs with a validated airway bill, bill of lading, or other appropriate documentation to evidence the exportation of the product.

(j) *Veterinary prescription drug retail establishment permit*.--A veterinary prescription drug retail establishment permit is required for any person that sells veterinary prescription drugs to the public but does not include a pharmacy licensed under chapter 465.

1. The sale to the public must be based on a valid written order from a veterinarian licensed in this state who has a valid client-veterinarian relationship with the purchaser's animal.

2. Veterinary prescription drugs may not be sold in excess of the amount clearly indicated on the order or beyond the date indicated on the order.

3. An order may not be valid for more than 1 year.

4. A veterinary prescription drug retail establishment may not purchase, sell, trade, or possess human prescription drugs or any controlled substance as defined in chapter 893.

5. A veterinary prescription drug retail establishment must sell a veterinary prescription drug in the original, sealed manufacturer's container with all labeling intact and legible. The department may adopt by rule additional labeling requirements for the sale of a veterinary prescription drug.

6. A veterinary prescription drug retail establishment must comply with all of the wholesale distribution requirements of s. 499.0121.

7. Prescription drugs sold by a veterinary prescription drug retail establishment pursuant to a practitioner's order may not be returned into the retail establishment's inventory.

(k) *Veterinary prescription drug wholesale distributor permit*.--A veterinary prescription drug wholesale distributor permit is required for any person that engages in the distribution of veterinary prescription drugs in or into this state. A veterinary prescription drug wholesale distributor that also distributes prescription drugs subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act which it did not manufacture must obtain a permit as a prescription drug wholesale distributor, an out-of-state prescription drug wholesale distributor, or a limited prescription drug veterinary wholesale distributor in lieu of the veterinary prescription drug wholesale distributor permit. A veterinary prescription drug wholesale distributor must comply with the requirements for wholesale distributors under s. 499.0121, but not those set forth in s. 499.01212.

(*l*) *Limited prescription drug veterinary wholesale distributor permit*.--Unless engaging in the activities of and permitted as a prescription drug manufacturer, nonresident prescription drug manufacturer, prescription drug wholesale distributor, or out-of-state prescription drug wholesale distributor, a limited prescription drug veterinary wholesale distributor permit is required for any person that engages in the distribution in or into this state of veterinary prescription drugs and prescription drugs subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act [FN1] under the following conditions:

1. The person is engaged in the business of wholesaling prescription and veterinary prescription

drugs to persons:

a. Licensed as veterinarians practicing on a full-time basis;

b. Regularly and lawfully engaged in instruction in veterinary medicine;

c. Regularly and lawfully engaged in law enforcement activities;

d. For use in research not involving clinical use; or

e. For use in chemical analysis or physical testing or for purposes of instruction in law enforcement activities, research, or testing.

2. No more than 30 percent of total annual prescription drug sales may be prescription drugs approved for human use which are subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act.

3. The person does not distribute in any jurisdiction prescription drugs subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act to any person who is authorized to sell, distribute, purchase, trade, or use these drugs on or for humans.

4. A limited prescription drug veterinary wholesale distributor that applies to the department for a new permit or the renewal of a permit must submit a bond of $20,000, or other equivalent means of security acceptable to the department, such as an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to the Florida Drug, Device, and Cosmetic Trust Fund. The purpose of the bond is to secure payment of any administrative penalties imposed by the department and any fees and costs incurred by the department regarding that

permit which are authorized under state law and which the permittee fails to pay 30 days after the fine or costs become final. The department may make a claim against such bond or security until 1 year after the permittee's license ceases to be valid or until 60 days after any administrative or legal proceeding authorized in this part which involves the permittee is concluded, including any appeal, whichever occurs later.

5. A limited prescription drug veterinary wholesale distributor must maintain at all times a license or permit to engage in the wholesale distribution of prescription drugs in compliance with laws of the state in which it is a resident.

6. A limited prescription drug veterinary wholesale distributor must comply with the requirements for wholesale distributors under ss. 499.0121 and 499.01212, except that a limited prescription drug veterinary wholesale distributor is not required to provide a pedigree paper as required by s. 499.01212 upon the wholesale distribution of a prescription drug to a veterinarian.

7. A limited prescription drug veterinary wholesale distributor may not return to inventory for subsequent wholesale distribution any prescription drug subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act which has been returned by a veterinarian.

8. A limited prescription drug veterinary wholesale distributor permit is not required for an intracompany sale or transfer of a prescription drug from an out-of-state establishment that is duly licensed to engage in the wholesale distribution of prescription drugs in its state of residence to a licensed limited prescription drug veterinary wholesale distributor in this state if both wholesale distributors conduct wholesale distributions of prescription drugs under the same business name. The recordkeeping requirements of ss. 499.0121(6) and 499.01212 must be followed for this transaction.

(m) *Medical oxygen retail establishment permit*.--A medical oxygen retail establishment permit is required for any person that sells medical oxygen to patients only. The sale must be based on an order from a practitioner authorized by law to prescribe. The term does not include a

pharmacy licensed under chapter 465.

1. A medical oxygen retail establishment may not possess, purchase, sell, or trade any prescription drug other than medical oxygen.

2. A medical oxygen retail establishment may refill medical oxygen for an individual patient based on an order from a practitioner authorized by law to prescribe. A medical oxygen retail establishment that refills medical oxygen must comply with all appropriate state and federal good manufacturing practices.

3. A medical oxygen retail establishment must comply with all of the wholesale distribution requirements of s. 499.0121.

4. Prescription medical oxygen sold by a medical oxygen retail establishment pursuant to a practitioner's order may not be returned into the retail establishment's inventory.

(n) *Compressed medical gas wholesale distributor permit*.--A compressed medical gas wholesale distributor is a wholesale distributor that is limited to the wholesale distribution of compressed medical gases to other than the consumer or patient. The compressed medical gas must be in the original sealed container that was purchased by that wholesale distributor. A compressed medical gas wholesale distributor may not possess or engage in the wholesale distribution of any prescription drug other than compressed medical gases. The department shall adopt rules that govern the wholesale distribution of prescription medical oxygen for emergency use. With respect to the emergency use of prescription medical oxygen, those rules may not be inconsistent with rules and regulations of federal agencies unless the Legislature specifically directs otherwise.

(*o*) *Compressed medical gas manufacturer permit*.--A compressed medical gas manufacturer permit is required for any person that engages in the manufacture of compressed medical gases

or repackages compressed medical gases from one container to another.

1. A compressed medical gas manufacturer may not manufacture or possess any prescription drug other than compressed medical gases.

2. A compressed medical gas manufacturer may engage in wholesale distribution of compressed medical gases manufactured at that establishment and must comply with all the provisions of this part and the rules adopted under this part that apply to a wholesale distributor.

3. A compressed medical gas manufacturer must comply with all appropriate state and federal good manufacturing practices.

(p) *Over-the-counter drug manufacturer permit*.--An over-the-counter drug manufacturer permit is required for any person that engages in the manufacture or repackaging of an over-the-counter drug.

1. An over-the-counter drug manufacturer may not possess or purchase prescription drugs.

2. A pharmacy is exempt from obtaining an over-the-counter drug manufacturer permit if it is operating in compliance with pharmacy practice standards as defined in chapter 465 and the rules adopted under that chapter.

3. An over-the-counter drug manufacturer must comply with all appropriate state and federal good manufacturing practices.

(q) *Device manufacturer permit*.--A device manufacturer permit is required for any person that engages in the manufacture, repackaging, or assembly of medical devices for human use in this

state, except that a permit is not required if the person is engaged only in manufacturing, repackaging, or assembling a medical device pursuant to a practitioner's order for a specific patient.

1. A manufacturer or repackager of medical devices in this state must comply with all appropriate state and federal good manufacturing practices and quality system rules.

2. The department shall adopt rules related to storage, handling, and recordkeeping requirements for manufacturers of medical devices for human use.

(r) *Cosmetic manufacturer permit*.--A cosmetic manufacturer permit is required for any person that manufactures or repackages cosmetics in this state. A person that only labels or changes the labeling of a cosmetic but does not open the container sealed by the manufacturer of the product is exempt from obtaining a permit under this paragraph.

(s) *Third party logistics provider permit*.--A third party logistics provider permit is required for any person that contracts with a prescription drug wholesale distributor or prescription drug manufacturer to provide warehousing, distribution, or other logistics services on behalf of a manufacturer or wholesale distributor, but who does not take title to the prescription drug or have responsibility to direct the sale or disposition of the prescription drug. Each third party logistics provider permittee shall comply with the requirements for wholesale distributors under ss. 499.0121 and 499.01212, with the exception of those wholesale distributions described in s. 499.01212(3)(a), and other rules that the department requires.

(t) *Health care clinic establishment permit*.--Effective January 1, 2009, a health care clinic establishment permit is required for the purchase of a prescription drug by a place of business at one general physical location that provides health care or veterinary services, which is owned and operated by a business entity that has been issued a federal employer tax identification number. For the purpose of this paragraph, the term "qualifying practitioner" means a licensed health care practitioner defined in s. 456.001, or a veterinarian licensed under chapter 474, who

is authorized under the appropriate practice act to prescribe and administer a prescription drug.

1. An establishment must provide, as part of the application required under s. 499.012, designation of a qualifying practitioner who will be responsible for complying with all legal and regulatory requirements related to the purchase, recordkeeping, storage, and handling of the prescription drugs. In addition, the designated qualifying practitioner shall be the practitioner whose name, establishment address, and license number is used on all distribution documents for prescription drugs purchased or returned by the health care clinic establishment. Upon initial appointment of a qualifying practitioner, the qualifying practitioner and the health care clinic establishment shall notify the department on a form furnished by the department within 10 days after such employment. In addition, the qualifying practitioner and health care clinic establishment shall notify the department within 10 days after any subsequent change.

2. The health care clinic establishment must employ a qualifying practitioner at each establishment.

3. In addition to the remedies and penalties provided in this part, a violation of this chapter by the health care clinic establishment or qualifying practitioner constitutes grounds for discipline of the qualifying practitioner by the appropriate regulatory board.

4. The purchase of prescription drugs by the health care clinic establishment is prohibited during any period of time when the establishment does not comply with this paragraph.

5. A health care clinic establishment permit is not a pharmacy permit or otherwise subject to chapter 465. A health care clinic establishment that meets the criteria of a modified Class II institutional pharmacy under s. 465.019 is not eligible to be permitted under this paragraph.

6. This paragraph does not apply to the purchase of a prescription drug by a licensed practitioner

under his or her license.

Florida Statutes Annotated

Title XXXIII. Regulation of Trade, Commerce, Investments, and Solicitations (Chapters 494-560)
Chapter 499. Drug, Cosmetic, and Household Products
Part I. Drugs; Devices; Cosmetics; Household Products
499.0121. Storage and handling of prescription drugs; recordkeeping

The department shall adopt rules to implement this section as necessary to protect the public health, safety, and welfare. Such rules shall include, but not be limited to, requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records.

(1) Establishments.--An establishment at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed must:

(a) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(b) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(c) Have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;

(d) Be maintained in a clean and orderly condition; and

(e) Be free from infestation by insects, rodents, birds, or vermin of any kind.

(2) Security.--

(a) An establishment that is used for wholesale drug distribution must be secure from unauthorized entry.

1. Access from outside the premises must be kept to a minimum and be well-controlled.

2. The outside perimeter of the premises must be well-lighted.

3. Entry into areas where prescription drugs are held must be limited to authorized personnel.

(b) An establishment that is used for wholesale drug distribution must be equipped with:

1. An alarm system to detect entry after hours; however, the department may exempt by rule establishments that only hold a permit as prescription drug wholesale distributor-brokers and establishments that only handle medical oxygen; and

2. A security system that will provide suitable protection against theft and diversion. When appropriate, the security system must provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(c) Any vehicle that contains prescription drugs must be secure from unauthorized access to the prescription drugs in the vehicle.

(3) Storage.--All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the official compendium.

(a) If no storage requirements are established for a prescription drug, the drug may be held at "controlled" room temperature, as defined in the official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(b) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, or logs must be used to document proper storage of prescription drugs.

(c) The recordkeeping requirements in subsection (6) must be followed for all stored prescription drugs.

(4) Examination of materials and records.--

(a) Upon receipt, each outside shipping container must be visually examined for identity and to prevent the acceptance of contaminated prescription drugs that are otherwise unfit for distribution. This examination must be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(b) Each outgoing shipment must be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have expired or been damaged in storage or held under improper conditions.

(c) The recordkeeping requirements in subsection (6) must be followed for all incoming and outgoing prescription drugs.

(d) Upon receipt, a wholesale distributor must 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. This includes authenticating each transaction listed on a pedigree paper, as defined in s. 499.003(36).

(5) Returned, damaged, or outdated prescription drugs.--

(a) 1. Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated must be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier. A quarantine section must be separate and apart from other sections where prescription drugs are stored so that prescription drugs in this section are not confused with usable prescription drugs.

2. Prescription drugs must be examined at least every 12 months, and drugs for which the expiration date has passed must be removed and quarantined.

(b) Any prescription drugs of which the immediate or sealed outer containers or sealed secondary containers have been opened or used must be identified as such and must be quarantined and physically separated from other prescription drugs until they are destroyed or returned to the supplier.

(c) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the drug must be destroyed or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale distributor must consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the conditions of the drug and its container, carton, or labeling, as a result of storage or shipping.

(d) The recordkeeping requirements in subsection (6) must be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs.

(6) Recordkeeping.--The department shall adopt rules that require keeping such records of prescription drugs as are necessary for the protection of the public health.

(a) Wholesale distributors must establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. These records must provide a complete audit trail from receipt to sale or other disposition, be readily retrievable for inspection, and 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.

(b) Inventories and records must be made available for inspection and photocopying by

authorized federal, state, or local officials for a period of 2 years following disposition of the drugs or 3 years after the creation of the records, whichever period is longer.

(c) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means must be readily available for authorized inspection during the retention period. Records that are kept at a central location outside of this state and that are not electronically retrievable must 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. Records that are maintained at a central location within this state must be maintained at an establishment that is permitted pursuant to this part and must be readily available.

(d) Each manufacturer or repackager of medical devices, over-the-counter drugs, or cosmetics must maintain records that include the name and principal address of the seller or transferor of the product, the address of the location from which the product was shipped, the date of the transaction, the name and quantity of the product involved, and the name and principal address of the person who purchased the product.

(e) When pedigree papers are required by this part, a wholesale distributor must maintain the pedigree papers separate and distinct from other records required under this part.

(7) Prescription drug purchase list.--Each wholesale distributor, except for a manufacturer, shall annually provide the department with a written list of all wholesale distributors and manufacturers from whom the wholesale distributor purchases prescription drugs. A wholesale distributor, except a manufacturer, shall notify the department not later than 10 days after any change to either list. Such portions of the information required pursuant to this subsection which are a trade secret, as defined in s. 812.081, shall be maintained by the department as trade secret information is required to be maintained under s. 499.051.

(8) Written policies and procedures.--Wholesale distributors must establish, maintain, and adhere

to written policies and procedures, which must be followed for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesale distributors must include in their written policies and procedures:

(a) A procedure whereby the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement, if the deviation is temporary and appropriate.

(b) A procedure to be followed for handling recalls and withdrawals of prescription drugs. Such procedure must be adequate to deal with recalls and withdrawals due to:

1. Any action initiated at the request of the Food and Drug Administration or any other federal, state, or local law enforcement or other government agency, including the department.

2. Any voluntary action by the manufacturer or repackager to remove defective or potentially defective drugs from the market; or

3. Any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design.

(c) A procedure to ensure that wholesale distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility if a strike, fire, flood, or other natural disaster, or a local, state, or national emergency, occurs.

(d) A procedure to ensure that any outdated prescription drugs are segregated from other drugs and returned to the manufacturer or repackager or destroyed. This procedure must provide for

written documentation of the disposition of outdated prescription drugs. This documentation must be maintained for 2 years after disposition of the outdated drugs.

(9) Responsible persons.--Wholesale distributors must establish and maintain lists of officers, directors, managers, designated representatives, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

(10) Compliance with federal, state, and local law.--A wholesale distributor must operate in compliance with applicable federal, state, and local laws and regulations.

(a) A wholesale distributor must allow the department and authorized federal, state, and local officials to enter and inspect its premises and delivery vehicles, and to audit its records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.

(b) A wholesale distributor that deals in controlled substances must register with the Drug Enforcement Administration and must comply with all applicable state, local, and federal laws. A wholesale distributor that distributes any substance controlled under chapter 893 must notify the department when registering with the Drug Enforcement Administration pursuant to that chapter and must provide the department with its DEA number.

(11) Salvaging and reprocessing.--A wholesale distributor is subject to any applicable federal, state, or local laws or regulations that relate to prescription drug product salvaging or reprocessing.

(12) Shipping and transportation.--The person responsible for shipment and transportation of a prescription drug in a wholesale distribution may use a common carrier; its own vehicle or employee acting within the scope of employment if authorized under s. 499.03 for the possession

of prescription drugs in this state; or, in the case of a prescription drug intended for domestic distribution, an independent contractor who must be the agent of the authorized seller or recipient responsible for shipping and transportation as set forth in a written contract between the parties. A person selling a prescription drug for export must obtain documentation, such as a validated airway bill, bill of lading, or other appropriate documentation that the prescription drug was exported. A person responsible for shipping or transporting prescription drugs is not required to maintain documentation from a common carrier that the designated recipient received the prescription drugs; however, the person must obtain such documentation from the common carrier and make it available to the department upon request of the department.

(13) Due diligence of suppliers.--Prior to purchasing any prescription drugs from another wholesale distributor, a prescription drug wholesale distributor, an out-of-state prescription drug wholesale distributor, or a prescription drug repackager must:

(a) Enter an agreement with the selling wholesale distributor by which the selling wholesale distributor will indemnify the purchasing wholesale distributor for any loss caused to the purchasing wholesale distributor related to the purchase of drugs from the selling wholesale distributor which are determined to be counterfeit or to have been distributed in violation of any federal or state law governing the distribution of drugs.

(b) Determine that the selling wholesale distributor has insurance coverage of not less than the greater of 1 percent of the amount of total dollar volume of the prescription drug sales reported to the department under s. 499.012(8)(g) or $500,000; however the coverage need not exceed $2 million.

(c) Obtain information from the selling wholesale distributor, including the length of time the selling wholesale distributor has been licensed in this state, a copy of the selling wholesale distributor's licenses or permits, and background information concerning the ownership of the selling wholesale distributor, including the experience of the wholesale distributor in the wholesale distribution of prescription drugs.

(d) Verify that the selling wholesale distributor's Florida permit is valid.

(e) Inspect the selling wholesale distributor's licensed 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:

1. Before purchasing any drug from the wholesale distributor, and at least once each subsequent year; or

2. Before purchasing any drug from the wholesale distributor, and each subsequent year obtain a complete copy of the most recent inspection report for the establishment which was prepared by the department or the regulatory authority responsible for wholesale distributors in the state in which the establishment is located.

Florida Statutes Annotated

Title XXXIII. Regulation of Trade, Commerce, Investments, and Solicitations (Chapters 494-560)
Chapter 499. Drug, Cosmetic, and Household Products
Part I. Drugs; Devices; Cosmetics; Household Products
499.01212. Pedigree paper

(1) Application.--Each person who is engaged in the wholesale distribution of a prescription drug must, prior to or simultaneous with each wholesale distribution, provide a pedigree paper to the person who receives the drug.

(2) Format.--A pedigree paper must contain the following information:

(a) For the wholesale distribution of a prescription drug within the normal distribution chain:

1. The following statement: "This wholesale distributor purchased the specific unit of the prescription drug directly from the manufacturer."

2. The manufacturer's national drug code identifier and the name and address of the wholesale distributor and the purchaser of the prescription drug.

3. The name of the prescription drug as it appears on the label.

4. The quantity, dosage form, and strength of the prescription drug.

The wholesale distributor must also maintain and make available to the department, upon request, the point of origin of the prescription drugs, including intracompany transfers, the date

of the shipment from the manufacturer to the wholesale distributor, the lot numbers of such drugs, and the invoice numbers from the manufacturer.

(b) For all other wholesale distributions of prescription drugs:

1. The quantity, dosage form, and strength of the prescription drugs.

2. The lot numbers of the prescription drugs.

3. The name and address of each owner of the prescription drug and his or her signature.

4. Shipping information, including the name and address of each person certifying delivery or receipt of the prescription drug.

5. An invoice number, a shipping document number, or another number uniquely identifying the transaction.

6. A certification that the recipient wholesale distributor has authenticated the pedigree papers.

7. The unique serialization of the prescription drug, if the manufacturer or repackager has uniquely serialized the individual prescription drug unit.

8. The name, address, telephone number, and, if available, e-mail contact information of each wholesale distributor involved in the chain of the prescription drug's custody.

When an affiliated group member obtains title to a prescription drug before distributing the prescription drug as the manufacturer under s. 499.003(31)(e), information regarding the distribution between those affiliated group members may be omitted from a pedigree paper required under this paragraph for subsequent distributions of that prescription drug.

(3) Exceptions.--A pedigree paper is not required for:

(a) The wholesale distribution of a prescription drug by the manufacturer or by a third party logistics provider performing a wholesale distribution of a prescription drug for a manufacturer.

(b) The wholesale distribution of a prescription drug by a freight forwarder within the authority of a freight forwarder permit.

(c) The wholesale distribution of a prescription drug by a limited prescription drug veterinary wholesale distributor to a veterinarian.

(d) The wholesale distribution of a compressed medical gas.

(e) The wholesale distribution of a veterinary prescription drug.

(f) A drop shipment, provided:

1. The wholesale distributor delivers to the recipient of the prescription drug, within 14 days after the shipment notification from the manufacturer, an invoice and the following sworn statement: "This wholesale distributor purchased the specific unit of the prescription drug listed on the invoice directly from the manufacturer, and the specific unit of prescription drug was shipped by the manufacturer directly to a person authorized by law to administer or dispense the

legend drug, as defined in s. 465.003, Florida Statutes, or a member of an affiliated group, with the exception of a repackager." The invoice must contain a unique cross-reference to the shipping document sent by the manufacturer to the recipient of the prescription drug.

2. The manufacturer of the prescription drug shipped directly to the recipient provides and the recipient of the prescription drug acquires, within 14 days after receipt of the prescription drug, a shipping document from the manufacturer that contains, at a minimum:

a. The name and address of the manufacturer, including the point of origin of the shipment, and the names and addresses of the wholesale distributor and the purchaser.

b. The name of the prescription drug as it appears on the label.

c. The quantity, dosage form, and strength of the prescription drug.

d. The date of the shipment from the manufacturer.

3. The wholesale distributor maintains and makes available to the department, upon request, the lot number of such drug if not contained in the shipping document acquired by the recipient.

4. The wholesale distributor that takes title to, but not possession of, the prescription drug is not a member of the affiliated group that receives the prescription drug directly from the manufacturer.

Failure of the manufacturer to provide, the recipient to acquire, or the wholesale distributor to deliver the documentation required under this paragraph shall constitute failure to acquire or deliver a pedigree paper under ss. 499.005(28) and 499.0051. Forgery by the manufacturer, the recipient, or the wholesale distributor of the documentation required to be acquired or delivered

under this paragraph shall constitute forgery of a pedigree paper under s. 499.0051.

(g) The wholesale distribution of a prescription drug by a warehouse within an affiliated group to a warehouse or retail pharmacy within its affiliated group, provided:

1. Any affiliated group member that purchases or receives a prescription drug from outside the affiliated group must receive a pedigree paper if the prescription drug is distributed in or into this state and a pedigree paper is required under this section and must authenticate the documentation as required in s. 499.0121(4), regardless of whether the affiliated group member is directly subject to regulation under this part; and

2. The affiliated group makes available, within 48 hours, to the department on request to one or more of its members all records related to the purchase or acquisition of prescription drugs by members of the affiliated group, regardless of the location where the records are stored, if the prescription drugs were distributed in or into this state.

(h) The repackaging of prescription drugs by a repackager solely for distribution to its affiliated group members for the exclusive distribution to and among retail pharmacies that are members of the affiliated group to which the repackager is a member.

1. The repackager must:

a. For all repackaged prescription drugs distributed in or into this state, state in writing under oath with each distribution of a repackaged prescription drug to an affiliated group member warehouse or repackager: "All repackaged prescription drugs are purchased by the affiliated group directly from the manufacturer or from a prescription drug wholesale distributor that purchased the prescription drugs directly from the manufacturer."

b. Purchase all prescription drugs it repackages:

(I) Directly from the manufacturer; or

(II) From a prescription drug wholesale distributor that purchased the prescription drugs directly from the manufacturer.

c. Maintain records in accordance with this section to document that it purchased the prescription drugs directly from the manufacturer or that its prescription drug wholesale supplier purchased the prescription drugs directly from the manufacturer.

2. All members of the affiliated group must provide, within 48 hours, to agents of the department on request to one or more of its members records of purchases by all members of the affiliated group of prescription drugs that have been repackaged, regardless of the location at which the records are stored or at which the repackager is located.

Florida Statutes Annotated

Title XXXIII. Regulation of Trade, Commerce, Investments, and Solicitations (Chapters 494-560)
Chapter 499. Drug, Cosmetic, and Household Products
Part I. Drugs; Devices; Cosmetics; Household Products
499.05. Rules

(1) The department shall adopt rules to implement and enforce this part with respect to:

(a) The definition of terms used in this part, and used in the rules adopted under this part, when the use of the term is not its usual and ordinary meaning.

(b) Labeling requirements for drugs, devices, and cosmetics.

(c) The establishment of fees authorized in this part.

(d) The identification of permits that require an initial application and onsite inspection or other prerequisites for permitting which demonstrate that the establishment and person are in compliance with the requirements of this part.

(e) The application processes and forms for product registration.

(f) Procedures for requesting and issuing certificates of free sale.

(g) Inspections and investigations conducted under s. 499.051, and the identification of information claimed to be a trade secret and exempt from the public records law as provided in s. 499.051(7).

(h) The establishment of a range of penalties, as provided in s. 499.066; requirements for notifying persons of the potential impact of a violation of this part; and a process for the uncontested settlement of alleged violations.

(i) Additional conditions that qualify as an emergency medical reason under s. 499.003(53)(b)2.

(j) Procedures and forms relating to the pedigree paper requirement of s. 499.01212.

(k) The protection of the public health, safety, and welfare regarding good manufacturing practices that manufacturers and repackagers must follow to ensure the safety of the products.

(*l*) Information required from each retail establishment pursuant to s. 499.012(3), including requirements for prescriptions or orders.

(m) The recordkeeping, storage, and handling with respect to each of the distributions of prescription drugs specified in s. 499.003(53)(a)-(d).

(n) Alternatives to compliance with s. 499.01212 for a prescription drug in the inventory of a permitted prescription drug wholesale distributor as of June 30, 2006, and the return of a prescription drug purchased prior to July 1, 2006. The department may specify time limits for such alternatives.

(2) With respect to products in interstate commerce, those rules must not be inconsistent with rules and regulations of federal agencies unless specifically otherwise directed by the Legislature.

(3) The department shall adopt rules regulating recordkeeping for and the storage, handling, and distribution of medical devices and over-the-counter drugs to protect the public from adulterated products.

Florida Statutes Annotated

Title XXXIII. Regulation of Trade, Commerce, Investments, and Solicitations (Chapters 494-560)
Chapter 499. Drug, Cosmetic, and Household Products
Part I. Drugs; Devices; Cosmetics; Household Products
499.051. Inspections and investigations

(1) The agents of the department and of the Department of Law Enforcement, after they present proper identification, may inspect, monitor, and investigate any establishment permitted pursuant to this part during business hours for the purpose of enforcing this part, chapters 465, 501, and 893, and the rules of the department that protect the public health, safety, and welfare.

(2) In addition to the authority set forth in subsection (1), the department and any duly designated officer or employee of the department may enter and inspect any other establishment for the purpose of determining compliance with this part and rules adopted under this part regarding any drug, device, or cosmetic product.

(3) Any application for a permit or product registration or for renewal of such permit or registration made pursuant to this part and rules adopted under this part constitutes permission for any entry or inspection of the premises in order to verify compliance with this part and rules; to discover, investigate, and determine the existence of compliance; or to elicit, receive, respond to, and resolve complaints and violations.

(4) Any application for a permit made pursuant to s. 499.012 and rules adopted under that section constitutes permission for agents of the department and the Department of Law Enforcement, after presenting proper identification, to inspect, review, and copy any financial document or record related to the manufacture, repackaging, or distribution of a drug as is necessary to verify compliance with this part and the rules adopted by the department to administer this part, in order to discover, investigate, and determine the existence of compliance, or to elicit, receive, respond to, and resolve complaints and violations.

(5) The authority to inspect under this section includes the authority to access, review, and copy any and all financial documents related to the activity of manufacturing, repackaging, or distributing prescription drugs.

(6) The authority to inspect under this section includes the authority to secure:

(a) Samples or specimens of any drug, device, or cosmetic; or

(b) Such other evidence as is needed for any action to enforce this part and the rules adopted under this part.

(7) The complaint and all information obtained pursuant to the investigation by the department are confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution until the investigation and the enforcement action are completed. However, trade secret information contained therein as defined by s. 812.081(1)(c) shall remain confidential and exempt from the provisions of s. 119.07(1) and s. 24(a), Art. I of the State Constitution, as long as the information is retained by the department. This subsection does not prohibit the department from using such information for regulatory or enforcement proceedings under this chapter or from providing such information to any law enforcement agency or any other regulatory agency. However, the receiving agency shall keep such records confidential and exempt as provided in this subsection. In addition, this subsection is not intended to prevent compliance with the provisions of s. 499.01212, and the pedigree papers required in that section shall not be deemed a trade secret.

Code of Georgia Annotated

Title 26. Food, Drugs, and Cosmetics
Chapter 4. Pharmacists and Pharmacies
Article 12. Prescription Medical Integrity Act
§ 26-4-201. Definitions

Effective upon appropriation of funds for purposes of Laws 2009, Act 245,§ 2.

As used in this article, the term:

(1) "Authenticate" means to affirmatively verify before any wholesale distribution of a prescription drug occurs that each transaction listed on the pedigree has occurred.
(2) "Authorized distributor of record" means a distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drugs.
(3) "Board" means the State Board of Pharmacy.
(4) "Broker" has the same meaning as a third party logistics provider.
(5) "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 that have the same common ownership or control.
(6) "Co-licensed pharmaceutical products" means pharmaceutical products:
(A) That have been approved by the federal Food and Drug Administration; and
(B) Concerning which two or more parties have the right to engage in a business activity or occupation concerning the pharmaceutical products.
(7) "Co-licensee" means a party to a co-licensed pharmaceutical product.
(8) "Distribute" means to deliver a drug or device other than by administering or dispensing.
(9) "Drop shipment arrangement" means the physical shipment of a prescription from a manufacturer, that manufacturer's co-licensee, that manufacturer's third-party logistics provider, or that manufacturer's authorized distributor of record directly to a chain pharmacy warehouse, pharmacy buying cooperative warehouse, pharmacy, or other persons authorized under law to dispense or administer prescription drugs but wherein the sale and title for the prescription drug passes between a wholesale drug distributor and the party that directly receives the prescription drug. In order to be considered part of the normal distribution channel and participate in a drop shipment as described in this paragraph, the wholesale drug distributor must be an authorized distributor of record.
(10) "Facility" means a facility of a wholesale distributor where prescription drugs are stored, handled, repackaged, or offered for sale.
(11) "Manufacturer" means a person licensed or approved by the federal Food and Drug Administration ("FDA") to engage in the manufacture of drugs or devices, consistent with the

FDA definition of "manufacturer" under the regulations and interpreted guidances implementing the Prescription Drug Marketing Act.
(12) "Manufacturer's exclusive distributor" means an entity that contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services for a manufacturer and takes title to that manufacturer's prescription drug. To be considered part of the normal distribution channel, a manufacturer's exclusive distribution must be an authorized distributor of record.
(13) "Normal distribution channel" means a chain of custody for a prescription drug, excluding all devices and veterinary prescription drugs, that goes directly or by drop shipment from a manufacturer of the prescription drug, or from that manufacturer to that manufacturer's co-licensed partner, or from that manufacturer to that manufacturer's third-party logistics provider, or from that manufacturer to that manufacturer's exclusive distributor, to:
(A) Either a pharmacy or to other designated persons authorized by law to dispense or administer such drug;
(B) An authorized distributor or record, and then to either a pharmacy, or to other designated persons authorized by law to dispense or administer such drug;
(C) An authorized distributor of record to one other authorized distributor of record to an office based health care practitioner authorized by law to dispense or administer such drug to a patient;
(D) An authorized distributor of record to a pharmacy warehouse or other entity that redistributes by intracompany sale to a pharmacy or other designated persons authorized to dispense or administer the drug;
(E) A pharmacy warehouse or other entity that redistributes by intracompany sale to a pharmacy or other designated persons authorized to dispense or administer the drug; or
(F) Another entity as prescribed by the board's regulations.
(14) "Ongoing relationship" means an association that exists when a wholesale drug distributor, including any member of its affiliated group, as defined in Section 1504 of the Internal Revenue Code, of which the wholesale drug distributor is a member:
(A) Is listed on the manufacturer's list of authorized distributors of record, which is updated by the manufacturer on no less than a monthly basis; or
(B) Has a written agreement currently in effect with the manufacturer evidencing such ongoing relationship.
(15) "Pedigree" means a document or electronic file containing information that records each distribution of any given prescription drug.
(16) "Pharmacy buying cooperative warehouse" means a permanent physical location that acts as a central warehouse for drugs and from which sales of drugs are made to a group of pharmacies that are member owners of the buying cooperative operating the warehouse. Pharmacy buying cooperative warehouses must be licensed as wholesale distributors.
(17) "Prescription drug" means any drug (including any biological product, except for blood and blood components intended for transfusion or biological products that are also medical devices) required by federal law (including federal 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 ("FFDCA").
(18) "Repackage" means repackaging or otherwise changing the container, wrapper, or labeling to further the distribution of a prescription drug; provided, however, that this shall not apply to pharmacists in the dispensing of prescription drugs to the patient.
(19) "Repackager" means a person who repackages.
(20) "Third-party logistics provider" means an entity that provides or coordinates warehousing, distribution, or other services on behalf of a manufacturer but does not take title to a drug or have general responsibility to direct the sale or other disposition of the drug. To be considered part of the normal distribution channel, a third party logistics provider must be an authorized distributor of record.
(21) "Wholesale distributor" means any person engaged in wholesale distribution of drugs, including but not limited to repackagers; own label distributors; private label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses and wholesale drug warehouses; independent wholesale drug traders; and retail and hospital pharmacies and chain pharmacy warehouses that conduct wholesale distributions. This term shall not include manufacturers.
(22) "Wholesale distribution" shall not include:
(A) Intracompany sales of prescription drugs, meaning any transaction or transfer between any division, subsidiary, parent, or affiliated or related company under common ownership or control of a corporate entity, except that nothing contained herein shall be construed to prohibit the board from requiring that other records of these transactions shall be kept in accordance with law and regulation not found in this article;
(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 including transfers of a prescription drug from retail pharmacy to retail pharmacy, except that nothing contained herein shall be construed to prohibit the board from requiring that other records of these transactions shall be kept in accordance with law and regulation not found in this article;
(C) The distribution of prescription drug samples by manufacturers' representatives;
(D) Prescription drug returns when conducted by a retail pharmacy or chain pharmacy warehouse, by a hospital, health care entity, or charitable institution in accordance with 21 C.F.R. Section 203.23, or by any designated persons authorized by law to dispense or administer the prescription drug except in cases where a pedigree is already required under the provisions of this article, in which case any return of that prescription drug to a wholesaler or manufacturer shall be subject to the provisions of Code Section 26-4-202;
(E) The sale of minimal quantities of prescription drugs by retail pharmacies to licensed practitioners for office use, except that nothing contained herein shall be construed to prohibit the board from requiring that other records of these transactions shall be kept in accordance with law and regulation not found in this article;

(F) Retail pharmacies' delivery of prescription drugs to a patient or patient's agent pursuant to the lawful order of a licensed practitioner;
(G) 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, and such common carrier does not store, warehouse, or take legal ownership of the prescription drug;
(H) The sale or transfer from a retail pharmacy, pharmacy buying cooperative warehouse, or chain pharmacy warehouse of expired, damaged, returned, or recalled prescription drugs to the original manufacturer, originating wholesale distributor, or to a third party returns processor, to the extent permitted by federal rule, regulation, or law; or
(I) 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.

Code of Georgia Annotated

Title 26. Food, Drugs, and Cosmetics
Chapter 4. Pharmacists and Pharmacies
Article 12. Prescription Medical Integrity Act
§ 26-4-202. Inventory and records of distribution of prescription drugs; date of implementation of electronic pedigrees; verification of pedigree; content of pedigree

Effective upon appropriation of funds for purposes of Laws 2009, Act 245,§ 2.

(a)(1) Each person who is engaged in wholesale distribution of prescription drugs shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of the prescription drugs. These records shall include pedigrees for all prescription drugs that leave or have ever left the normal distribution channel in accordance with rules and regulations adopted by the board.

(2) A retail pharmacy or chain pharmacy warehouse shall comply with the requirements of this Code section only if the retail pharmacy or chain pharmacy warehouse engages in wholesale distribution of prescription drugs.
(3) The board shall conduct a study to be completed no later than July 1, 2009, which shall include consultation with manufacturers, distributors, and pharmacies responsible for the sale and distribution of prescription drug products in this state. Based on the results of the study, the board shall establish a mandated implementation date for electronic pedigrees which shall be no sooner than December 31, 2011, and may be extended by the board in one year increments if it appears the technology is not universally available across the entire prescription pharmaceutical supply; provided, however, that no provision of this article shall be effective until such time as the General Assembly appropriates reasonable funds for administration of this subsection. Effective at a date established by the board, pedigrees may be implemented through an approved and readily available system based on electronic track and trace pedigree technology. This electronic tracking system will be deemed to be readily available for use on a wide scale across the entire pharmaceutical supply chain which includes manufacturers, wholesale distributors, and pharmacies. Consideration must be given to the large-scale implementation of this technology across the supply chain and the technology must be proven to have no negative impact on the safety and efficacy of the pharmaceutical product.

(b) Each person in possession of a pedigree for a prescription drug who is engaged in the wholesale distribution of a prescription drug, including repackagers but excluding the original manufacturer of the finished form of the prescription drug and any entity engaged in the activities listed in paragraph (9) of Code Section 26-4-201, and who attempts to further distribute that prescription drug shall affirmatively verify before any distribution of a prescription drug

occurs that each transaction listed on the pedigree has occurred.

(c) The pedigree shall include all necessary identifying information concerning each sale in the chain of distribution of the product from the manufacturer, to acquisition and sale by any wholesale distributor or repackager, and to final sale to a pharmacy or other person dispensing or administering the prescription drug. At a minimum, the pedigree shall include:

(1) The name, address, telephone number, and, if available, e-mail address of each owner of the prescription drug and each wholesale distributor of the prescription drug;
(2) The name and address of each location from which the prescription drug was shipped, if different from the owner's;
(3) Transaction dates;
(4) Certification that each recipient, excluding retail or hospital pharmacies, has authenticated the pedigree;
(5) The name of the prescription drug;
(6) Dosage form and strength of the prescription drug;
(7) Size of the container;
(8) Number of containers;
(9) Lot number of the prescription drug; and
(10) The name of the manufacturer of the finished dosage form.

(d) Each pedigree shall be:

(1) Maintained by the wholesale distributor at its licensed location, unless given written authorization from the board to do otherwise, for three years from the date of sale or transfer; and
(2) Available for inspection, copying, or use at the licensed location upon a verbal request by the board or its designee.

(e) The board shall adopt rules and regulations, including a standard form, relating to the requirements of this article no later than 90 days after the effective date of this article.

(f) Pharmacies licensed pursuant to this chapter shall not be required to possess or maintain any pedigree issued pursuant to this Code section.

Code of Georgia Annotated

Title 26. Food, Drugs, and Cosmetics
Chapter 4. Pharmacists and Pharmacies
Article 12. Prescription Medical Integrity Act
§ 26-4-203. Violation of article or falsified pedigree; hearing

Effective upon appropriation of funds for purposes of Laws 2009, Act 245,§ 2.

(a) If the board finds that there is a reasonable probability that:

(1) A wholesale distributor, other than a manufacturer, has:
(A) Violated a provision of this article; or
(B) Falsified a pedigree, provided a falsified pedigree, or sold, distributed, transferred, manufactured, repackaged, handled, or held a counterfeit prescription drug intended for human use;
(2) The prescription drug at issue in subparagraph (B) of paragraph (1) of this subsection could cause serious, adverse health consequences or death; and
(3) Other procedures would result in unreasonable delay,

the board shall issue an order requiring the appropriate person including the distributors or retailers of the prescription drug to immediately cease distribution of the prescription drug in or to this state.

(b) An order under subsection (a) of this Code section shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than ten calendar days after the date of the issuance of the order, on the actions required by the order. If, after such a hearing, the board determines that inadequate grounds exist to support the actions required by the order, the board shall vacate the order.

Code of Georgia Annotated

Title 26. Food, Drugs, and Cosmetics
Chapter 4. Pharmacists and Pharmacies
Article 12. Prescription Medical Integrity Act
§ 26-4-204. Unlawful acts

Effective upon appropriation of funds for purposes of Laws 2009, Act 245,§ 2.

It shall be unlawful for a person to perform or cause the performance of or aid and abet any of the following acts in this state:

(1) Selling, distributing, or transferring a prescription drug to a person that is not authorized to receive the prescription drug under the law of the jurisdiction in which the person receives the prescription drug;
(2) Failing to maintain or provide pedigrees as required by the board;
(3) Failing to obtain, transfer, or authenticate a pedigree as required by the board;
(4) Providing the board or any of its representatives or any federal official with false or fraudulent records, including, but not limited to falsified pedigrees, or making false or fraudulent statements regarding any matter within the provisions of this article;
(5) Obtaining or attempting to obtain a prescription drug by fraud, deceit, or misrepresentation or engaging in misrepresentation or fraud in the distribution of a prescription drug; and
(6) Except for the wholesale distribution by manufacturers of a prescription drug that has been delivered into commerce pursuant to an application approved under federal law by the Food and Drug Administration, the manufacturing, repackaging, selling, transferring, delivering, holding, or offering for sale of any prescription drug that is adulterated, misbranded, counterfeit, suspected of being counterfeit, or has otherwise been rendered unfit for distribution.

Code of Georgia Annotated

Title 26. Food, Drugs, and Cosmetics
Chapter 4. Pharmacists and Pharmacies
Article 12. Prescription Medical Integrity Act
§ 26-4-205. Sentence and punishment

Effective upon appropriation of funds for purposes of Laws 2009, Act 245,§ 2.

(a) Notwithstanding Code Section 26-4-115, any person who engages without knowledge in the wholesale distribution of prescription drugs, including providing a falsified pedigree or other records, in violation of this article may be fined not more than $10,000.00.

(b) If a person engages in wholesale distribution of prescription drugs in violation of this article, including providing a falsified pedigree or other records, and acts in a grossly negligent manner in violation of this article, the person may be punished by imprisonment for not more than 15 years, fined not more than $50,000.00, or both.

(c) Notwithstanding Code Section 26-4-115, any person who knowingly engages in wholesale distribution of prescription drugs in violation of this article, including providing a falsified pedigree or other records, shall be guilty of a felony and, upon conviction thereof, shall be punished by imprisonment for not more than 25 years, by fine not to exceed $500,000.00, or both.

Idaho Code Annotated

Title 54. Professions, Vocations, and Businesses
Chapter 17. Pharmacists
§ 54-1752. Definitions

As used in sections 54-1751 through 54-1759, Idaho Code:

(1) "Authentication" means to affirmatively verify before any wholesale distribution of a prescription drug occurs that each transaction listed on the pedigree has occurred.

(2) "Authorized distributor of record" means a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drug. An ongoing relationship is deemed to exist between such wholesale distributor and a manufacturer when the wholesale distributor, including any affiliated group of the wholesale distributor, as defined in section 1504 of the Internal Revenue Code, complies with the following:

(a) The wholesale distributor has a written agreement currently in effect with the manufacturer evidencing such ongoing relationship; and
(b) The wholesale distributor is listed on the manufacturer's current list of authorized distributors of record, which is updated by the manufacturer on no less than a monthly basis.

(3) "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 that have the same common ownership and control.

(4) "Colicensed partner or product" means an instance where two (2) or more parties have the right to engage in the manufacturing and/or marketing of a prescription drug, consistent with the federal food and drug administration's implementation of the prescription drug marketing act.

(5) "Drop shipment" means the sale of a prescription drug to a wholesale distributor or chain pharmacy warehouse by the manufacturer of the prescription drug, or that manufacturer's colicensed product partner, that manufacturer's third party logistics provider or that manufacturer's exclusive distributor, whereby the wholesale distributor or chain pharmacy warehouse takes title but not physical possession of such prescription drug and the wholesale distributor invoices the pharmacy or chain pharmacy warehouse, or other person authorized by

law to dispense or administer such drug to a patient, and the pharmacy or chain pharmacy warehouse or other authorized person receives delivery of the prescription drug directly from the manufacturer, or that manufacturer's third party logistics provider, or that manufacturer's exclusive distributor.

(6) "Facility" means a facility of a wholesale distributor where prescription drugs are stored, handled, repackaged or offered for sale.

(7) "Manufacturer" means a person licensed or approved by the federal food and drug administration to engage in the manufacture of drugs or devices, consistent with the federal food and drug administration definition of "manufacturer" under its regulations and guidance implementing the prescription drug marketing act.

(8) "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 that 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 wholesale distributor under section 54-1753, Idaho Code, and to be considered part of the normal distribution channel, must also be an authorized distributor of record.

(9) "Normal distribution channel" means a chain of custody for a prescription drug that goes from a manufacturer of the prescription drug, from that manufacturer to that manufacturer's colicensed partner, from that manufacturer to that manufacturer's third party logistics provider, from that manufacturer to that manufacturer's exclusive distributor, or from that manufacturer directly or through its colicensed partner, third party logistics provider or manufacturer's exclusive distributor to a repackager who is an authorized distributor of record for the manufacturer, whose facility is registered with the United States food and drug administration and who engages in the practice of repackaging the original dosage form of a prescription drug in accordance with applicable regulations and guidelines of the United States food and drug administration, either directly or by drop shipment, to:

(a) A pharmacy to a patient;
(b) Other designated persons authorized by law to dispense or administer such drug to a patient;
(c) A wholesale distributor to a pharmacy to a patient or other designated persons authorized by law to dispense or administer such drug to a patient;

(d) A wholesale distributor 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
(e) A chain pharmacy warehouse to the 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.

(10) "Pedigree" means a document or electronic file containing information that records each wholesale distribution of any given prescription drug.

(11) "Prescription drug" means any drug, including any biological product, except for blood and blood components intended for transfusion or biological products that are also medical devices, required by federal law or federal 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.

(12) "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.

(13) "Repackager" means a person who repackages.

(14) "Third party logistics provider" means anyone who contracts with a prescription drug manufacturer to provide or coordinate warehousing, distribution or other services on behalf of a manufacturer, but does not take title to the prescription drug or have general responsibility to direct the prescription drug's sale or disposition. Such third party logistics provider must be licensed as a wholesale distributor under section 54-1753, Idaho Code, and to be considered part of the normal distribution channel, must also be an authorized distributor of record.

(15) "Wholesale distributor" means anyone engaged in the wholesale distribution of prescription drugs including, but not limited to:

(a) Manufacturers;
(b) Repackagers;
(c) Own-label distributors;
(d) Private-label distributors;

(e) Jobbers;
(f) Brokers;
(g) Warehouses, including manufacturers' and distributors' warehouses;
(h) Manufacturer's exclusive distributors;
(i) Authorized distributors of record;
(j) Drug wholesalers or distributors;
(k) Independent wholesale drug traders;
(l) Specialty wholesale distributors;
(m) Third party logistics providers;
(n) Retail pharmacies that conduct wholesale distribution; and
(o) Chain pharmacy warehouses that conduct wholesale distribution.

To be considered part of the normal distribution channel, such wholesale distributor, except for a chain pharmacy warehouse not engaged in wholesale distribution, must also be an authorized distributor of record.

(16) "Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

(a) Intracompany sales of prescription drugs, meaning any transaction or transfer between any division, subsidiary, parent or affiliated or related company under common ownership and control of a corporate entity, or any transaction or transfer between colicensees of a colicensed product.
(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.
(c) The distribution of prescription drug samples by manufacturers' representatives.
(d) Drug returns, when conducted by a hospital, health care entity or charitable institution in accordance with 21 CFR 203.23.
(e) Drug donations, when conducted in accordance with sections 54-1760 through 54-1765, Idaho Code.
(f) The sale of minimal quantities of prescription drugs by retail pharmacies to licensed practitioners for office use.
(g) The sale, purchase or trade of a drug, an offer to sell, purchase or trade a drug, or the dispensing of a drug pursuant to a prescription.
(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 sale, purchase, distribution, trade or transfer of a prescription drug from one (1) authorized distributor of record to one (1) additional authorized distributor of record when the manufacturer has stated in writing to the receiving authorized distributor of record that the

manufacturer is unable to supply such prescription drug and the supplying authorized distributor of record states in writing that the prescription drug being supplied had, until that time, been exclusively in the normal distribution channel.
(j) 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, and such common carrier does not store, warehouse or take legal ownership of the prescription drug.
(k) 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 third party returns processor, including a reverse distributor.

Idaho Code Annotated

Title 54. Professions, Vocations, and Businesses
Chapter 17. Pharmacists
§ 54-1754. Restrictions on transactions

(1) A wholesale distributor shall receive prescription drug returns or exchanges from a pharmacy or chain pharmacy warehouse pursuant to the terms and conditions of the agreement between the wholesale distributor and the pharmacy or chain pharmacy warehouse. Returns of expired, damaged, recalled or otherwise nonsaleable pharmaceutical product shall be distributed by the receiving wholesale distributor only to either the original manufacturer or third party returns processor, including a reverse distributor. The returns or exchanges of prescription drugs, saleable or otherwise, including any redistribution by a receiving wholesaler, shall not be subject to the pedigree requirement of section 54-1755, Idaho Code, so long as they are exempt from pedigree under the federal food and drug administration's currently applicable prescription drug marketing act guidance. Wholesale distributors and pharmacies shall be held accountable for administering their returns process and ensuring that the aspects of this operation are secure and do not permit the entry of adulterated and counterfeit product.

(2) A manufacturer or wholesale distributor shall furnish prescription drugs only to a person licensed by the board or other appropriate state licensing authorities. Before furnishing prescription drugs to a person not known to the manufacturer or wholesale distributor, the manufacturer or wholesale distributor shall affirmatively verify that the person is legally authorized to receive the prescription drugs by contacting the appropriate state licensing authorities.

(3) Prescription drugs furnished by a manufacturer or wholesale distributor shall be delivered only to the premises listed on the license; provided that the manufacturer or wholesale distributor may furnish prescription drugs to an authorized person or agent of that person at the premises of the manufacturer or wholesale distributor if:

(a) The identity and authorization of the recipient is properly established; and
(b) This method of receipt is employed only to meet the immediate needs of a particular patient of the authorized person.

(4) Prescription drugs may be furnished to a hospital pharmacy receiving area provided that a pharmacist or authorized receiving personnel signs, at the time of delivery, a receipt showing the

type and quantity of the prescription drug so received. Any discrepancy between receipt and the type and quantity of the prescription drug actually received shall be reported to the delivering manufacturer or wholesale distributor by the next business day after the delivery to the pharmacy receiving area.

(5) A manufacturer or wholesale distributor shall not accept payment for, or allow the use of, a person's credit to establish an account for the purchase of prescription drugs from any person other than the owner(s) of record, the chief executive officer or the chief financial officer listed on the license of a person legally authorized to receive prescription drugs. Any account established for the purchase of prescription drugs must bear the name of the licensee.

Idaho Code Annotated

Title 54. Professions, Vocations, and Businesses
Chapter 17. Pharmacists
§ 54-1755. Pedigree

(1) In General. Each person who is engaged in wholesale distribution of prescription drugs, including repackagers, but excluding the original manufacturer of the finished form of the prescription drug, that leaves, or has ever left, the normal distribution channel shall, before each wholesale distribution of such drug, provide a pedigree to the person who receives such drug.

(a) A retail pharmacy or chain pharmacy warehouse shall comply with the requirements of this section only if the pharmacy or chain pharmacy warehouse engages in wholesale distribution of prescription drugs.
(b) The board shall determine by July 1, 2009, a targeted implementation date for electronic track and trace pedigree technology. Such a determination shall be based on consultation with manufacturers, distributors and pharmacies responsible for the sale and distribution of prescription drug products in this state. After consultation with interested stakeholders and prior to implementation of the electronic pedigree, the board shall deem that the technology is universally available across the entire prescription pharmaceutical supply chain. The implementation date for the mandated electronic track and trace pedigree technology will be no sooner than July 1, 2010, and may be extended by the board in one (1) year increments if it appears the technology is not universally available across the entire prescription pharmaceutical supply chain.

(2) Authentication. Each person who is engaged in the wholesale distribution of a prescription drug, including repackagers, but excluding the original manufacturer of the finished form of the prescription drug, who is provided a pedigree for a prescription drug and attempts to further distribute that prescription drug, shall affirmatively verify before any wholesale distribution of a prescription drug occurs that each transaction listed on the pedigree has occurred.

(3) Contents. The pedigree shall:

(a) Include all necessary identifying information concerning each sale in the chain of distribution of the product from the manufacturer, or the manufacturer's third party logistics provider, colicensed product partner, manufacturer's exclusive distributor, or a repackager who is an authorized distributor of record for the manufacturer, whose facility is registered with the United States food and drug administration and who engages in the practice of repackaging the original dosage form of a prescription drug in accordance with applicable regulations and guidelines of

the United States food and drug administration, through acquisition and sale by any wholesale distributor or repackager, until final sale to a pharmacy or other person dispensing or administering the drug. At minimum, the necessary pedigree information shall include:
(i) Name, address, telephone number and, if available, the e-mail address, of each owner of the prescription drug, and each wholesale distributor of the prescription drug;
(ii) Name and address of each location from which the product was shipped, if different from the owner's;
(iii) Transaction dates; and
(iv) Certification that each recipient has authenticated the pedigree.
(b) At minimum, the pedigree shall also include the:
(i) Name of the prescription drug;
(ii) Dosage form and strength of the prescription drug;
(iii) Size of the container;
(iv) Number of containers;
(v) Lot number and national drug code number of the prescription drug; and
(vi) Name of the manufacturer of the finished dosage form.

(4) Maintenance Provisions. Each pedigree or electronic file shall be:

(a) Notwithstanding the provisions in section 54-1735, Idaho Code, maintained by the purchaser and the wholesale distributor for not less than three (3) years from the date of sale or transfer; and
(b) Available for inspection or use within five (5) business days upon a request of an authorized officer of the law.

(5) Implementation. The board shall adopt rules and a form relating to the requirements of this section no later than ninety (90) days after the effective date of this act.

Idaho Code Annotated

Title 54. Professions, Vocations, and Businesses
Chapter 17. Pharmacists
§ 54-1756. Enforcement--Order to cease distribution of a drug

(1) If the board finds that there is a reasonable probability that:

(a) A wholesale distributor, other than a manufacturer, has:
(i) Violated a provision in this act; or
(ii) Falsified a pedigree, or sold, distributed, transferred, manufactured, repackaged, handled or held a counterfeit prescription drug intended for human use; and
(b) The prescription drug at issue as a result of a violation in paragraph (a) of this subsection could cause serious, adverse health consequences or death; and
(c) Other procedures would result in unreasonable delay; the board shall issue an order requiring the appropriate person, including the distributors or retailers of the drug, to immediately cease distribution of the drug within the state.

(2) An order under subsection (1) of this section shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than ten (10) days after the date of the issuance of the order, on the actions required by the order. If, after providing an opportunity for such a hearing, the board determines that inadequate grounds exist to support the actions required by the order, the board shall vacate the order.

Idaho Code Annotated

Title 54. Professions, Vocations, and Businesses
Chapter 17. Pharmacists
§ 54-1758. Prohibited acts

(1) It shall be unlawful for a person to knowingly perform, or cause the performance of, or aid and abet any of the following acts in this state:

(a) Failure to obtain a license when a license is required by this act;
(b) Operate as a wholesale distributor without a valid license when a license is required by this act;
(c) Purchase from or otherwise receive, return or exchange a prescription drug from a pharmacy or chain pharmacy warehouse, other than in compliance with section 54-1754(1), Idaho Code;
(d) When a state license is required pursuant to section 54-1754(2), Idaho Code, sell, distribute, transfer or otherwise furnish a prescription drug to a person who is not authorized under the law of the jurisdiction in which the person received the prescription drug to receive the prescription drug;
(e) Failure to deliver prescription drugs to specified premises, as required by section 54-1754(3), Idaho Code;
(f) Acceptance of payment or credit for the purchase of prescription drugs, other than in compliance with section 54-1754(5), Idaho Code;
(g) Failure to maintain or provide pedigrees as required by this act;
(h) Failure to obtain, pass or authenticate a pedigree, as required by this act;
(i) Provide the board or any of its representatives or any federal official with false or fraudulent records or make false or fraudulent statements regarding any matter within the provisions of this act;
(j) Obtain, or attempt to obtain, a prescription drug by fraud, deceit or misrepresentation or engage in misrepresentation or fraud in the distribution of a prescription drug;
(k) Manufacture, repackage, sell, transfer, deliver, hold or offer for sale any prescription drug that is adulterated, misbranded, counterfeit, suspected of being counterfeit or otherwise has been rendered unfit for distribution;
(l) Adulterate, misbrand or counterfeit any prescription drug;
(m) Receive any prescription drug that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit or suspected of being counterfeit;
(n) Deliver or proffer delivery of, for pay or otherwise, any prescription drug that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit or suspected of being counterfeit;
(o) Alter, mutilate, destroy, obliterate or remove the whole or any part of the labeling of a prescription drug or commit any other act with respect to a prescription drug that results in the prescription drug being misbranded; or

(p) Sell, deliver, transfer or offer to sell to a person not authorized under law to receive the return or exchange of a prescription drug, a prescription drug that has expired, been damaged or recalled by either the original manufacturer, a third party returns processor or a reverse distributor.

(2) The acts prohibited in subsection (1) of this section do not include a prescription drug manufacturer, or agent of a prescription drug manufacturer, who obtains or attempts to obtain a prescription drug for the sole purpose of testing the prescription drug for authenticity.

West's Smith-Hurd Illinois Compiled Statutes Annotated

Chapter 225. Professions and Occupations
Health
Act 120. Wholesale Drug Distribution Licensing Act
120/15. Definitions

§ 15. Definitions. As used in this Act:

"Authentication" means the affirmative verification, before any wholesale distribution of a prescription drug occurs, that each transaction listed on the pedigree has occurred.

"Authorized distributor of record" means a wholesale distributor 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 wholesale distributor and a manufacturer when the wholesale distributor, including any affiliated group of the wholesale distributor, as defined in Section 1504 of the Internal Revenue Code, complies with the following:

(1) The wholesale distributor has a written agreement currently in effect with the manufacturer evidencing the ongoing relationship; and
(2) The wholesale distributor is listed on the manufacturer's current list of authorized distributors of record, which is updated by the manufacturer on no less than a monthly basis.

"Blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

"Blood component" means that part of blood separated by physical or mechanical means.

"Board" means the State Board of Pharmacy of the Department of Professional Regulation.

"Chain pharmacy warehouse" means a physical location for prescription drugs that acts as a central warehouse and performs intracompany sales or transfers of the drugs to a group of chain or mail order pharmacies that have the same common ownership and control. Notwithstanding any other provision of this Act, a chain pharmacy warehouse shall be considered part of the normal distribution channel.

"Co-licensed partner or product" means an instance where one or more parties have the right to engage in the manufacturing or marketing of a prescription drug, consistent with the FDA's implementation of the Prescription Drug Marketing Act.

"Department" means the Department of Financial and Professional Regulation.

"Drop shipment" means the sale of a prescription drug to a wholesale distributor by the manufacturer of the prescription drug or that manufacturer's co-licensed product partner, that manufacturer's third party logistics provider, or that manufacturer's exclusive distributor or by an authorized distributor of record that purchased the product directly from the manufacturer or one of these entities whereby the wholesale distributor or chain pharmacy warehouse takes title but not physical possession of such prescription drug and the wholesale distributor invoices the pharmacy, chain pharmacy warehouse, or other person authorized by law to dispense or administer such drug to a patient and the pharmacy, chain pharmacy warehouse, or other authorized person receives delivery of the prescription drug directly from the manufacturer, that manufacturer's third party logistics provider, or that manufacturer's exclusive distributor or from an authorized distributor of record that purchased the product directly from the manufacturer or one of these entities.

"Drug sample" means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

"Facility" means a facility of a wholesale distributor where prescription drugs are stored, handled, repackaged, or offered for sale.

"FDA" means the United States Food and Drug Administration.

"Manufacturer" means a person licensed or approved by the FDA to engage in the manufacture of drugs or devices, consistent with the definition of "manufacturer" set forth in the FDA's regulations and guidances implementing the Prescription Drug Marketing Act.

"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 that manufacturer's prescription drug, but who does not have general responsibility to direct the sale or disposition of the manufacturer's prescription drug. A manufacturer's exclusive distributor must be licensed as a wholesale distributor under this Act and, in order to be considered part of the normal distribution channel, must also be an authorized distributor of record.

"Normal distribution channel" means a chain of custody for a prescription drug that goes, directly or by drop shipment, from (i) a manufacturer of the prescription drug, (ii) that manufacturer to that manufacturer's co-licensed partner, (iii) that manufacturer to that manufacturer's third party logistics provider, or (iv) that manufacturer to that manufacturer's exclusive distributor to:

(1) a pharmacy or to other designated persons authorized by law to dispense or administer the drug to a patient;
(2) a wholesale distributor to a pharmacy or other designated persons authorized by law to dispense or administer the drug to a patient;
(3) a wholesale distributor 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 the drug to a patient;
(4) a chain pharmacy warehouse to the chain pharmacy warehouse's intracompany pharmacy or other designated persons authorized by law to dispense or administer the drug to the patient;
(5) an authorized distributor of record to one other authorized distributor of record to an office-based health care practitioner authorized by law to dispense or administer the drug to the patient; or
(6) an authorized distributor to a pharmacy or other persons licensed to dispense or administer the drug.

"Pedigree" means a document or electronic file containing information that records each wholesale distribution of any given prescription drug from the point of origin to the final wholesale distribution point of any given prescription drug.

"Person" means and includes a natural person, partnership, association or corporation.

"Pharmacy distributor" means any pharmacy licensed in this State or hospital pharmacy that is engaged in the delivery or distribution of prescription drugs either to any other pharmacy licensed in this State or to any other person or entity including, but not limited to, a wholesale

drug distributor engaged in the delivery or distribution of prescription drugs who is involved in the actual, constructive, or attempted transfer of a drug in this State to other than the ultimate consumer except as otherwise provided for by law.

"Prescription drug" means any human drug, including any biological product (except for blood and blood components 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 of the Federal Food, Drug and Cosmetic Act. [FN1]

"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 the product to a patient.

"Secretary" means the Secretary of Financial and Professional Regulation.

"Third party logistics provider" means anyone who contracts with a prescription drug manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer, but does not take title to the 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 Act and, in order to be considered part of the normal distribution channel, must also be an authorized distributor of record.

"Wholesale distribution" means the distribution of prescription drugs to persons other than a consumer or patient, but does not include any of the following:

(1) Intracompany sales of prescription drugs, meaning (i) any transaction or transfer between any division, subsidiary, parent, or affiliated or related company under the common ownership and control of a corporate entity or (ii) any transaction or transfer between co-licensees of a co-licensed product.
(2) 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.
(3) The distribution of prescription drug samples by manufacturers' representatives.
(4) Drug returns, when conducted by a hospital, health care entity, or charitable institution in accordance with federal regulation.

(5) The sale of minimal quantities of prescription drugs by retail pharmacies to licensed practitioners for office use.
(6) The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription.
(7) 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.
(8) The sale, purchase, distribution, trade, or transfer of a prescription drug from one authorized distributor of record to one additional authorized distributor of record when the manufacturer has stated in writing to the receiving authorized distributor of record that the manufacturer is unable to supply the prescription drug and the supplying authorized distributor of record states in writing that the prescription drug being supplied had until that time been exclusively in the normal distribution channel.
(9) The delivery of or the offer to deliver a prescription drug by a common carrier solely in the common carrier's usual course of business of transporting prescription drugs when the common carrier does not store, warehouse, or take legal ownership of the prescription drug.
(10) The sale or transfer from a retail pharmacy, mail order pharmacy, or chain pharmacy warehouse of expired, damaged, returned, or recalled prescription drugs to the original manufacturer, the originating wholesale distributor, or a third party returns processor.

"Wholesale drug distributor" means anyone engaged in the wholesale distribution of prescription drugs, including without limitation manufacturers; repackers; own label distributors; jobbers; private label distributors; brokers; warehouses, including manufacturers' and distributors' warehouses; manufacturer's exclusive distributors; and authorized distributors of record; drug wholesalers or distributors; independent wholesale drug traders; specialty wholesale distributors; third party logistics providers; and retail pharmacies that conduct wholesale distribution; and chain pharmacy warehouses that conduct wholesale distribution. In order to be considered part of the normal distribution channel, a wholesale distributor must also be an authorized distributor of record.

Smith-Hurd Illinois Compiled Statutes Annotated

Chapter 225. Professions and Occupations
Health
Act 120. Wholesale Drug Distribution Licensing Act
120/56. Restrictions on transactions

§ 56. Restrictions on transactions.

(a) A licensee shall receive prescription drug returns or exchanges from a pharmacy or other persons authorized to administer or dispense drugs 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. Returns of expired, damaged, recalled, or otherwise non-saleable pharmaceutical products shall be distributed by the receiving wholesale distributor only to either the original manufacturer or a third party returns processor. Returns or exchanges of prescription drugs, saleable or otherwise, including any redistribution by a receiving wholesaler, shall not be subject to the pedigree requirements of Section 57 of this Act, so long as they are exempt from the pedigree requirement of the FDA's currently applicable Prescription Drug Marketing Act guidance. Both licensees under this Act and pharmacies or other persons authorized to administer or dispense drugs shall be accountable for administering their returns process and ensuring that the aspects of this operation are secure and do not permit the entry of adulterated and counterfeit product.

(b) A manufacturer or wholesale distributor licensed under this Act may furnish prescription drugs only to a person licensed by the appropriate state licensing authorities. Before furnishing prescription drugs to a person not known to the manufacturer or wholesale distributor, the manufacturer or wholesale distributor must affirmatively verify that the person is legally authorized to receive the prescription drugs by contacting the appropriate state licensing authorities.

(c) Prescription drugs furnished by a manufacturer or wholesale distributor licensed under this Act may be delivered only to the premises listed on the license, provided that the manufacturer or wholesale distributor may furnish prescription drugs to an authorized person or agent of that person at the premises of the manufacturer or wholesale distributor if:

(1) the identity and authorization of the recipient is properly established; and

(2) this method of receipt is employed only to meet the immediate needs of a particular patient of the authorized person.

(d) Prescription drugs may be furnished to a hospital pharmacy receiving area, provided that a pharmacist or authorized receiving personnel 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 wholesale distributor by the next business day after the delivery to the pharmacy receiving area.

(e) A manufacturer or wholesale distributor licensed under this Act may not accept payment for, or allow the use of, a person 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 the prescription drugs. Any account established for the purchase of prescription drugs must bear the name of the licensee. This subsection (e) shall not be construed to prohibit a pharmacy or chain pharmacy warehouse from receiving prescription drugs if payment for the prescription drugs is processed through the pharmacy's or chain pharmacy warehouse's contractual drug manufacturer or wholesale distributor.

Smith-Hurd Illinois Compiled Statutes Annotated

Chapter 225. Professions and Occupations
Health
Act 120. Wholesale Drug Distribution Licensing Act
120/57. Pedigree

§ 57. Pedigree.

(a) Each person who is engaged in the wholesale distribution of prescription drugs, including repackagers, but excluding the original manufacturer of the finished form of the prescription drug, that leave or have ever left the normal distribution channel shall, before each wholesale distribution of the drug, provide a pedigree to the person who receives the drug. A retail pharmacy, mail order pharmacy, or chain pharmacy warehouse must comply with the requirements of this Section only if the pharmacy or chain pharmacy warehouse engages in the wholesale distribution of prescription drugs. On or before July 1, 2009, the Department shall determine a targeted implementation date for electronic track and trace pedigree technology. This targeted implementation date shall not be sooner than July 1, 2010. Beginning on the date established by the Department, pedigrees may be implemented through an approved and readily available system that electronically tracks and traces the wholesale distribution of each prescription drug starting with the sale by the manufacturer through acquisition and sale by any wholesale distributor and until final sale to a pharmacy or other authorized person administering or dispensing the prescription drug. This electronic tracking system shall be deemed to be readily available only upon there being available a standardized system originating with the manufacturers and capable of being used on a wide scale across the entire pharmaceutical chain, including manufacturers, wholesale distributors, and pharmacies. Consideration must also be given to the large-scale implementation of this technology across the supply chain and the technology must be proven to have no negative impact on the safety and efficacy of the pharmaceutical product.

(b) Each person who is engaged in the wholesale distribution of a prescription drug who is provided a pedigree for a prescription drug and attempts to further distribute that prescription drug, including repackagers, but excluding the original manufacturer of the finished form of the prescription drug, must affirmatively verify before any distribution of a prescription drug occurs that each transaction listed on the pedigree has occurred.

(c) The pedigree must include all necessary identifying information concerning each sale in the

chain of distribution of the product from the manufacturer or the manufacturer's third party logistics provider, co-licensed product partner, or exclusive distributor through acquisition and sale by any wholesale distributor or repackager, until final sale to a pharmacy or other person dispensing or administering the drug. This necessary chain of distribution information shall include, without limitation all of the following:

(1) The name, address, telephone number and, if available, the e-mail address of each owner of the prescription drug and each wholesale distributor of the prescription drug.
(2) The name and address of each location from which the product was shipped, if different from the owner's.
(3) Transaction dates.
(4) Certification that each recipient has authenticated the pedigree.

(d) The pedigree must also include without limitation all of the following information concerning the prescription drug:

(1) The name and national drug code number of the prescription drug.
(2) The dosage form and strength of the prescription drug.
(3) The size of the container.
(4) The number of containers.
(5) The lot number of the prescription drug.
(6) The name of the manufacturer of the finished dosage form.

(e) Each pedigree or electronic file shall be maintained by the purchaser and the wholesale distributor for at least 3 years from the date of sale or transfer and made available for inspection or use within 5 business days upon a request of the Department.

Smith-Hurd Illinois Compiled Statutes Annotated

Chapter 225. Professions and Occupations
Health
Act 120. Wholesale Drug Distribution Licensing Act
120/58. Prohibited acts

§ 58. Prohibited acts. It is unlawful for a person to perform or cause the performance of or aid and abet any of the following acts:

(1) Failure to obtain a license in accordance with this Act or operating without a valid license when a license is required by this Act.
(2) If the requirements of subsection (a) of Section 56 of this Act are applicable and are not met, the purchasing or otherwise receiving of a prescription drug from a pharmacy.
(3) If licensure is required pursuant to subsection (b) of Section 56 of this Act, the sale, distribution, or transfer of a prescription drug to a person that is not authorized under the law of the jurisdiction in which the person receives the prescription drug to receive the prescription drug.
(4) Failure to deliver prescription drugs to specified premises, as required by subsection (c) of Section 56 of this Act.
(5) Accepting payment or credit for the sale of prescription drugs in violation of subsection (e) of Section 56 of this Act.
(6) Failure to maintain or provide pedigrees as required by this Act.
(7) Failure to obtain, pass, or authenticate a pedigree as required by this Act.
(8) Providing the Department or any federal official with false or fraudulent records or making false or fraudulent statements regarding any matter within the provisions of this Act.
(9) Obtaining or attempting to obtain a prescription drug by fraud, deceit, or misrepresentation or engaging in misrepresentation or fraud in the distribution of a prescription drug.
(10) The manufacture, repacking, sale, transfer, delivery, holding, or offering for sale of any prescription drug that is adulterated, misbranded, counterfeit, suspected of being counterfeit, or that has otherwise been rendered unfit for distribution, except for the wholesale distribution by manufacturers of a prescription drug that has been delivered into commerce pursuant to an application approved under federal law by the FDA.
(11) The adulteration, misbranding, or counterfeiting of any prescription drug, except for the wholesale distribution by manufacturers of a prescription drug that has been delivered into commerce pursuant to an application approved under federal law by the FDA.
(12) The receipt of any prescription drug that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit, or suspected of being counterfeit and the delivery or proffered delivery of such drug for pay or otherwise.

(13) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of a prescription drug or the commission of any other act with respect to a prescription drug that results in the prescription drug being misbranded. The acts prohibited in this Section do not include the obtaining or the attempt to obtain a prescription drug for the sole purpose of testing the prescription drug for authenticity performed by a prescription drug manufacturer or the agent of a prescription drug manufacturer.

Smith-Hurd Illinois Compiled Statutes Annotated

Chapter 225. Professions and Occupations
Health
Act 120. Wholesale Drug Distribution Licensing Act
120/59. Enforcement; order to cease distribution of a drug

§ 59. Enforcement; order to cease distribution of a drug.

(a) The Department shall issue an order requiring the appropriate person, including the distributors or retailers of a drug, to immediately cease distribution of the drug within this State, if the Department finds that there is a reasonable probability that:

(1) a wholesale distributor has (i) violated a provision in this Act or (ii) falsified a pedigree or sold, distributed, transferred, manufactured, repackaged, handled, or held a counterfeit prescription drug intended for human use;
(2) the prescription drug at issue, as a result of a violation in paragraph (1) of this subsection (a), could cause serious, adverse health consequences or death; and
(3) other procedures would result in unreasonable delay.

(b) An order issued under this Section shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 days after the date of the issuance of the order, on the actions required by the order. If, after providing an opportunity for a hearing, the Department determines that inadequate grounds exist to support the actions required by the order, the Department shall vacate the order.

Annotated Indiana Code

Title 25. Professions and Occupations
Article 26. Pharmacists, Pharmacies, Drug Stores
Chapter 14. Wholesale Legend Drug Distributors
25-26-14-1.7 "Authenticate" defined

Sec. 1.7. As used in this chapter, "authenticate" means to affirmatively verify before distribution occurs that each transaction that is listed on:

(1) the pedigree of a legend drug; and
(2) other accompanying documentation for a legend drug;

has occurred.

Annotated Indiana Code

Title 25. Professions and Occupations
Article 26. Pharmacists, Pharmacies, Drug Stores
Chapter 14. Wholesale Legend Drug Distributors
25-26-14-8.7 "Pedigree" defined

Sec. 8.7. As used in this chapter, "pedigree" means a statement or record in a written or an electronic form that is approved by the board, that:

(1) records each wholesale distribution of a legend drug from the sale by the manufacturer that leaves the normal distribution chain of custody and that includes information designated by the board through rules for each transaction; or
(2) complies with a legend drug pedigree law or regulation in another state or United States territory that meets the pedigree requirements under this chapter.

Annotated Indiana Code

Title 25. Professions and Occupations
Article 26. Pharmacists, Pharmacies, Drug Stores
Chapter 14. Wholesale Legend Drug Distributors
25-26-14-14.5 Restriction on possession or distribution of legend drugs after June 30, 2006

Sec. 14.5. After June 30, 2006, a wholesale drug distributor may not accept or deliver a legend drug without a current, accompanying pedigree as required under section 17 of this chapter.

Annotated Indiana Code

Title 25. Professions and Occupations
Article 26. Pharmacists, Pharmacies, Drug Stores
Chapter 14. Wholesale Legend Drug Distributors
25-26-14-17 Applicant assurances as condition to grant of license

Sec. 17. As a condition for receiving and retaining a wholesale drug distributor license issued under this chapter, an applicant must satisfy the board that the applicant has and will continuously maintain the following:

(1) Acceptable storage and handling conditions and facilities standards for each facility at which legend drugs are received, stored, warehoused, handled, held, offered, marketed, or displayed, or from which legend drugs are transported, including:
(A) suitable construction of the facility and appropriate monitoring equipment to ensure that legend drugs in the facility are maintained in accordance with labeling or in compliance with official compendium standards;
(B) suitable size and construction to facilitate cleaning, maintenance, and proper wholesale distribution operations;
(C) adequate storage areas to provide appropriate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;
(D) a quarantine area for separate storage of legend drugs that are outdated, damaged, deteriorated, misbranded, adulterated, counterfeit, suspected counterfeit, otherwise unfit for distribution, or contained in immediate or sealed secondary containers that have been opened;
(E) maintenance of the facility in a clean and orderly condition;
(F) maintenance of the facility in a commercial, nonresidential building; and
(G) freedom of the facility from infestation.
(2) Security of each facility from unauthorized entry as follows:
(A) Entry into areas where legend drugs are held is limited to authorized personnel.
(B) Each facility is equipped with a security system that includes:
(i) an after hours central alarm or a comparable entry detection capability;
(ii) restricted premises access;
(iii) adequate outside perimeter lighting;
(iv) safeguards against theft and diversion, including employee theft and theft or diversion facilitated or hidden by tampering with computers or electronic records; and
(v) a means of protecting the integrity and confidentiality of data and documents and of making the data and documents readily available to the board and other state and federal law enforcement officials.
(3) A reasonable system of record keeping as follows:

(A) The system describes all the wholesale distributor's activities governed by this chapter for the three (3) year period after the disposition of each product, and all records are maintained for at least three (3) years after disposition of the legend drug to which the record applies.
(B) The system is reasonably accessible as determined by board rules in any inspection authorized by the board.
(C) The system provides a means to establish and maintain inventories and records of transactions regarding the receipt and distribution or other disposition of all legend drugs, including the following:
(i) For legend drugs manufactured by a manufacturer for which the wholesale drug distributor is an authorized distributor, a pedigree for each distributed legend drug that leaves the normal distribution chain of custody, as determined by rules adopted by the board.
(ii) For legend drugs manufactured by a manufacturer for which the wholesale drug distributor is not an authorized distributor, a pedigree for each distributed legend drug that leaves the normal chain of custody.
(iii) After January 1, 2007, and after consulting with the federal Food and Drug Administration, at the board's discretion, for each legend drug received and distributed by the wholesale drug distributor, an electronic pedigree developed in accordance with standards and requirements of the board to authenticate, track, and trace legend drugs. The standards and requirements of the board may indicate the information required to be part of the electronic pedigree.
(iv) Dates of receipt and distribution or other disposition of the legend drugs by the wholesale drug distributor.
(v) Availability for inspection and photocopying by any authorized official of a local, state, or federal governmental agency for three (3) years after the creation date of the inventories and records.
(D) Onsite electronic inventories and records are immediately available for inspection, and records kept at a central location apart from the inspection site and not electronically retrievable are available for inspection within two (2) working days after a request by an authorized official of a local, state, or federal governmental agency.
(E) The system maintains an ongoing list of persons with whom the wholesale drug distributor does business.
(F) The system provides for reporting counterfeit or suspected counterfeit legend drugs or counterfeiting or suspected counterfeiting activities to the board and the federal Food and Drug Administration.
(G) The system provides for mandatory reporting of significant shortages or losses of legend drugs to the board and the federal Food and Drug Administration, if applicable, if diversion is known or suspected.
(4) Written policies and procedures to which the wholesale drug distributor adheres for the receipt, security, storage, inventory, transport, shipping, and distribution of legend drugs, and that assure reasonable wholesale distributor preparation for, protection against, and handling of any facility security or operation problems, including the following:

(A) Facility security or operation problems caused by natural disaster or government emergency.
(B) Correction of inventory inaccuracies.
(C) Product shipping and receiving problems.
(D) Quarantine and return to the manufacturer or destruction in accordance with state and federal law of all outdated products and outdated or expired legend drugs, including appropriate documentation and witnessing.
(E) Appropriate disposition of returned goods.
(F) Product recalls.
(G) Identifying, recording, and reporting losses or thefts.
(H) Recalls and withdrawals of legend drugs due to:
(i) an action initiated by the federal Food and Drug Administration or another federal, state, or local governmental agency;
(ii) a volunteer action by the manufacturer to remove defective or potentially defective legend drugs from the market; or
(iii) an action undertaken to promote public health and safety by replacing existing merchandise with an improved product or a new package design.
(I) Disposition and destruction of containers, labels, and packaging to ensure that the containers, labels, and packaging are not used in counterfeiting activities, including necessary documentation and witnessing in accordance with state and federal law.
(J) Investigation of discrepancies in the inventory involving counterfeit, suspected counterfeit, contraband, or suspected contraband legend drugs and reporting of discrepancies within three (3) business days to the board and any other appropriate state or federal governmental agency.
(K) Reporting of criminal or suspected criminal activities involving the inventory of legend drugs to the board within three (3) business days.
(L) Conducting for cause authentication as required under sections 17.2 and 17.8 of this chapter.
(5) Written policies and procedures and sufficient inspection procedures for all incoming and outgoing product shipments, including the following:
(A) Upon receipt, visual examination of each shipping container in a manner adequate to identify the legend drugs in the container and to determine whether the legend drugs may be outdated, adulterated, misbranded, contaminated, contraband, counterfeit, suspected counterfeit, damaged, or otherwise unfit for distribution.
(B) Upon receipt, review of records by the wholesale drug distributor for the acquisition of legend drugs for accuracy and completeness, considering the:
(i) total facts and circumstances surrounding each transaction involving the legend drugs; and
(ii) wholesale drug distributors involved.
(C) Quarantine of a legend drug considered to be outdated, adulterated, misbranded, contaminated, contraband, counterfeit, suspected counterfeit, damaged, or otherwise unfit for distribution until:

(i) examination and a determination that the legend drug is not outdated, adulterated, misbranded, contaminated, contraband, counterfeit, damaged, or otherwise unfit for distribution; or
(ii) the legend drug is destroyed or returned to the manufacturer or wholesale drug distributor from which the legend drug was acquired.
(D) Written policies and procedures to ensure that if the wholesale drug distributor determines that a legend drug is adulterated, misbranded, counterfeit, or suspected counterfeit, the wholesale drug distributor provides notice of the adulteration, misbranding, counterfeiting, or suspected counterfeiting to the board, the federal Food and Drug Administration, and the manufacturer or wholesale drug distributor from which the legend drug was acquired within three (3) business days.
(E) Written policies and procedures to ensure that if the immediate or sealed outer or secondary container or labeling of a legend drug is adulterated, misbranded, counterfeit, or suspected counterfeit, the wholesale drug distributor:
(i) quarantines the legend drug until the legend drug is destroyed or returned to the manufacturer or wholesale drug distributor from which the legend drug was acquired; and
(ii) provides notice of the adulteration, misbranding, counterfeiting, or suspected counterfeiting to the board, the federal Food and Drug Administration, and the manufacturer or wholesale drug distributor from which the legend drug was acquired within three (3) business days.
(F) Written policies and procedures to ensure that a legend drug that has been opened or used, but is not adulterated, misbranded, counterfeit, or suspected counterfeit, is identified as such and quarantined until the legend drug is destroyed or returned to the manufacturer or wholesale drug distributor from which the legend drug was acquired.
(G) Written policies and procedures to ensure that:
(i) a legend drug that will be returned to a manufacturer or wholesale drug distributor is kept under proper conditions for storage, handling, transport, and shipment before the return; and
(ii) documentation showing that proper conditions were maintained is provided to the manufacturer or wholesale drug distributor to which the legend drug is returned.
(H) Inspection of each outgoing shipment for identity of the legend drugs and to ensure that the legend drugs have not been damaged in storage or held under improper conditions.
(I) Written policies and procedures to ensure that if conditions under which a legend drug has been returned to the wholesale drug distributor cast doubt on the legend drug's safety, identity, strength, quality, or purity, the legend drug is destroyed or returned to the manufacturer or wholesale drug distributor from which the legend drug was acquired unless examination, testing, or other investigation proves that the legend drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a legend drug has been returned cast doubt on the legend drug's safety, identity, strength, quality, or purity, the wholesale drug distributor considers the conditions under which the legend drug has been held, stored, or shipped before or during the legend drug's return and the condition of the legend drug and the legend drug's container, carton, or labeling upon receipt of the returned legend drug.

(J) Written policies and procedures to ensure that contraband, counterfeit, or suspected counterfeit legend drugs, other evidence of criminal activity, and accompanying documentation are retained until a disposition is authorized by the board and the federal Food and Drug Administration.
(K) Written policies and procedures to ensure that any shipping, immediate, or sealed outer or secondary container or labeling, and accompanying documentation, suspected of or determined to be counterfeit or fraudulent, are retained until a disposition is authorized by the board and the federal Food and Drug Administration.
(6) Operations in compliance with all federal legal requirements applicable to wholesale drug distribution.
(7) Written policies and procedures to provide for the secure and confidential storage of information with restricted access and to protect the integrity and confidentiality of the information.
(8) A pedigree as required under this chapter, including an electronic pedigree developed in accordance with standards and requirements of the board under subdivision (3)(C)(iii).
(9) Appropriate inventory management and control systems to:
(A) prevent; and
(B) allow detection and documentation of;
theft, counterfeiting, or diversion of legend drugs.
(10) If the wholesale drug distributor is involved in the distribution of controlled substances, registration with the federal Drug Enforcement Administration and the board and compliance with all laws related to the storage, handling, transport, shipment, and distribution of controlled substances.
(11) Isolation of controlled substances from noncontrolled substances and storage of the controlled substances in a secure area in accordance with federal Drug Enforcement Administration security requirements and standards.
(12) Technology and equipment that allow the wholesale drug distributor to authenticate, track, and trace legend drugs. The technology and equipment meet standards set by the board and are used as required by the board to conduct for cause and random tracking, tracing, and authentication of legend drugs.
(13) Employment, training, and documentation of the training concerning the proper use of the technology and equipment required under subdivision (12).
(14) Packaging operations in accordance with an official compendium allowing the identification of a compromise in the integrity of the legend drugs due to tampering or adverse storage conditions.

Annotated Indiana Code

Title 25. Professions and Occupations
Article 26. Pharmacists, Pharmacies, Drug Stores
Chapter 14. Wholesale Legend Drug Distributors
25-26-14-17.8 Purchases from unlicensed wholesale distributors

Sec. 17.8. (a) A wholesale drug distributor licensed under this chapter that purchases legend drugs from a wholesale drug distributor that is not licensed under this chapter shall act with due diligence as required under this section and rules adopted by the board. However, the due diligence requirements of this section do not apply to purchases from an unlicensed wholesale drug distributor that has obtained accreditation through the National Association of Boards of Pharmacy's Verified-Accredited Wholesale Distributors program.

(b) Before the initial purchase of legend drugs from the unlicensed wholesale drug distributor, the licensed wholesale drug distributor shall obtain the following information from the unlicensed wholesale drug distributor:

(1) A list of states in which the unlicensed wholesale drug distributor is licensed.
(2) A list of states into which the unlicensed wholesale drug distributor ships legend drugs.
(3) Copies of all state and federal regulatory licenses and registrations held by the unlicensed wholesale drug distributor.
(4) The unlicensed wholesale drug distributor's most recent facility inspection reports.
(5) Information regarding general and product liability insurance maintained by the unlicensed wholesale drug distributor, including copies of relevant policies.
(6) A list of other names under which the unlicensed wholesale drug distributor does business or has been previously known.
(7) A list of corporate officers and managerial employees of the unlicensed wholesale drug distributor.
(8) A list of all owners of the unlicensed wholesale drug distributor that own more than ten percent (10%) of the unlicensed wholesale drug distributor, unless the unlicensed wholesale drug distributor is publicly traded.
(9) A list of all disciplinary actions taken against the unlicensed wholesale drug distributor by state and federal agencies.
(10) A description, including the address, dimensions, and other relevant information, of each facility used by the unlicensed wholesale drug distributor for legend drug storage and distribution.
(11) A description of legend drug import and export activities of the unlicensed wholesale drug distributor.

(12) A description of the unlicensed wholesale drug distributor's procedures to ensure compliance with this chapter.
(13) A statement:
(A) as to whether; and
(B) of the identity of each manufacturer for which;
the unlicensed wholesale drug distributor is an authorized distributor.

(c) Before the initial purchase of legend drugs from an unlicensed wholesale drug distributor, the licensed wholesale drug distributor shall:

(1) request that the board obtain and consider the results of a national criminal history background check (as defined in IC 10-13-3-12) through the state police department of all individuals associated with the unlicensed wholesale drug distributor as specified for licensure of a wholesale drug distributor under section 16(b) of this chapter; and
(2) verify the unlicensed wholesale drug distributor's status as an authorized distributor, if applicable.

(d) If an unlicensed wholesale drug distributor's facility has not been inspected by the board or the board's agent within three (3) years after a contemplated purchase described in subsection (a), the licensed wholesale drug distributor shall conduct an inspection of the unlicensed wholesale drug distributor's facility:

(1) before the initial purchase of legend drugs from the unlicensed wholesale drug distributor; and
(2) at least once every three (3) years unless the unlicensed wholesale drug distributor's facility has been inspected by the board, or the board's agent, during the same period;

to ensure compliance with applicable laws and regulations relating to the storage and handling of legend drugs. A third party may be engaged to conduct the site inspection on behalf of the licensed wholesale drug distributor.

(e) At least annually, a licensed wholesale drug distributor that purchases legend drugs from an unlicensed wholesale drug distributor shall ensure that the unlicensed wholesale drug distributor maintains a record keeping system that meets the requirements of section 17(3) of this chapter.

(f) If a licensed wholesale drug distributor that purchases legend drugs from an unlicensed wholesale drug distributor has reason to believe that a legend drug purchased from the unlicensed wholesale drug distributor is misbranded, adulterated, counterfeit, or suspected counterfeit, the licensed wholesale drug distributor shall conduct a for cause authentication of

each distribution of the legend drug back to the manufacturer.

(g) An unlicensed wholesale drug distributor that has engaged in the distribution of a legend drug for which a licensed wholesale drug distributor conducts a for cause authentication under subsection (f) shall provide, upon request, detailed information regarding the distribution of the legend drug, including the:

(1) date of purchase of the legend drug;
(2) lot number of the legend drug;
(3) sales invoice number of the legend drug; and
(4) contact information, including name, address, telephone number, and any electronic mail address of the unlicensed wholesale drug distributor that sold the legend drug.

(h) If a licensed wholesale drug distributor conducts a for cause authentication under subsection (f) and is unable to authenticate each distribution of the legend drug, the licensed wholesale drug distributor shall quarantine the legend drug and report the circumstances to the board and the federal Food and Drug Administration within ten (10) business days after completing the attempted authentication.

(i) If a licensed wholesale drug distributor authenticates the distribution of a legend drug back to the manufacturer under subsection (f), the licensed wholesale drug distributor shall maintain records of the authentication for three (3) years and shall provide the records to the board upon request.

(j) A licensed wholesale drug distributor that purchases legend drugs from an unlicensed wholesale drug distributor shall, at least annually, conduct random authentications of required pedigrees on at least ten percent (10%) of sales units of distributions of legend drugs that were purchased from unlicensed wholesale drug distributors.

(k) An unlicensed wholesale drug distributor from which a licensed wholesale drug distributor has purchased legend drugs shall cooperate with the random authentications of pedigrees under this section and provide requested information in a timely manner.

(l) If a wholesale drug distributor conducts a random authentication under subsection (j) and is unable to authenticate each distribution of the legend drug, the wholesale drug distributor shall quarantine the legend drug and report the circumstances to the board and the federal Food and Drug Administration not more than ten (10) business days after completing the attempted authentication.

Annotated Indiana Code

Title 25. Professions and Occupations
Article 26. Pharmacists, Pharmacies, Drug Stores
Chapter 14. Wholesale Legend Drug Distributors
25-26-14-21.5 Prohibited actions; sanctions for violations

Sec. 21.5. (a) A person may not perform, cause the performance of, or aid the performance of the following:

(1) The manufacture, repackaging, sale, delivery, holding, or offering for sale of a legend drug that is adulterated, misbranded, counterfeit, suspected counterfeit, or is otherwise unfit for distribution.
(2) The adulteration, misbranding, or counterfeiting of a legend drug.
(3) The receipt of a legend drug that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit, or suspected counterfeit, and the delivery or proffered delivery of the legend drug for pay or otherwise.
(4) The alteration, mutilation, destruction, obliteration, or removal of the whole or a part of the labeling of a legend drug or the commission of another act with respect to a legend drug that results in the legend drug being misbranded.
(5) Forging, counterfeiting, simulating, or falsely representing a legend drug using a mark, stamp, tag, label, or other identification device without the authorization of the manufacturer.
(6) The purchase or receipt of a legend drug from a person that is not licensed to distribute legend drugs to the purchaser or recipient.
(7) The sale or transfer of a legend drug to a person that is not authorized under the law of the jurisdiction in which the person receives the legend drug to purchase or receive legend drugs from the person selling or transferring the legend drug.
(8) Failure to maintain or provide records as required under this chapter.
(9) Providing the board, a representative of the board, or a state or federal official with false or fraudulent records or making false or fraudulent statements regarding a matter related to this chapter.
(10) The wholesale distribution of a legend drug that was:
(A) purchased by a public or private hospital or other health care entity;
(B) donated or supplied at a reduced price to a charitable organization; or
(C) stolen or obtained by fraud or deceit.
(11) Obtaining or attempting to obtain a legend drug by fraud, deceit, misrepresentation, or engaging in fraud, deceit, or misrepresentation in the distribution of a legend drug.
(12) Failure to obtain, authenticate, or provide a required pedigree.
(13) The receipt of a legend drug through wholesale distribution without first receiving a required pedigree attested to as accurate and complete by the wholesale drug distributor.

(14) Distributing a legend drug that was previously dispensed by a retail pharmacy or distributed by a practitioner.
(15) Failure to report an act prohibited by this section.

(b) The board may impose the following sanctions if, after a hearing under IC 4-21.5-3, the board finds that a person has violated subsection (a):

(1) Revoke the wholesale drug distributor's license issued under this chapter if the person is a wholesale drug distributor.
(2) Assess a civil penalty against the person. A civil penalty assessed under this subdivision may not be more than ten thousand dollars ($ 10,000) per violation.

Annotated Indiana Code

Title 25. Professions and Occupations
Article 26. Pharmacists, Pharmacies, Drug Stores
Chapter 14. Wholesale Legend Drug Distributors
25-26-14-26 Distribution of legend drug without license; offense

Sec. 26. (a) A person who knowingly or intentionally engages in the wholesale distribution of a legend drug without a license issued under this chapter commits a Class D felony.

(b) A person who engages in the wholesale distribution of a legend drug and:

(1) who, with intent to defraud or deceive:
(A) fails to obtain or deliver to another person a complete and accurate required pedigree concerning a legend drug before:
(i) obtaining the legend drug from another person; or
(ii) transferring the legend drug to another person; or
(B) falsely swears or certifies that the person has authenticated any documents related to the wholesale distribution of legend drugs;
(2) who knowingly or intentionally:
(A) destroys, alters, conceals, or fails to maintain a complete and accurate required pedigree concerning a legend drug in the person's possession;
(B) purchases or receives legend drugs from a person not authorized to distribute legend drugs in wholesale distribution;
(C) sells, barters, brokers, or transfers a legend drug to a person not authorized to purchase the legend drug in the jurisdiction in which the person receives the legend drug in a wholesale distribution;
(D) forges, counterfeits, or falsely creates a pedigree;
(E) falsely represents a factual matter contained in a pedigree; or
(F) fails to record material information required to be recorded in a pedigree; or
(3) who:
(A) possesses a required pedigree concerning a legend drug;
(B) knowingly or intentionally fails to authenticate the matters contained in the pedigree as required; and
(C) distributes or attempts to further distribute the legend drug;

commits a Class D felony.

Iowa Code Annotated

Title IV. Public Health [Chs. 123-158]
Subtitle 3. Health-Related Professions [Chs. 147-158]
Chapter 155A. Pharmacy
155A.3. Definitions

As used in this chapter, unless the context otherwise requires:

1. "Administer" means the direct application of a prescription drug, whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject by one of the following:

a. A practitioner or the practitioner's authorized agent.

b. The patient or research subject at the direction of a practitioner.

2. "Authorized agent" means an individual designated by a practitioner who is under the supervision of the practitioner and for whom the practitioner assumes legal responsibility.

3. "Board" means the board of pharmacy.

4. "Brand name" or "trade name" means the registered trademark name given to a drug product or ingredient by its manufacturer, labeler, or distributor.

5. "College of pharmacy" means a school, university, or college of pharmacy that satisfies the accreditation standards of the accreditation council for pharmacy education to the extent those standards are adopted by the board, or that has degree requirements which meet the standards of

accreditation adopted by the board.

6. "Controlled substance" means a drug substance, immediate precursor, or other substance listed in division II of chapter 124.

7. "Controlled substances Act" means chapter 124.

8. "Deliver" or "delivery" means the actual, constructive, or attempted transfer of a prescription drug or device or controlled substance from one person to another, whether or not for a consideration.

9. "Demonstrated bioavailability" means the rate and extent of absorption of a drug or drug ingredient from a specified dosage form, as reflected by the time-concentration curve of the drug or drug ingredient in the systemic circulation.

10. "Device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component part or accessory, that is required under federal or state law to be ordered or prescribed by a practitioner.

11. "Dispense" means to deliver a prescription drug, device, or controlled substance to an ultimate user or research subject by or pursuant to the lawful prescription drug order or medication order of a practitioner, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery.

12. "Distribute" means the delivery of a prescription drug or device.

13. "Drug" means one or more of the following:

a. A substance recognized as a drug in the current official United States Pharmacopoeia and National Formulary, official Homeopathic Pharmacopoeia, or other drug compendium or any supplement to any of them.

b. A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals.

c. A substance, other than food, intended to affect the structure or any function of the body of humans or other animals.

d. A substance intended for use as a component of any substance specified in paragraph "a", "b", or "c".

e. A controlled substance.

14. "Drug product selection" means the act of selecting the source of supply of a drug product.

15. "Drug sample" means a drug that is distributed without consideration to a pharmacist or practitioner.

16. "Electronic order" or "electronic prescription" means an order or prescription which is transmitted by a computer device in a secure manner, including computer-to-computer transmission and computer-to-facsimile transmission.

17. "Electronic signature" means a confidential personalized digital key, code, or number used

for secure electronic transmissions which identifies and authenticates the signatory.

18. "Facsimile order" or " facsimile prescription" means an order or prescription which is transmitted by a device which sends an exact image to the receiver.

19. "Generic name" means the official title of a drug or drug ingredient published in the current official United States Pharmacopoeia and National Formulary, official Homeopathic Pharmacopoeia, or other drug compendium published by the United States pharmacopoeial convention or any supplement to any of them.

20. "Internship" means a practical experience program approved by the board for persons training to become pharmacists.

21. "Label" means written, printed, or graphic matter on the immediate container of a drug or device.

22. "Labeling" means the process of preparing and affixing a label including information required by federal or state law or regulation to a drug or device container. The term does not include the labeling by a manufacturer, packer, or distributor of a nonprescription drug or commercially packaged prescription drug or device or unit dose packaging.

23. "Limited drug and device distributor" means a person operating or maintaining, either within or outside this state, a location at which limited noncontrolled prescription drugs, prescription devices, and medical gases, are distributed to patients in this state pursuant to a prescription drug order; or a person operating or maintaining a location at which limited quantities of drugs, devices, or medical gases are distributed at wholesale in this state. A "limited drug and device distributor" does not include a pharmacy licensed pursuant to this chapter or a drug wholesaler providing prescription drugs to patients in this state pursuant to a drug manufacturer's prescription drug assistance program.

24. "Logistics provider" means an entity that provides or coordinates warehousing, distribution, or other services on behalf of a manufacturer or other owner of a drug, but does not take title to the drug or have general responsibility to direct its sale or other disposition.

25. "Medical gas" means a gas or liquid oxygen intended for human consumption.

26. "Medication order" means a written order from a practitioner or an oral order from a practitioner or the practitioner's authorized agent for administration of a drug or device.

27. "Pedigree" means a recording of each distribution of any given drug or device, from the sale by the manufacturer through acquisition and sale by any wholesaler, pursuant to rules adopted by the board.

28. "Pharmacist" means a person licensed by the board to practice pharmacy.

29. "Pharmacist in charge" means the pharmacist designated on a pharmacy license as the pharmacist who has the authority and responsibility for the pharmacy's compliance with laws and rules pertaining to the practice of pharmacy.

30. "Pharmacist-intern" means an undergraduate student enrolled in the professional sequence of a college of pharmacy approved by the board, or a graduate of a college of pharmacy, who is participating in a board-approved internship under the supervision of a preceptor.

31. "Pharmacy" means a location where prescription drugs are compounded, dispensed, or sold by a pharmacist and where prescription drug orders are received or processed in accordance with the pharmacy laws.

32. "Pharmacy license" means a license issued to a pharmacy or other place where prescription drugs or devices are dispensed to the general public pursuant to a prescription drug order.

33. "Pharmacy technician" means a person registered by the board who is in a technician training program or who is employed by a pharmacy under the responsibility of a licensed pharmacist to assist in the technical functions of the practice of pharmacy.

34. "Practice of pharmacy" is a dynamic patient-oriented health service profession that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use and related drug therapy.

35. "Practitioner" means a physician, dentist, podiatric physician, veterinarian, or other person licensed or registered to distribute or dispense a prescription drug or device in the course of professional practice in this state or a person licensed by another state in a health field in which, under Iowa law, licensees in this state may legally prescribe drugs.

36. "Preceptor" means a pharmacist in good standing licensed in this state to practice pharmacy and approved by the board to supervise and be responsible for the activities and functions of a pharmacist-intern in the internship program.

37. "Prescription drug" means any of the following:

a. A substance for which federal or state law requires a prescription before it may be legally dispensed to the public.

b. A drug or device that under federal law is required, prior to being dispensed or delivered, to be

labeled with one of the following statements:

(1) Caution: Federal law prohibits dispensing without a prescription.

(2) Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) Caution: Federal law restricts this device to sale by, or on the order of, a physician.

(4) Rx only.

c. A drug or device that is required by any applicable federal or state law or regulation to be dispensed on prescription only, or is restricted to use by a practitioner only.

38. "Prescription drug order" means a written, electronic, or facsimile order from a practitioner or an oral order from a practitioner or the practitioner's authorized agent who communicates the practitioner's instructions for a prescription drug or device to be dispensed.

39. "Proprietary medicine" or "over-the-counter medicine" means a nonnarcotic drug or device that may be sold without a prescription and that is labeled and packaged in compliance with applicable state or federal law.

40. "Tech-check-tech program" means a program formally established by a pharmacist in charge of a pharmacy who has determined that one or more certified pharmacy technicians are qualified to safely check the work of other certified pharmacy technicians and thereby provide final verification for drugs which are dispensed for subsequent administration to patients in an institutional setting.

41. "Ultimate user" means a person who has lawfully obtained and possesses a prescription drug or device for the person's own use or for the use of a member of the person's household or for administering to an animal owned by the person or by a member of the person's household.

42. "Unit dose packaging" means the packaging of individual doses of a drug in containers which preserve the identity and integrity of the drug from the point of packaging to administration and which are properly labeled pursuant to rules of the board.

43. "Wholesaler" means a person operating or maintaining, either within or outside this state, a manufacturing plant, wholesale distribution center, wholesale business, or any other business in which prescription drugs or devices, medicinal chemicals, medicines, or poisons are sold, manufactured, compounded, dispensed, stocked, exposed, distributed from, or offered for sale at wholesale in this state. "Wholesaler" does not include those wholesalers who sell only proprietary or over-the-counter medicines. "Wholesaler" also does not include a commercial carrier that temporarily stores prescription drugs or devices, medicinal chemicals, medicines, or poisons while in transit.

44. "Wholesale salesperson" or "manufacturer's representative" means an individual who takes purchase orders on behalf of a wholesaler for prescription drugs, medicinal chemicals, medicines, or poisons. "Wholesale salesperson" or "manufacturer's representative" does not include an individual who sells only proprietary medicines.

Iowa Code Annotated

Title IV. Public Health [Chs. 123-158]
Subtitle 3. Health-Related Professions [Chs. 147-158]
Chapter 155A. Pharmacy
155A.17. Wholesale drug license

1. A person shall not establish, conduct, or maintain a wholesale drug business as defined in this chapter without a license. The license shall be identified as a wholesale drug license.

2. The board shall establish standards for drug wholesaler licensure and may define specific types of wholesaler licenses. The board may deny, suspend, or revoke a drug wholesale license for failure to meet the applicable standards or for a violation of the laws of this state, another state, or the United States relating to prescription drugs, devices, or controlled substances, or for a violation of this chapter, chapter 124, 124A, 124B, 126, or 205, or a rule of the board.

3. The board shall adopt rules pursuant to chapter 17A on matters pertaining to the issuance of a wholesale drug license. The rules shall provide for conditions of licensure, compliance standards, licensure fees, disciplinary action, and other relevant matters. Additionally, the rules shall establish provisions or exceptions for pharmacies, chain pharmacy distribution centers, logistics providers, and other types of wholesalers relating to pedigree requirements, drug or device returns, and other related matters, so as not to prevent or interfere with usual, customary, and necessary business activities.

4. This section does not apply to a manufacturer's representative acting in the usual course of business or employment as a manufacturer's representative.

Iowa Code Annotated

Title IV. Public Health [Chs. 123-158]
Subtitle 3. Health-Related Professions [Chs. 147-158]
Chapter 155A. Pharmacy
155A.24. Penalties

1. Except as otherwise provided in this section, a person who violates a provision of section 155A.23 or who sells or offers for sale, gives away, or administers to another person any prescription drug or device in violation of this chapter commits a public offense and shall be punished as follows:

a. If the prescription drug is a controlled substance, the person shall be punished pursuant to section 124.401, subsection 1, and other provisions of chapter 124, division IV.

b. If the prescription drug is not a controlled substance, the person, upon conviction of a first offense, is guilty of a serious misdemeanor. For a second offense, or if in case of a first offense the offender previously has been convicted of any violation of the laws of the United States or of any state, territory, or district thereof relating to prescription drugs or devices, the offender is guilty of an aggravated misdemeanor. For a third or subsequent offense or if in the case of a second offense the offender previously has been convicted two or more times in the aggregate of any violation of the laws of the United States or of any state, territory, or district thereof relating to prescription drugs or devices, the offender is guilty of a class "D" felony.

2. A person who violates any provision of this chapter by selling, giving away, or administering any prescription drug or device to a minor is guilty of a class "C" felony.

3. A wholesaler who, with intent to defraud or deceive, fails to deliver to another person, when required by rules of the board, complete and accurate pedigree concerning a drug prior to transferring the drug to another person is guilty of a class "C" felony.

4. A wholesaler who, with intent to defraud or deceive, fails to acquire, when required by rules of the board, complete and accurate pedigree concerning a drug prior to obtaining the drug from another person is guilty of a class "C" felony.

5. A wholesaler who knowingly destroys, alters, conceals, or fails to maintain, as required by rules of the board, complete and accurate pedigree concerning any drug in the person's possession is guilty of a class "C" felony.

6. A wholesaler who is in possession of pedigree documents required by rules of the board, and who knowingly fails to authenticate the matters contained in the documents as required, and who nevertheless distributes or attempts to further distribute drugs is guilty of a class "C" felony.

7. A wholesaler who, with intent to defraud or deceive, falsely swears or certifies that the person has authenticated any documents related to the wholesale distribution of drugs or devices is guilty of a class "C" felony.

8. A wholesaler who knowingly forges, counterfeits, or falsely creates any pedigree, who falsely represents any factual matter contained in any pedigree, or who knowingly fails to record material information required to be recorded in a pedigree is guilty of a class "C" felony.

9. A wholesaler who knowingly purchases or receives drugs or devices from a person not authorized to distribute drugs or devices in wholesale distribution is guilty of a class "C" felony.

10. A wholesaler who knowingly sells, barters, brokers, or transfers a drug or device to a person not authorized to purchase the drug or device under the jurisdiction in which the person receives the drug or device in a wholesale distribution is guilty of a class "C" felony.

11. A person who knowingly manufacturers, sells, or delivers, or who possesses with intent to sell or deliver, a counterfeit, misbranded, or adulterated drug or device is guilty of the following:

a. If the person manufactures or produces a counterfeit, misbranded, or adulterated drug or device; or if the quantity of a counterfeit, misbranded, or adulterated drug or device being sold, delivered, or possessed with intent to sell or deliver exceeds one thousand units or dosages; or if the violation is a third or subsequent violation of this subsection, the person is guilty of a class "C" felony.

b. If the quantity of a counterfeit, misbranded, or adulterated drug or device being sold, delivered, or possessed with intent to sell or deliver exceeds one hundred units or dosages but does not exceed one thousand units or dosages; or if the violation is a second or subsequent violation of this subsection, the person is guilty of a class "D" felony.

c. All other violations of this subsection shall constitute an aggravated misdemeanor.

12. A person who knowingly forges, counterfeits, or falsely creates any label for a drug or device or who falsely represents any factual matter contained on any label of a drug or device is guilty of a class "C" felony.

13. A person who knowingly possesses, purchases, or brings into the state a counterfeit, misbranded, or adulterated drug or device is guilty of the following:

a. If the quantity of a counterfeit, misbranded, or adulterated drug or device being possessed, purchased, or brought into the state exceeds one hundred units or dosages; or if the violation is a second or subsequent violation of this subsection, the person is guilty of a class "D" felony.

b. All other violations of this subsection shall constitute an aggravated misdemeanor.

14. This section does not prevent a licensed practitioner of medicine, dentistry, podiatry, nursing, veterinary medicine, optometry, or pharmacy from acts necessary in the ethical and legal performance of the practitioner's profession.

15. Subsections 1 and 2 shall not apply to a parent or legal guardian administering, in good faith, a prescription drug or device to a child of the parent or a child for whom the individual is designated a legal guardian.

Kansas Statutes Annotated

Chapter 65. Public Health
Article 16. Regulation of Pharmacists
65-1651a. Study of regulating wholesale prescription drug distributors; pedigrees for prescription drugs

The state board of pharmacy shall conduct a study on the issue of licensing wholesale prescription drug distributors and the use of pedigree for prescription drugs and the penalty aspects for violation of any pedigree requirements. The results of such study shall be completed and presented along with a licensing and pedigree plan and recommendations for licensing and pedigree legislation to the legislature no later than January 15, 2007.

Baldwin's Kentucky Revised Statutes Annotated

Title XXVI. Occupations and Professions
Chapter 315. Pharmacists and Pharmacies
Distribution of Prescription Drugs
315.400 Definitions for KRS 315.400 to 315.412

As used in KRS 315.400 to 315.412:

(1) "Authorized distributor of record" means a wholesale distributor that:
(a) Has established an ongoing relationship with a manufacturer to distribute the manufacturer's prescription drug. An ongoing relationship exists between a wholesale distributor and a manufacturer if the wholesale distributor, including any affiliated group of the wholesale distributor as defined in Section 1504 of the Internal Revenue Code, has a written agreement for distribution in effect; and
(b) Is listed on the manufacturer's current list of authorized distributors of record;

(2) "Co-licensed partner" means two (2) or more entities that have the right to engage in the manufacturing or marketing or both of a prescription drug consistent with the Federal Drug Administration's implementation of the federal Prescription Drug Marketing Act;

(3) "Co-licensed product" means a prescription drug manufactured by two (2) or more co-licensed partners;

(4) "Counterfeit prescription drug" means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed the drug and which thereby 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;

(5) "Drop shipment" means the sale of a prescription drug to a wholesale distributor by the drug's manufacturer, the manufacturer's co-licensed partner, the manufacturer's third-party logistics provider, the manufacturer's exclusive distributor, or by an authorized distributor of record that purchased the product directly from the manufacturer, the manufacturer's co-licensed partner, the manufacturer's third-party logistics provider, or the manufacturer's exclusive distributor, and:
(a) The wholesale distributor takes title to but not physical possession of the drug;
(b) The wholesale distributor invoices the pharmacy, pharmacy warehouse, or other person authorized by law to dispense or administer a prescription drug; and

(c) The pharmacy, pharmacy warehouse, or other person authorized by law to dispense or administer a prescription drug receives delivery directly from the manufacturer, the manufacturer's co-licensed partner, the manufacturer's third-party logistics provider, the manufacturer's exclusive distributor, or an authorized distributor of record;

(6) "Emergency medical reasons" includes but is not limited to:
(a) Transfers of a prescription drug between health-care entities or between a health-care entity and a retail pharmacy to alleviate a temporary shortage of a prescription drug arising from delays in or interruptions of the regular distribution schedules;
(b) Sales of drugs for use in the treatment of acutely ill or injured persons to nearby emergency medical services providers, firefighting organizations, or licensed health-care practitioners in the same marketing or service area;
(c) The provision of emergency supplies of drugs to nearby nursing homes, home health agencies, or hospice organizations for emergency use when necessary drugs cannot be obtained; or
(d) Transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage;

(7) "End user" means a patient or consumer that uses a prescription drug as prescribed by an authorized health-care professional;

(8) "FDA" means the United States Food and Drug Administration and any successor agency;

(9) "Manufacturer" means the same as defined in KRS 315.010;
(10) "Manufacturer's exclusive distributor" means a distributor who:
(a) Contracts with a manufacturer to provide or coordinate the warehousing, distributing, or other similar services on behalf of a manufacturer;
(b) Takes title of the prescription drug but does not have responsibility to direct the sale of the manufacturer's prescription drug;
(c) Is licensed under KRS 315.402; and
(d) Is an authorized distributor of record;
(11) "Normal distribution channel" means a chain of custody for a prescription drug from a manufacturer, a manufacturer's co-licensed partner, a manufacturer's third-party logistics provider, or a manufacturer's exclusive distributor that goes directly, by drop shipment or by intracompany transfer, to:
(a) A pharmacy or other designated person authorized by law to distribute a prescription drug to an end user;
(b) A pharmacy warehouse that performs intracompany sales or transfers of prescription drugs to a group of pharmacies under common ownership and control to a patient, pursuant to a prescription for a patient, or to a person authorized by law to administer a prescription drug for use by a patient;

(c) An authorized distributor of record:
1. Then to a pharmacy or other designated person authorized by law to distribute a prescription drug to an end user;
2. Then to a pharmacy warehouse as specified in paragraph (b) of this subsection; or
3. Then to another authorized distributor of record to a licensed health-care facility or pharmacy, or a practitioner authorized by law to distribute a prescription drug to an end user; or
(d) A nonprofit organization under state contract to distribute prescription drugs to pharmacies pursuant to the state's emergency response plan and the subsequent distribution of those prescription drugs to pharmacies;
(12) "Pedigree" means a document or electronic file containing information that records each distribution of a prescription drug;
(13) "Pharmacy warehouse" means a physical location for prescription drugs that acts as a central warehouse and performs intracompany sales or transfers of prescription drugs to a group of pharmacies under common ownership and control;
(14) "Prescription drug" means the same as defined in KRS 315.010;
(15) "Reverse distributor" means every person who acts as an agent for pharmacies, drug wholesalers, manufacturers, or other entities by receiving, taking inventory, and managing the disposition of outdated or nonsalable drugs;
(16) "Third-party logistics provider" means an entity that contracts with a manufacturer to provide or coordinate the warehousing, distribution, or other similar services on behalf of a manufacturer, but does not take title to the drug or have responsibility to direct the sale of the manufacturer's drug. A third-party logistics provider who is a licensed wholesale distributor under KRS 315.402 and is a manufacturer's authorized distributor of record shall be considered as part of the normal distribution channel;
(17) "Wholesale distribution" means the distribution of a prescription drug to persons other than an end user, but does not include:
(a) Intracompany sales or transfers;
(b) The sale, purchase, distribution, trade, or transfer of a prescription drug for emergency medical reasons;
(c) The distribution of prescription drug samples by a manufacturer or authorized distributor;
(d) Drug returns or transfers to the original manufacturer, original wholesale distributor, or transfers to a reverse distributor or third-party returns processor;
(e) The sale, purchase, or trade of a drug pursuant to a prescription;
(f) The delivery of a prescription drug by a common carrier;
(g) The purchase or acquisition by a health-care entity or pharmacy that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization, or health-care entities or pharmacies that are members of the group organization;
(h) The sale, purchase, distribution, trade, or transfer of a drug by a charitable health-care entity to a nonprofit affiliate of the organization as otherwise permitted by law;

(i) The sale, transfer, merger, or consolidation of all or part of the business of a pharmacy with another pharmacy or pharmacies; or

(j) The distribution of a prescription drug to a health-care practitioner or to another pharmacy if the total number of units transferred during a twelve (12) month period does not exceed five percent (5%) of the total number of all units dispensed by the pharmacy during the immediate twelve (12) month period; and

(18) "Wholesale distributor" means an entity engaged in the wholesale distribution of prescription drugs, including but not limited to manufacturers, manufacturers' exclusive distributors, authorized distributors of record, drug wholesalers or distributors, third-party logistics providers, third-party returns processors, reverse distributors, and pharmacy warehouses and retail pharmacies that engage in the wholesale distribution of a prescription drug.

Baldwin's Kentucky Revised Statutes Annotated

Title XXVI. Occupations and Professions
Chapter 315. Pharmacists and Pharmacies
Distribution of Prescription Drugs
315.404 Returns or exchanges of prescription drugs

(a) A wholesale distributor may receive prescription drug returns or exchanges from a pharmacy, pharmacy warehouse, or other person authorized to distribute a prescription drug to an end user under the terms and conditions of an agreement between the parties.

(b) Returns of expired, damaged, recalled, or otherwise nonsalable prescription drugs shall be distributed by the receiving wholesale distributor only to the original manufacturer, a third-party returns processor, or a reverse distributor licensed as a wholesale distributor.

(c) Returns or exchanges of prescription drugs that may or may not be salable, including any redistribution by a receiving wholesaler, shall not be subject to the requirements of KRS 315.406 if they are exempt from the pedigree requirements of the federal regulations for the federal Prescription Drug Marketing Act of 1987 as amended by the Prescription Drug Amendments of 1992 and any amendments thereto.

(2) A manufacturer or wholesale distributor shall supply prescription drugs only to a person or entity licensed to possess or distribute prescription drugs to an end user.

(3) Prescription drugs supplied by a manufacturer or wholesale distributor shall be delivered only to the business address of the licensee or the address listed on the license, to the address of a health-care entity authorized by the licensee, or to an authorized person or agent of the licensee at the premises of the manufacturer or wholesale distributor if the identity and authority of the authorized agent is established.

(4) A licensed wholesale distributor, pharmacy, or other person authorized by law to furnish prescription drugs to an end user shall be accountable for their returns process and shall ensure that all aspects of their operations are secure and do not permit the entry of adulterated or counterfeit prescription drugs.

Baldwin's Kentucky Revised Statutes Annotated

Title XXVI. Occupations and Professions
Chapter 315. Pharmacists and Pharmacies
Distribution of Prescription Drugs
315.406 Prescription drug pedigree for drugs leaving normal distribution channel; administrative regulations

(a) As of the date specified by an administrative regulation promulgated by the board pursuant to KRS Chapter 13A, each person or entity engaged in the wholesale distribution of prescription drugs that leave or that have ever left the normal distribution channel shall, prior to the distribution of the prescription drug, provide a pedigree to the person receiving the prescription drug.

(b) A retail pharmacy or a pharmacy warehouse shall comply with paragraph (a) of this subsection only if it engages in wholesale distribution of prescription drugs.

(2) The board shall specify the requirements for the contents and maintenance of a pedigree that are consistent with the federal requirements.

(3) The board shall promulgate an administrative regulation pursuant to KRS Chapter 13A to implement the provisions of this section no later than one hundred eighty (180) days after July 15, 2008.

Baldwin's Kentucky Revised Statutes Annotated

Title XXVI. Occupations and Professions
Chapter 315. Pharmacists and Pharmacies
Distribution of Prescription Drugs
315.408 Electronic track and trace system

(1) The board shall not require the use of an electronic track and trace system to initiate, provide, receive, or maintain a pedigree by a person or entity licensed to possess, distribute, dispense, or administer prescription drugs for use by an end user until the FDA develops and implements standards for identification, validation, authentication, and tracking and tracing of prescription drugs pursuant to 21 U.S.C. sec. 355e. The electronic track and trace system requirements by the board shall meet the FDA's standards for all prescription drugs covered by the FDA standards.

(2) Upon implementation of FDA standards for an electronic track and trace system, the requirements relating to a pedigree in KRS 315.406 shall be superseded by the FDA standards and shall not apply to any prescription drugs specified in the FDA standards.

(3) Prior to promulgation of any administrative regulation under KRS Chapter 13A that requires the use of an electronic track and trace system, the board shall consult with manufacturers, wholesale distributors, and pharmacies regarding implementation of the electronic track and trace system requirements and publish a report on its Web site about implementation issues, including but not limited to universal availability, technical and operational feasibility, and reliability for manufacturers, wholesale distributors, and pharmacies.

Baldwin's Kentucky Revised Statutes Annotated

Title XXVI. Occupations and Professions
Chapter 315. Pharmacists and Pharmacies
Distribution of Prescription Drugs
315.410 Order to cease distribution of prescription drugs; hearing

(1) The board shall issue an order to the appropriate person or entity, including but not limited to wholesale distributors or retailers, to immediately cease distribution of prescription drugs within the Commonwealth if there are reasonable grounds to believe:

(a) 1. The distribution of the prescription drug is in violation of KRS 315.406;
2. The prescription drug is accompanied by a falsified pedigree in violation of KRS 315.406; or
3. The prescription drug is a counterfeit prescription drug; and
(b) Other procedures to intercede would result in an unreasonable delay.

(2) A person in receipt of an order to cease distribution shall be notified in writing of the right to an administrative hearing to be conducted in accordance with KRS Chapter 13B no later than ten (10) days, excluding weekends and holidays, after the date of the order. If, after a hearing is conducted, the hearing officer determines that there are inadequate grounds to support the order, the order shall be vacated.

Louisiana Statutes Annotated

Louisiana Revised Statutes
Title. Professions and Occupations
Chapter 54. Wholesale Drug Distributors
§ 3467. Duties and powers of the board

A. The board shall:

(1) Approve, deny, revoke, or suspend licenses of qualified applicants for licensure as wholesale drug distributors and renew licenses.

(2) Regulate the distribution of legend drugs or legend devices by wholesale drug distributors.

(3) Monitor compliance with all federal and state laws and regulations regarding the distribution of wholesale legend drugs or legend devices by wholesale drug distributors and promulgate rules and regulations relative thereto.

(4) Conduct inspections of wholesale drug facilities.

(5) Conduct hearings on charges relative to the violation of any provision of this Chapter.

(6) Exercise all other powers necessary and proper to perform its duties within the scope of this Chapter.

B. The board may:

(1) Issue subpoenas and administer oaths to persons giving testimony at hearings.

(2) Employ and fix compensation of persons necessary to carry on the work of the board.

(3) Appoint an attorney to represent the board in all matters pertaining to the administration of this Chapter, define his duties, and fix his compensation.

(4) Adopt all rules and regulations necessary to implement the provisions of this Chapter.

(5) Require licensees to provide a legend drug pedigree.

C. The board shall make rules and regulations, not inconsistent with law, and shall take such other action as may be necessary to comply with the requirements set forth in the Federal Food, Drug, and Cosmetic Act, as it pertains to wholesale drug distribution, and with the rules and regulations promulgated pursuant thereto, and other pertinent federal authority.

West's Annotated Code of Maryland
Health Occupations
Title 12. Pharmacists and Pharmacies
Subtitle 6C. Wholesale Distributor Permitting and Prescription Drug Integrity Act
§ 12-6C-01. Definitions

In general

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

Authenticate

(b) "Authenticate" means to affirmatively verify, before any wholesale distribution of a prescription drug occurs, that each transaction listed on the pedigree for the prescription drug has occurred.

Authorized distributor of record

(c) "Authorized distributor of record" means a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drug.

Co-licensed partner

(d) "Co-licensed partner" means a person in a relationship in which two or more persons have the right to engage in the manufacturing or marketing of a prescription drug, consistent with the U.S. Food and Drug Administration's implementation of the federal Prescription Drug Marketing Act.

Co-licensed product

(e) "Co-licensed product" means a product of co-licensed partners.

Designated representative

(f) "Designated representative" means an individual who:

(1) Is designated by a wholesale distributor;
(2) Serves as the primary contact of the wholesale distributor with the Board; and
(3) Is actively involved in and aware of the daily operation of the wholesale distributor.

Drop shipment

(g) "Drop shipment" means the sale of a prescription drug:

(1) To a wholesale distributor by:
(i) The manufacturer of the prescription drug; or
(ii) The manufacturer's co-licensed partner, third party logistics provider, or manufacturer's exclusive distributor; and
(2) Through which:
(i) The wholesale distributor or a pharmacy warehouse takes title to but not physical possession of the prescription drug;
(ii) The wholesale distributor invoices the pharmacy, pharmacy warehouse, or other person authorized by law to dispense or administer the prescription drug to a patient; and
(iii) The pharmacy, pharmacy warehouse, or other authorized person receives delivery of the prescription drug directly from:
1. The manufacturer; or
2. The manufacturer's third party logistics provider or the manufacturer's exclusive distributor.

Facility

(h) "Facility" means a facility of a wholesale distributor where prescription drugs are stored, handled, repackaged, or offered for sale.

Intracompany sales

(i) "Intracompany sales" means a:

(1) Transaction or transfer of prescription drugs between a division, subsidiary, parent, or affiliated or related company under common ownership and control of a corporate entity; or
(2) Transaction or transfer of a co-licensed product between co-licensed partners.

Manufacturer

(j) "Manufacturer" means a person licensed or approved by the U.S. Food and Drug Administration to engage in the manufacture of prescription drugs or prescription devices, consistent with the definition of "manufacturer" under the U.S. Food and Drug Administration's regulations and guidelines implementing the Prescription Drug Marketing Act.

Manufacturer's exclusive distributor

(k) "Manufacturer's exclusive distributor" means a person who:

(1) Contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of the manufacturer; and
(2) Takes title to the manufacturer's prescription drug, but does not have general responsibility to direct the sale or disposition of the manufacturer's prescription drug.

Normal distribution channel

(l) "Normal distribution channel" means a chain of custody for a prescription drug that, directly or by drop shipment, goes:

(1) From:
(i) A manufacturer of the prescription drug; or
(ii) The manufacturer's co-licensed partner, third party logistics provider, or manufacturer's exclusive distributor; and
(2) To:
(i) A pharmacy or other designated person authorized by law to dispense or administer the prescription drug to a patient;
(ii) A wholesale distributor to a pharmacy or other designated person authorized by law to dispense or administer the prescription drug to a patient;
(iii) A wholesale distributor to a pharmacy warehouse to the pharmacy warehouse's intracompany pharmacy or other designated person authorized by law to dispense or administer the prescription drug to a patient;
(iv) A pharmacy warehouse to the pharmacy warehouse's intracompany pharmacy or other designated person authorized by law to dispense or administer the prescription drug to a patient; or
(v) An authorized distributor of record to another authorized distributor of record solely for distribution to an office-based health care practitioner authorized by law to dispense or administer the prescription drug to a patient.

Ongoing relationship

(m) "Ongoing relationship" means a relationship that exists between a wholesale distributor, including any affiliated group of the wholesale distributor, as defined in § 1504 of the Internal Revenue Code, and a manufacturer when the wholesale distributor:

(1) Has a written agreement currently in effect with the manufacturer evidencing the ongoing relationship; and
(2) Is listed on the manufacturer's current list of authorized distributors of record.

Pedigree

(n) "Pedigree" means a document or electronic file containing information that records each wholesale distribution of a prescription drug.

Pharmacy warehouse

(o) "Pharmacy warehouse" means a physical location for storage of prescription drugs that:

(1) Serves as a central warehouse; and
(2) Performs intracompany sales or transfers of the prescription drugs to a group of pharmacies that are under common ownership and control with the pharmacy warehouse.

Prescription drug

(p)(1) "Prescription drug" means any drug required by federal law or regulation to be dispensed only by a prescription.

(2) "Prescription drug" includes:
(i) A biological product; and
(ii) Finished dosage forms and bulk drug substances subject to § 503(b) of the Federal Food, Drug, and Cosmetic Act.
(3) "Prescription drug" does not include blood and blood components intended for transfusion or biological products that are also medical devices.

Prescription device

(q) "Prescription device" means any device required by federal law or regulation to be dispensed only by a prescription.

Repackage

(r)(1) "Repackage" means to repackage or otherwise change the container, wrapper, or labeling of a prescription drug to further the distribution of the prescription drug.

(2) "Repackage" does not include changes to a container, wrapper, or labeling of a prescription drug completed by the pharmacist responsible for dispensing the prescription drug to a patient.

Repackager

(s) "Repackager" means a person who repackages prescription drugs.

Third party logistics provider

(t) "Third party logistics provider" means a person who:

(1) Contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of the manufacturer; but
(2) Does not take title to the prescription drug or have general responsibility to direct the prescription drug's sale or disposition.

Wholesale distribution

(u)(1) "Wholesale distribution" means the distribution of prescription drugs or prescription devices to persons other than a consumer or patient.

(2) "Wholesale distribution" does not include:
(i) Intracompany sales;
(ii) The sale, purchase, distribution, trade, or transfer of a prescription drug or an offer to sell, purchase, distribute, trade, or transfer a prescription drug for emergency medical reasons;
(iii) The sale, purchase, distribution, trade, or transfer of a prescription drug or prescription device by the Department for public health purposes;
(iv) The distribution of samples of a prescription drug by a manufacturer's representative;
(v) Prescription drug returns conducted by a hospital, health care entity, or charitable institution in accordance with 21 C.F.R. § 203.23;
(vi) The sale of minimal quantities of prescription drugs by retail pharmacies to licensed health care practitioners for office use;
(vii) The sale, purchase, or trade of a prescription drug, an offer to sell, purchase, or trade a prescription drug, or the dispensing of a prescription drug in accordance with a prescription;

(viii) The sale, transfer, merger, or consolidation of all or part of the business of a pharmacy to or with another pharmacy, whether accomplished as a purchase and sale of stock or business assets;
(ix) The sale, purchase, distribution, trade, or transfer of a prescription drug from one authorized distributor of record to one additional authorized distributor of record if:
1. The manufacturer has stated in writing to the receiving authorized distributor of record that the manufacturer is unable to supply the prescription drug; and
2. The supplying authorized distributor of record states in writing that the prescription drug being supplied had until that time been exclusively in the normal distribution channel;
(x) The delivery of, or offer to deliver, a prescription drug by a common carrier solely in the common carrier's usual course of business of transporting prescription drugs, if the common carrier does not store, warehouse, or take legal ownership of the prescription drug; or
(xi) The sale or transfer from a retail pharmacy or pharmacy warehouse of expired, damaged, returned, or recalled prescription drugs to the original manufacturer or to a third party returns processor.

Wholesale distributor

(v)(1) "Wholesale distributor" means a person that is engaged in the wholesale distribution of prescription drugs or prescription devices.

(2) "Wholesale distributor" includes:
(i) A manufacturer;
(ii) A repackager;
(iii) An own-label distributor;
(iv) A private-label distributor;
(v) A jobber;
(vi) A broker;
(vii) A warehouse, including a manufacturer's or distributor's warehouse;
(viii) A manufacturer's exclusive distributor or an authorized distributor of record;
(ix) A drug wholesaler or distributor;
(x) An independent wholesale drug trader;
(xi) A third party logistics provider;
(xii) A retail pharmacy that conducts wholesale distribution, if the wholesale distribution business accounts for more than 5% of the retail pharmacy's annual sales; and
(xiii) A pharmacy warehouse that conducts wholesale distribution.

Wholesale distributor permit

(w) "Wholesale distributor permit" means a permit issued by the Board under this subtitle to

distribute prescription drugs or prescription devices into, out of, or within the State as a wholesale distributor.

Annotated Code of Maryland

Health Occupations
Title 12. Pharmacists and Pharmacies
Subtitle 6C. Wholesale Distributor Permitting and Prescription Drug Integrity Act
§ 12-6C-09. Returns or exchanges of prescription drugs; wholesale distributors

In general

(a)(1) A wholesale distributor shall receive prescription drug returns or exchanges from a pharmacy or pharmacy warehouse according to the terms and conditions of the agreement between the wholesale distributor and the pharmacy or pharmacy warehouse.

(2) Returns of expired, damaged, recalled, or otherwise nonsaleable prescription drugs shall be distributed by the receiving wholesale distributor only to either the original manufacturer or a third party returns processor.
(3) Returns or exchanges of prescription drugs, saleable or otherwise, including any redistribution by a receiving wholesaler, are not subject to the pedigree requirements of § 12-6C-10 of this subtitle if they are exempt from the pedigree requirement of the U.S. Food and Drug Administration's currently applicable Prescription Drug Marketing Act guidelines.
(4) Wholesale distributors and pharmacies shall be accountable for:
(i) Administering their returns process; and
(ii) Ensuring that the returns process is secure and does not permit the entry of adulterated and counterfeit product.

Supply of drugs to authorized persons

(b) A wholesale distributor may supply prescription drugs only to a person authorized by law to dispense or receive prescription drugs.

Authorized persons or agents

(c)(1) Except as provided in paragraph (2) of this subsection, a wholesale distributor may deliver prescription drugs only to:

(i) The premises listed on the recipient's license or permit; or

(ii) An authorized person or an agent of an authorized person at the premises of the wholesale distributor if:
1. The identity and authorization of the person or agent is properly established; and
2. This method of delivery is employed only to meet the immediate needs of a particular patient of the authorized person.
(2)(i) Prescription drugs may be supplied to a hospital pharmacy receiving area if a pharmacist or authorized receiving personnel of the hospital pharmacy signs, at the time of delivery, a receipt showing the type and quantity of the prescription drug received.
(ii) Any discrepancy between the type and quantity of the prescription drug indicated on the receipt and the type and quantity of the prescription drug received:
1. Shall be reported to the delivering wholesale distributor by the next business day after the delivery to the hospital pharmacy receiving area; and
2. May be reported to the Board for investigation.

Payments

(d)(1) A wholesale distributor may not accept payment or allow the use of a person's credit to establish an account for the purchase of prescription drugs from any person other than the owner of record, the chief executive officer, or the chief financial officer listed on the license or permit of a person legally authorized to receive prescription drugs.

(2) Any account established for the purchase of prescription drugs shall bear the name of the license or permit holder.

Residence

(e) A wholesale distributor may not operate out of a residence.

Annotated Code of Maryland

Health Occupations
Title 12. Pharmacists and Pharmacies
Subtitle 6C. Wholesale Distributor Permitting and Prescription Drug Integrity Act
§ 12-6C-10. Pedigree requirements; contents

Pedigree required

(a) A person who is engaged in the wholesale distribution of a prescription drug that leaves, or has ever left, the normal distribution channel shall provide, before each wholesale distribution of the prescription drug, a pedigree to the person who receives the prescription drug.

Compliance

(b) A retail pharmacy or pharmacy warehouse shall comply with the requirements of this section only if the pharmacy or pharmacy warehouse engages in the wholesale distribution of a prescription drug in the State.

Normal distribution channel defined

(c)(1) To be considered part of the normal distribution channel, a wholesale distributor, a manufacturer's exclusive distributor, and a manufacturer's third party logistics provider also must be an authorized distributor of record.

(2) Notwithstanding paragraph (1) of this subsection, a pharmacy warehouse that is not an authorized distributor of record shall be considered part of the normal distribution channel.

Authentication

(d) Each person who engages in the wholesale distribution of a prescription drug, including repackagers but excluding the original manufacturer of the finished form of the prescription drug, who is provided a pedigree for the prescription drug and attempts to further distribute the prescription drug, shall authenticate, before any distribution of the prescription drug occurs, that each transaction listed on the pedigree has occurred.

Contents of pedigree

(e) The pedigree shall include:

(1) All necessary identifying information relating to each sale in the chain of distribution of the prescription drug from the manufacturer or the manufacturer's third party logistics provider, co-licensed partner, or manufacturer's exclusive distributor, through acquisition and sale by any wholesale distributor or repackager, until final sale to a pharmacy or other person dispensing or administering the prescription drug, including:
(i) The name, address, telephone number, and if available, electronic mail address, of each owner and each wholesale distributor of the prescription drug;
(ii) The name and address of each location from which the prescription drug was shipped, if different from the owner's;
(iii) Transaction dates; and
(iv) Certification that each recipient has authenticated the pedigree;
(2) The name of the prescription drug;
(3) The dosage form and strength of the prescription drug;
(4) The size of the container;
(5) The number of containers;
(6) The lot number and National Drug Code of the prescription drug; and
(7) The name of the manufacturer of the finished dosage form.

Maintenance

(f) Each pedigree for a prescription drug shall be:

(1) Maintained by the purchaser and the wholesale distributor for 3 years from the date of sale or transfer; and
(2) Available for inspection or use within 5 business days on request of the Board, the Board's designee, or an authorized law enforcement officer.

Annotated Mississippi Code

Title 73. Professions and Vocations
Chapter 21. Pharmacists
Mississippi Pharmacy Practice Act
§ 73-21-126. Promulgation of rules regarding licenses and permits for wholesale distributors, chain pharmacies and re-packagers

(1) The State Board of Pharmacy shall promulgate rules regarding the issuance and renewal of licenses and permits for new or renewal application requirements for both in and out of state wholesale distributors, chain pharmacy warehouses and re-packagers shipping into Mississippi. Requirements for new and on renewal applications, if information has not been previously provided to the board, will include, but not be limited to, the following:

(a) Type of ownership (individual, partnership or corporation);
(b) Names of principal owners or officers and social security numbers;
(c) Names of designated representatives and social security numbers;
(d) Criminal background checks of applicants and designated representatives as required by rule;
(e) Copy of license in home state;
(f) Bond requirements.

(2) The board shall promulgate rules for the establishment of a pedigree or electronic file to be used by wholesale distributors, chain pharmacy warehouses and re-packagers for the purpose of ensuring the integrity of drugs owned, purchased, distributed, returned, transferred and sold when the products leave the normal distribution channel.

(3) The board is authorized to use an outside agency to accredit wholesale distributors and re-packagers, including the National Association of Boards of Pharmacy's (NABP) Verified Accredited Wholesale Distributors (VAWD) program.

(4) Pharmacies shall not be responsible for verification or adjudication of the pedigree for pharmaceuticals.

(5) The board may exempt wholesalers accredited by the VAWD program from the above

requirements.

North Dakota Century Code Annotated

Title 43. Occupations and Professions
Chapter 43-15.3. Wholesale Drug Pedigree
§ 43-15.3-01. Definitions

As used in this chapter, unless the context otherwise requires:

1. "Authentication" means to affirmatively verify before any wholesale distribution of a prescription drug occurs that each transaction listed on the pedigree has occurred.
2. "Authorized distributor of record" means a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drug. An ongoing relationship is deemed to exist between the wholesale distributor and a manufacturer when the wholesale distributor, including any affiliated group of the wholesale distributor as defined in section 1504 of the Internal Revenue Code [26 U.S.C. 1504], complies with the following:
a. The wholesale distributor has a written agreement currently in effect with the manufacturer evidencing the ongoing relationship; and
b. The wholesale distributor is listed on the manufacturer's current list of authorized distributors of record, which is updated by the manufacturer on no less than a monthly basis.
3. "Board" means the state board of pharmacy.
4. "Chain pharmacy warehouse" means a physical location for prescription drugs which acts as a central warehouse and performs intracompany sales or transfers of the drugs to a group of chain pharmacies that have the same common ownership and control.
5. "Colicensed product" means a prescription drug in which two or more parties have the right to engage in the manufacturing or marketing or in the manufacturing and marketing of the drug.
6. "Drop shipment" means the sale of a prescription drug to a wholesale distributor by the manufacturer of the prescription drug, or that manufacturer's colicensed product partner, that manufacturer's third-party logistics provider, or that manufacturer's exclusive distributor, under the terms of which the wholesale distributor or chain pharmacy warehouse takes title but not physical possession of the prescription drug and the wholesale distributor invoices the pharmacy or chain pharmacy warehouse, or other person authorized by law to dispense or administer the drug to a patient, and the pharmacy or chain pharmacy warehouse or other authorized person receives delivery of the prescription drug directly from the manufacturer, or that manufacturer's third-party logistics provider, or that manufacturer's exclusive distributor.
7. "Facility" means a facility of a wholesale distributor where prescription drugs are stored, handled, repackaged, or offered for sale.
8. "Manufacturer" means a person licensed or approved by the federal food and drug administration to engage in the manufacture of drugs or devices.

9. "Manufacturer's exclusive distributor" means any person that contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer and which takes title to that manufacturer's prescription drug, but which does not have general responsibility to direct the sale or disposition of the manufacturer's prescription drug. The manufacturer's exclusive distributor must be licensed as a wholesale distributor under this chapter, and to be considered part of the normal distribution channel also must be an authorized distributor of record.
10. "Normal distribution channel" means a chain of custody for a prescription drug which goes, directly or by drop shipment, from a manufacturer of the prescription drug, from that manufacturer to that manufacturer's colicensed partner, from that manufacturer to that manufacturer's third-party logistics provider, or from that manufacturer to that manufacturer's exclusive distributor to:
a. A pharmacy, to a patient or other designated person authorized by law to dispense or administer the drug to a patient;
b. A wholesale distributor, to a pharmacy, to a patient or other designated person authorized by law to dispense or administer the drug to a patient;
c. A wholesale distributor, to a chain pharmacy warehouse, to that chain pharmacy warehouse's intracompany pharmacy, to a patient or other designated person authorized by law to dispense or administer the drug to a patient; or
d. A chain pharmacy warehouse, to the chain pharmacy warehouse's intracompany pharmacy, to a patient or other designated person authorized by law to dispense or administer the drug to a patient.
11. "Pedigree" means a document or an electronic file containing information that records each distribution of any given prescription drug.
12. "Prescription drug" means any drug, including any biological product, except for blood and blood components intended for transfusion or biological products that are also medical devices, required by federal law, including federal 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 [21 U.S. C. 3539(b)].
13. "Repackage" means repackaging or otherwise changing the container, wrapper, or labeling to further the distribution of a prescription drug, excluding actions completed by the pharmacists responsible for dispensing product to the patient.
14. "Repackager" means a person who repackages.
15. "Third-party logistics provider" means anyone who contracts with a prescription drug manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer, but does not take title to the prescription drug or have general responsibility to direct the prescription drug's sale or disposition. The third-party logistics provider must be licensed as a wholesale distributor under this chapter and to be considered part of the normal distribution channel must also be an authorized distributor of record.

16. "Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient. The term does not include:
a. Intracompany sales of prescription drugs, meaning any transaction or transfer between any division, subsidiary, parent or affiliated or related company under common ownership and control of a corporate entity, or any transaction or transfer between colicensees of a colicensed product.
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.
c. The distribution of prescription drug samples by manufacturers' representatives.
d. Drug returns, when conducted by a hospital, health care entity, or charitable institution in accordance with title 21, Code of Federal Regulations, section 203.23.
e. The sale of minimal quantities of prescription drugs by retail pharmacies to licensed practitioners for office use.
f. The sale, purchase, or trade of a drug; an offer to sell, purchase, or trade a drug; or the dispensing of a drug pursuant to a prescription.
g. The sale, transfer, merger, or consolidation of all or part of the business of a pharmacy from or with another pharmacy, whether accomplished as a purchase and sale of stock or business assets.
h. The sale, purchase, distribution, trade, or transfer of a prescription drug from one authorized distributor of record to one additional authorized distributor of record when the manufacturer has stated in writing to the receiving authorized distributor of record that the manufacturer is unable to supply such prescription drug and the supplying authorized distributor of record states in writing that the prescription drug being supplied had until that time been exclusively in the normal distribution channel.
i. 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, and the common carrier does not store, warehouse, or take legal ownership of the prescription drug.
j. 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.
17. "Wholesale distributor" means anyone engaged in the wholesale distribution of prescription drugs, including, manufacturers; repackagers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses; manufacturer's exclusive distributors; authorized distributors of record; drug wholesalers or distributors; independent wholesale drug traders; specialty wholesale distributors; third-party logistics providers; retail pharmacies that conduct wholesale distribution; and chain pharmacy warehouses that conduct wholesale distribution. To be considered part of the normal distribution channel such wholesale distributor must also be an authorized distributor of record.

North Dakota Century Code Annotated

Title 43. Occupations and Professions
Chapter 43-15.3. Wholesale Drug Pedigree
§ 43-15.3-02. Rulemaking authority

The board shall adopt rules that conform with wholesale drug distributor licensing guidelines adopted by the federal food and drug administration, including rules necessary to carry out the purposes of this chapter, that incorporate and set detailed standards for meeting each of the license prerequisites set forth in this chapter, and that establish reasonable fees to carry out this chapter.

North Dakota Century Code Annotated

Title 43. Occupations and Professions
Chapter 43-15.3. Wholesale Drug Pedigree
§ 43-15.3-03. Wholesale drug distributor licensing requirement--Minimum requirements for licensure

1. A wholesale distributor that engages in the wholesale distribution of prescription drugs must be licensed by the board under this chapter and must be properly licensed in any other state in which the wholesale distributor engages in the distribution of prescription drugs before engaging in wholesale distributions of wholesale prescription drugs in this state. However, information and qualification requirements for licensure beyond that required by federal law or regulation do not apply to manufacturers distributing their own United States food and drug administration-approved drugs, unless particular requirements are deemed necessary and appropriate following rulemaking.
2. The board shall require the following minimum information from each wholesale distributor applying to get a license under subsection 1:
a. The name, full business address, and telephone number of the licensee.
b. All trade or business names used by the licensee.
c. Addresses, telephone numbers, and the names of contact persons for all facilities used by the licensee for the storage, handling, and distribution of prescription drugs.
d. The type of ownership or operation.
e. The name of every owner and operator of the licensee, including:
(1) If an individual, the name of the individual;
(2) If a partnership, the name of each partner, and the name of the partnership;
(3) If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation; and
(4) If a sole proprietorship, the full name of the sole proprietor and the name of the business entity.
f. A list of all licenses and permits issued to the applicant by any other state that authorizes the applicant to purchase or possess prescription drugs.
g. The name of the applicant's designated representative for the facility, together with the personal information statement and fingerprints, required pursuant to subdivision h for the individual.
h. Each individual required by subdivision g to provide a personal information statement and fingerprints shall provide the following information to the state:
(1) The individual's places of residence for the past seven years;
(2) The individual's date and place of birth;
(3) The individual's occupations, positions of employment, and offices held during the past seven years;

(4) The principal business and address of any business, corporation, or other organization in which each office of the individual was held or in which each occupation or position of employment was carried on;
(5) Whether the individual has been, during the past seven years, the subject of any proceeding for the revocation of any license or any criminal violation and, if so, the nature of the proceeding and the disposition of the proceeding;
(6) Whether, during the past seven years, the individual has been enjoined, either temporarily or permanently, by a court of competent jurisdiction from violating any federal or state law regulating the possession, control, or distribution of prescription drugs or criminal violations, together with details concerning any of those events;
(7) A description of any involvement by the individual with any business, including any investments, other than the ownership of stock in a publicly traded company or mutual fund, during the past seven years, which manufactured, administered, prescribed, distributed, or stored pharmaceutical products and any lawsuits in which the businesses were named as a party;
(8) A description of any misdemeanor or felony criminal offense of which the individual, as an adult, was found guilty, regardless of whether adjudication of guilt was withheld or whether the individual pled guilty or nolo contendere. If the individual indicates that a criminal conviction is under appeal and submits a copy of the notice of appeal of that criminal offense, the applicant must, within fifteen days after the disposition of the appeal, submit to the state a copy of the final written order of disposition; and
(9) A photograph of the individual taken in the previous one hundred eighty days.
3. The information required under subsection 2 must be provided under oath.
4. The board may not issue a wholesale distributor license to an applicant, unless the board:
a. Inspects or appoints a third party recognized by the board for the purpose of inspecting the wholesale distribution operations of the facility before initial licensure and continues to inspect periodically thereafter in accordance with a schedule to be determined by the board, but not less than every three years. Manufacturing facilities are exempt from inspection by the board if the manufacturing facilities are currently registered with the federal food and drug administration in accordance with section 510 of the federal Food, Drug, and Cosmetic Act [21 U.S.C. 301]; and
b. Determines that the designated representative meets the following qualifications:
(1) Is at least twenty-one years of age;
(2) Has been employed full time for at least three years in a pharmacy or with a wholesale distributor in a capacity related to the dispensing and distribution of, and recordkeeping relating to, prescription drugs;
(3) Is employed by the applicant full time in a managerial level position;
(4) Is actively involved in and aware of the actual daily operation of the wholesale distributor;
(5) Is physically present at the facility of the applicant during regular business hours, except when the absence of the designated representative is authorized, including sick leave and vacation leave;

(6) Is serving in the capacity of a designated representative for only one applicant at a time, except where more than one licensed wholesale distributor is colocated in the same facility and the wholesale distributors are members of an affiliated group, as defined in section 1504 of the Internal Revenue Code [26 U.S.C. 1504];
(7) Does not have any convictions under any federal, state, or local laws relating to wholesale or retail prescription drug distribution or distribution of controlled substances; and
(8) Does not have any felony conviction under federal, state, or local laws.
5. The board shall submit the fingerprints provided by an individual with a license application for a statewide and nationwide criminal history background record check. The nationwide criminal history background record check must be conducted in the manner provided in section 12-60-24. All costs associated with the background check are the responsibility of the applicant.
6. The board shall require every wholesale distributor applying for a license to submit a bond of at least one hundred thousand dollars, or other equivalent means of security acceptable to the state, including an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to a fund established by the state under subsection 7. A chain pharmacy warehouse that is engaged only in intracompany transfers is not subject to the bond requirement. The purpose of the bond is to secure payment of any fines or penalties imposed by the state and any fees and costs incurred by the state regarding that license which are authorized under state law and which the licensee fails to pay thirty days after the fines, penalties, or costs become final. The state may make a claim against the bond or security until one year after the licensee's license ceases to be valid. A single bond may cover all facilities operated by the applicant in the state. Any chain pharmacy warehouse that is engaged only in intracompany transfers is exempt from the bond requirement.
7. The board shall establish a fund in which to deposit the wholesale distributor bonds. Money in the fund is appropriated to the board on a continuing basis.
8. If a wholesale distributor distributes prescription drugs from more than one facility, the wholesale distributor shall obtain a license for each facility.
9. In accordance with each licensure renewal, the board shall send to each wholesale distributor licensed under this section a form setting forth the information that the wholesale distributor provided pursuant to subsection 2. Within thirty days of receiving the form, the wholesale distributor must identify and state under oath to the state licensing authority all changes or corrections to the information that was provided under subsection 2. Changes in, or corrections to, any information in subsection 2 must be submitted to the board as required by that authority. The board may suspend, revoke, or refuse to renew the license of a wholesale distributor if the board determines that the wholesale distributor no longer qualifies for the license issued under this section.
10. The designated representative identified pursuant to subdivision g of subsection 2 must receive and complete continuing training in applicable federal and state laws governing wholesale distribution of prescription drugs.

11. Information provided under subdivision h of subsection 2 may not be disclosed to any person other than a government agency that needs the information for licensing or monitoring purposes.

North Dakota Century Code Annotated

Title 43. Occupations and Professions
Chapter 43-15.3. Wholesale Drug Pedigree
§ 43-15.3-04. Requirements to distribute prescription drugs

1. A person may not engage in wholesale distributions of prescription drugs without, after December 31, 2007, obtaining and maintaining accreditation or certification from the national association of boards of pharmacy's verified accredited wholesale distributor or an accreditation body approved by the board under subsection 4, obtaining and maintaining a license issued by the board, and paying any reasonable fee required by the board. By action of the board, the deadline may be extended through December 31, 2008.
2. The board may not issue or renew the license of a wholesale drug distributor that does not comply with this chapter. The board shall require a separate license for each facility or location where wholesale distribution operations are conducted. An agent or employee of any licensed wholesale drug distributor does not need a license and may lawfully possess pharmaceutical drugs when acting in the usual course of business or employment. The issuance of a license under this chapter does not affect tax liability imposed by the tax department on any wholesale drug distributor.
3. The board may adopt rules that permit out-of-state wholesale drug distributors to obtain a license on the basis of reciprocity if an out-of-state wholesale drug distributor possesses a valid license granted by another state and the legal standards for licensure in the other state are comparable to the standards under this chapter and the other state extends reciprocity to wholesale drug distributors licensed in this state. However, if the requirements for licensure under this chapter are more restrictive than the standards of the other state, the out-of-state wholesale drug distributor must comply with the additional requirements of this chapter to obtain a license under this chapter.
4. The board may adopt rules to approve an accreditation body to evaluate a wholesale drug distributor's operations to determine compliance with professional standards, this chapter and any other applicable law, and perform inspections of each facility and location where wholesale distribution operations are conducted by the wholesale drug distributor.

North Dakota Century Code Annotated

Title 43. Occupations and Professions
Chapter 43-15.3. Wholesale Drug Pedigree
§ 43-15.3-05. Restrictions on transactions

1. A wholesale distributor shall receive prescription drug returns or exchanges from a pharmacy or chain pharmacy warehouse under the terms and conditions of the agreement between the wholesale distributor and the pharmacy or between the wholesale distributor and the chain pharmacy warehouse, including the returns of expired, damaged, and recalled pharmaceutical product to either the original manufacturer or a third-party returns processor, and the returns or exchanges are not subject to the pedigree requirement of section 43-15.3-06 if they are exempt from pedigree under the federal food and drug administration's currently applicable guidance for the federal Prescription Drug Marketing Act of 1987 [Pub. L. 100-293; 102 Stat. 95]. Wholesale distributors and pharmacies must ensure that the aspects of this operation are secure and do not permit the entry of adulterated and counterfeit product.
2. A manufacturer or wholesale distributor shall furnish prescription drugs only to a person licensed by the appropriate state licensing authorities. Before furnishing prescription drugs to a person not known to the manufacturer or wholesale distributor, the manufacturer or wholesale distributor shall affirmatively verify that the person is legally authorized to receive the prescription drugs by contacting the appropriate state licensing authorities.
3. Prescription drugs furnished by a manufacturer or wholesale distributor may be delivered only to the premises listed on the license. The manufacturer or wholesale distributor may furnish prescription drugs to an individual or agent of that individual at the premises of the manufacturer or wholesale distributor if:
a. The identity and authorization of the recipient are properly established; and
b. This method of receipt is employed only to meet the immediate needs of a particular patient of the authorized individual.
4. Prescription drugs may be furnished to a hospital pharmacy receiving area if a pharmacist or authorized receiving personnel signs, at the time of delivery, a receipt showing the type and quantity of the prescription drug so received. Any discrepancy between receipt and the type and quantity of the prescription drug actually received must be reported to the delivering manufacturer or wholesale distributor by the next business day after the delivery to the pharmacy receiving area.
5. A manufacturer or wholesale distributor may not accept payment for or allow the use of a person's credit to establish an account for the purchase of prescription drugs from any individual other than the owner of record, the chief executive officer, or the chief financial officer listed on the license of an individual legally authorized to receive prescription drugs. Any account established for the purchase of prescription drugs must bear the name of the licensee.

North Dakota Century Code Annotated

Title 43. Occupations and Professions
Chapter 43-15.3. Wholesale Drug Pedigree
§ 43-15.3-06. Pedigree

1. Each person who is engaged in wholesale distribution of prescription drugs, including repackagers but excluding the original manufacturer of the finished form of the prescription drug which leave or have ever left the normal distribution channel, before each wholesale distribution of the drug, must provide a pedigree to the person who receives the drug.
a. A retail pharmacy or chain pharmacy warehouse must comply with the requirements of this section only if the pharmacy or chain pharmacy warehouse engages in wholesale distribution of prescription drugs.
b. The board shall determine by July 1, 2009, a targeted implementation date for electronic track and trace pedigree technology. The determination must be based on consultation with manufacturers, distributors, and pharmacies responsible for the sale and distribution of prescription drug products in this state. After consultation with interested stakeholders and before implementation of the electronic track and trace pedigree technology, the board must determine that the technology is universally available across the entire prescription pharmaceutical supply chain. The implementation date for the mandated electronic track and trace pedigree technology may not be before July 1, 2010, and may be extended by the board in one-year increments if it appears the technology is not universally available across the entire prescription pharmaceutical supply chain.
2. Each person engaged in the wholesale distribution of a prescription drug, including a repackager but excluding the original manufacturer of the finished form of the prescription drug, that is provided a pedigree for a prescription drug and attempts to further distribute that prescription drug shall verify affirmatively before any distribution of a prescription drug occurs that each transaction listed on the pedigree has occurred.
3. The pedigree must:
a. Include all necessary identifying information concerning each sale in the chain of distribution of the product from the manufacturer, or the manufacturer's third-party logistics provider, colicensed product partner, or manufacturer's exclusive distributor, through acquisition and sale by any wholesale distributor or repackager, until final sale to a pharmacy or other person dispensing or administering the drug. At minimum, the necessary chain of distribution information must include:
(1) The name, address, telephone number, and if available, the e-mail address, of each owner of the prescription drug, and each wholesale distributor of the prescription drug;
(2) The name and address of each location from which the product was shipped, if different from the owner's;
(3) The transaction dates; and
(4) A certification that each recipient has authenticated the pedigree.

b. At minimum, the pedigree must also include the:
(1) Name of the prescription drug;
(2) Dosage form and strength of the prescription drug;
(3) Size of the container;
(4) Number of containers;
(5) Lot number of the prescription drug;
(6) Name of the manufacturer of the finished dosage form; and
(7) National drug code (NDC) number.
4. Each pedigree or electronic file must be:
a. Maintained by the purchaser and the wholesale distributor for three years from the date of sale or transfer; and
b. Available for inspection or use within five business days upon a request of an authorized officer of the law or the board.
5. The board shall adopt rules and a form relating to the requirements of this section.

North Dakota Century Code Annotated

Title 43. Occupations and Professions
Chapter 43-15.3. Wholesale Drug Pedigree
§ 43-15.3-07. Order to cease distribution

1. The board shall issue an order requiring the appropriate person, including the distributors or retailers of the drug, to immediately cease distribution of the drug within the state if the board finds that there is a reasonable probability that:
a. A wholesale distributor, other than a manufacturer, has violated a provision in this chapter or falsified a pedigree or sold, distributed, transferred, manufactured, repackaged, handled, or held a counterfeit prescription drug intended for human use;
b. The prescription drug at issue as a result of a violation in subdivision a could cause serious, adverse health consequences or death; and
c. Other procedures would result in unreasonable delay.
2. An order under subsection 1 must provide the individual subject to the order with an opportunity for an informal hearing, to be held not later than ten days after the date of the issuance of the order, on the actions required by the order. If, after providing an opportunity for such a hearing, the board determines that inadequate grounds exist to support the actions required by the order, the board shall vacate the order.

North Dakota Century Code Annotated

Title 43. Occupations and Professions
Chapter 43-15.3. Wholesale Drug Pedigree
§ 43-15.3-08. Prohibited acts--Penalty

1. Except as otherwise provided under section 43-15.3-09, it is a class B misdemeanor for a person to perform or cause the performance of or aid and abet any of the following acts in this state:
a. Failing to obtain a license under this chapter or operating without a valid license when a license is required by this chapter.
b. If the requirements of subsection 1 of section 43-15.3-05 are applicable and are not met, purchasing or otherwise receiving a prescription drug from a pharmacy.
c. If a state license is required under subsection 2 of section 43-15.3-05, selling, distributing, or transferring a prescription drug to a person that is not authorized under the law of the jurisdiction in which the person receives the prescription drug to receive the prescription drug.
d. Failing to deliver prescription drugs to specified premises, as required by subsection 3 of section 43-15.3-05.
e. Accepting payment or credit for the sale of prescription drugs in violation of subsection 5 of section 43-15.3-05.
f. Failing to maintain or provide pedigrees as required by this chapter.
g. Failing to obtain, pass, or authenticate a pedigree, as required by this chapter.
h. Providing the board or any of the board's representatives or any federal official with false or fraudulent records or making false or fraudulent statements regarding any matter within the provisions of this chapter.
i. Obtaining or attempting to obtain a prescription drug by fraud, deceit, misrepresentation, or engaging in misrepresentation or fraud in the distribution of a prescription drug.
j. Except for the wholesale distribution by manufacturers of a prescription drug that has been delivered into commerce pursuant to an application approved under federal law by the federal food and drug administration, manufacturing, repacking, selling, transferring, delivering, holding, or offering for sale any prescription drug that is adulterated, misbranded, counterfeit, suspected of being counterfeit, or has otherwise been rendered unfit for distribution.
k. Except for the wholesale distribution by a manufacturer of a prescription drug that has been delivered into commerce under an application approved under federal law by the federal food and drug administration, adulterating, misbranding, or counterfeiting any prescription drug.
l. Receiving any prescription drug that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit, or suspected of being counterfeit, and the delivery or proffered delivery of such drug for pay or otherwise.
m. Altering, mutilating, destroying, obliterating, or removing the whole or any part of the labeling of a prescription drug or the commission of any other act with respect to a prescription drug that results in the prescription drug being misbranded.

2. The prohibited acts in subsection 1 do not include a prescription drug manufacturer or agent of a prescription drug manufacturer obtaining or attempting to obtain a prescription drug for the sole purpose of testing the prescription drug for authenticity.

North Dakota Century Code Annotated

Title 43. Occupations and Professions
Chapter 43-15.3. Wholesale Drug Pedigree
§ 43-15.3-09. Penalties

1. The board may impose the following sanctions if, after a hearing under chapter 28-32, the board finds that a person has violated section 43-15.3- 08:
a. Revoke the wholesale drug distributor's license issued under this chapter if the person is a wholesale drug distributor; or
b. Assess a civil penalty against the person. A civil penalty assessed may not exceed ten thousand dollars per violation.
2. The board, upon a showing of a violation of this chapter, may revoke, suspend, or limit a license issued under this chapter after a proceeding under chapter 28-32. After a proceeding under chapter 28-32, the board may assess a civil penalty against a licensed wholesale drug distributor of not more than ten thousand dollars for each occurrence. If the licensed wholesale drug distributor fails to pay the civil penalty within the time specified by the board, the board may suspend the license without additional proceedings.
3. Upon application by the board, a court may grant an injunction, a restraining order, or other order to enjoin a person from offering to engage or engaging in the performance of any practices for which a permit or license is required by any applicable federal or state law including this chapter, upon a showing that the practices were or are likely to be performed or offered to be performed without a permit or license. An action brought under this subsection must be commenced either in the county where the conduct occurred or is likely to occur or in the county in the state where the defendant resides. An action brought under this subsection is in addition to any other penalty provided by law and may be brought concurrently with other actions to enforce this chapter.
4. A person that knowingly purchases or receives a prescription drug through any source other than a person licensed under this chapter, including a wholesale distributor, manufacturer, pharmacy distributor, or pharmacy commits a class A misdemeanor. A subsequent unrelated violation of this subsection is a class C felony.
5. A person who knowingly or intentionally engages in the wholesale distribution of a prescription drug without a license issued under this chapter commits a class C felony. A person is guilty of a class C felony if that person engages in the wholesale distribution of a prescription drug and with intent to defraud or deceive fails to obtain or deliver to another person a complete and accurate required pedigree concerning a prescription drug before obtaining the prescription drug from another person or transferring the prescription drug to another person or falsely swears or certifies that the person has authenticated any documents to the wholesale distribution of prescription drugs.
6. A person is guilty of a class C felony if that person engages in the wholesale distribution of a prescription drug and knowingly or intentionally:

a. Destroys, alters, conceals, or fails to maintain a complete and accurate required pedigree concerning a prescription drug in the person's possession;
b. Purchases or receives prescription drugs from a person not authorized to distribute prescription drugs in wholesale distribution;
c. Sells, barters, brokers, or transfers a prescription drug to a person not authorized to purchase the prescription drug in the jurisdiction in which the person receives the prescription drug in a wholesale distribution;
d. Forges, counterfeits, or falsely creates a pedigree;
e. Falsely represents a factual matter contained in a pedigree; or
f. Fails to record material information required to be recorded in a pedigree.
7. A person is guilty of a class C felony if that person engages in the wholesale distribution of a prescription drug and possesses a required pedigree concerning a prescription drug, knowingly or intentionally fails to authenticate the matters contained in the pedigree as required, and distributes or attempts to further distribute the prescription drug.

Revised Statutes of Nebraska Annotated

Chapter 71. Public Health and Welfare
Article 74. Wholesale Drug Distributor Licensing
71-7440. Pedigree, defined

Pedigree means a written or electronic documentation of every transfer of a prescription drug as provided in sections 71-7455 and 71-7456.

Revised Statutes of Nebraska Annotated

Chapter 71. Public Health and Welfare
Article 74. Wholesale Drug Distributor Licensing
71-7455. Records; pedigree; requirements

(1) A wholesale drug distributor engaged in the wholesale distribution of prescription drugs in this state shall establish and maintain accurate records of all transactions regarding the receipt and distribution or other disposition of prescription drugs as provided in this section.

(2) The department shall adopt and promulgate rules and regulations to require that all prescription drugs that leave the normal distribution chain be accompanied by a paper or electronic pedigree as provided in section 71- 7456. Such rules and regulations shall be adopted and promulgated no later than July 1, 2007.

(3) The department shall develop standards and requirements for electronic pedigrees in order to effectively authenticate, track, and trace prescription drugs. Prior to the development of such standards and requirements, the department shall consult with the federal Food and Drug Administration, manufacturers, wholesale drug distributors, pharmacies, and other interested parties regarding the feasibility and the ways, means, and practicality of requiring that all prescription drugs that leave the normal distribution chain be accompanied by an electronic pedigree. The standards and requirements may prescribe the information required to be included as part of the electronic pedigree. Such standards and requirements shall be developed no later than July 1, 2008. All prescription drugs that leave the normal distribution chain shall not be required to be accompanied solely by an electronic pedigree prior to such date.

(4) A retail pharmacy or chain pharmacy warehouse shall comply with the requirements of this section only if the pharmacy or chain pharmacy warehouse engages in the wholesale distribution of prescription drugs in this state.

(5) A wholesale drug distributor, other than the original manufacturer of the finished form of the prescription drug, shall verify all transactions listed on the pedigree before attempting to further distribute such drug.

West's Revised Statutes of Nebraska Annotated

Chapter 71. Public Health and Welfare
Article 74. Wholesale Drug Distributor Licensing
71-7456. Pedigree; contents

(1) The pedigree required under section 71-7455 shall include all necessary identifying information concerning each sale or other transfer in the chain of distribution of the prescription drug from the manufacturer, through acquisition and sale by any wholesale drug distributor or repackager, until final sale to a pharmacy or other person dispensing or administering such drug, including, but not limited to:

(a) Name of the prescription drug;
(b) Dosage form and strength of the prescription drug;
(c) Size of the container;
(d) Number of containers;
(e) Lot number of the prescription drug;
(f) Name of the original manufacturer of the finished dosage form of the prescription drug;
(g) Name, address, telephone number, and if available, the email address of each owner of the prescription drug and each wholesale drug distributor who does not take title to the prescription drug;
(h) Name and address of each location from which the prescription drug was shipped if different from the owner's;
(i) Transaction dates;
(j) Certification that each recipient has authenticated the pedigree;
(k) Name of any repackager, if applicable; and
(l) Name and address of person certifying the delivery.

(2) Each paper or electronic pedigree shall be maintained by the purchaser and the wholesale drug distributor for three years from the date of sale or transfer and available for inspection or use upon request of law enforcement or an authorized agent of the department.

Revised Statutes of Nebraska Annotated

Chapter 71. Public Health and Welfare
Article 74. Wholesale Drug Distributor Licensing
71-7460. Order to cease distribution

(1) If the department finds there is a reasonable probability that (a) a wholesale drug distributor has falsified a pedigree or has sold, distributed, transferred, manufactured, repackaged, handled, or held a counterfeit prescription drug intended for human use and (b) such drug could cause serious, adverse health consequences or death, the department shall issue an order to immediately cease distribution of such drug.

(2) Persons subjected to any order issued by the department under this section shall be provided with notice and an opportunity for an informal hearing to be held not later than ten days after the date the order was issued. If the department determines, after such hearing, that inadequate grounds exist to support the actions required by the order, the department shall vacate the order.

New Jersey Statutes Annotated

Title 24. Food and Drugs
Subtitle 1. Food and Drugs
Chapter 6B. Drugs, Manufacturers and Wholesalers
24:6B-29. Violations applicable to prescription drug distribution; penalties

a. A person is guilty of a crime of the third degree if the person:

(1) engages in the wholesale distribution of prescription drugs and, with intent to defraud or deceive, fails to deliver to another person a complete and accurate pedigree, when required, prior to transferring the prescription drug to another person;

(2) engages in the wholesale distribution of prescription drugs and, with intent to defraud or deceive, fails to acquire a complete and accurate pedigree, when required, concerning a prescription drug prior to obtaining the prescription drug from another person;

(3) engages in the wholesale distribution of prescription drugs, and knowingly destroys, alters, conceals or fails to maintain a complete and accurate pedigree concerning any prescription drug in the person's possession;

(4) engages in the wholesale distribution of prescription drugs and possesses pedigree documents required by the department, and knowingly fails to authenticate the matters contained in the documents as required, but nevertheless distributes or attempts to further distribute prescription drugs;

(5) engages in the wholesale distribution of prescription drugs and, with intent to defraud or deceive, falsely swears or certifies that the person has authenticated any documents related to the wholesale distribution of prescription drugs;

(6) engages in the wholesale distribution of prescription drugs and knowingly forges, counterfeits or falsely creates any pedigree, and falsely represents any factual matter contained on any pedigree or knowingly omits to record material information required to be recorded in a pedigree;

(7) engages in the wholesale distribution of prescription drugs and knowingly purchases or receives prescription drugs from a person not authorized to distribute prescription drugs in wholesale distribution;

(8) engages in the wholesale distribution of prescription drugs and knowingly sells, barters, brokers or transfers prescription drugs to a person not authorized to purchase prescription drugs, under the jurisdiction in which the person receives the prescription drugs in a wholesale distribution;

(9) knowingly possesses, actually or constructively, any amount of a contraband prescription drug and knowingly sells or delivers, or possesses with intent to sell or deliver, any amount of the contraband prescription drug;

(10) knowingly forges, counterfeits or falsely creates any label for a prescription drug or falsely represents any factual matter contained in any label of a prescription drug; or

(11) knowingly manufactures, purchases, sells, delivers or brings into the State, or is knowingly in actual or constructive possession of any amount of a contraband prescription drug.

b. A person who knowingly manufactures, purchases, sells, delivers or brings into the State, or is knowingly in actual or constructive possession of, any amount of a contraband prescription drug, and whose actions as described in this subsection result in the death of a person, is guilty of a crime of the first degree.

c. A person who engages in the wholesale distribution of prescription drugs without having registered with the department as required pursuant to this act is guilty of a disorderly persons offense.

New Jersey Statutes Annotated

Title 24. Food and Drugs
Subtitle 1. Food and Drugs
Chapter 6B. Drugs, Manufacturers and Wholesalers
24:6B-27. Records and lists of wholesale prescription drug distributors; reporting counterfeiting activities or shortages or losses of prescription drugs

a. A person who receives or passes a pedigree or certification pursuant to this act shall maintain the document or record for three years from receipt or passing of the document or record.

b. A wholesale distributor shall:

(1) establish and maintain records of all transactions regarding the receipt, distribution or other disposition of all prescription drugs, including the dates of receipt and distribution or other disposition of the prescription drugs; and

(2) make its inventories and other records available for inspection and copying by an authorized official of any local, State or federal governmental agency for a period of three years following the creation of those records.

c. A wholesale distributor shall ensure that its records as described in this section:

(1) if kept at the inspection site or immediately retrievable by computer or other electronic means, are readily available for authorized inspection during the retention period; and

(2) if kept at a central location apart from the inspection site and not electronically retrievable, are made available for inspection within two business days of a request by an authorized official of any State or federal governmental agency charged with enforcement of the provisions of this

act.

d. A wholesale distributor shall maintain an ongoing list of persons with whom it does business related to prescription drugs.

e. A wholesale distributor shall establish and maintain procedures for reporting counterfeit or suspected counterfeit prescription drugs, or counterfeiting or suspected counterfeiting activities to the department.

f. A wholesale distributor shall maintain a system for mandatory reporting to the department of significant shortages or losses of prescription drugs when diversion of prescription drugs is known or suspected.

New Jersey Statutes Annotated

Title 24. Food and Drugs
Subtitle 1. Food and Drugs
Chapter 6B. Drugs, Manufacturers and Wholesalers
24:6B-23. Authentication of prescription drug distributions; drug quarantines; random authentications

a. (1) A wholesale distributor shall authenticate every distribution of a prescription drug back to the manufacturer if the wholesale distributor has reason to believe that a prescription drug purchased from another wholesale distributor is adulterated, misbranded or counterfeit.

(2) A wholesale distributor who distributed a prescription drug that is the subject of an authentication pursuant to this section shall provide, upon request, information regarding the distribution of the prescription drug, including: date of purchase; sales invoice number; and contact information for the wholesale distributor who sold the prescription drug, including the name, address, telephone number and e-mail address, if available.

(3) If a wholesale distributor is unable to authenticate each transfer, the wholesale distributor shall quarantine the prescription drug and report this to the department within 14 days after completing the attempted authentication.

(4) If the wholesale distributor satisfactorily completes the authentication, the wholesale distributor shall maintain records of the authentication for two years, and produce them to the department and the Department of Law and Public Safety, upon request.

b. (1) A wholesale distributor shall conduct annual random authentications on at least 10% of pedigrees as required by this act.

(2) A wholesale distributor shall conduct annual random authentications on at least 90% of the

pedigrees of prescription drugs designated on the specified list of susceptible products for which a pedigree is required.

(3) A wholesale distributor and a manufacturer from whom other wholesale distributors have purchased prescription drugs shall cooperate with random authentications of pedigrees and provide requested information in a timely manner.

New Jersey Statutes Annotated

Title 24. Food and Drugs
Subtitle 1. Food and Drugs
Chapter 6B. Drugs, Manufacturers and Wholesalers
24:6B-21. Duties of selling wholesale distributor of prescription drugs

a. Before the sale or return of a prescription drug to another wholesale distributor, a selling wholesale distributor shall provide a pedigree or a certification in accordance with the following specifications:

(1) if the seller is an authorized distributor of record, a pedigree for each prescription drug that is included on the specified list of susceptible products and was not purchased directly from the manufacturer; or

(2) if the seller is neither the prescription drug manufacturer nor an authorized distributor of record, a pedigree for each prescription drug that is distributed.

b. A wholesale distributor shall provide for the secure and confidential storage of information with restricted access and policies and procedures to protect the integrity and confidentiality of the information.

c. A wholesale distributor shall conduct business in a commercial location, and not a personal dwelling or residence.

d. A wholesale distributor shall provide and maintain appropriate inventory controls in order to detect and document any theft, counterfeiting or diversion of prescription drugs.

New Jersey Statutes Annotated

Title 24. Food and Drugs
Subtitle 1. Food and Drugs
Chapter 6B. Drugs, Manufacturers and Wholesalers
24:6B-14. Definitions applicable to wholesale prescription drug distribution

As used in sections 5 through 24 of P.L.2005, c.206 (C.24:6B-14 et seq.):

"Adulterated" means a prescription drug that is adulterated pursuant to R.S.24:5-10.

"Authenticate" means to affirmatively verify before any distribution of a prescription drug that each transaction listed on the pedigree has occurred.

"Authorized distributor" or "authorized distributor of record" means a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's product. An ongoing relationship is deemed to exist when the wholesale distributor, or any member of its affiliated group as defined in section 1504 of the Internal Revenue Code of 1986 (26 U.S.C. s.1504): is listed on the manufacturer's list of authorized distributors; has a written agreement currently in effect with the manufacturer; or has a verifiable account with the manufacturer and meets or exceeds the following transaction or volume requirement thresholds:

a. 5,000 sales units per company within 12 months; or

b. 12 purchases by invoice at the manufacturer's minimum purchasing requirement per invoice within 12 months.

"Centralized prescription processing" means the processing by a pharmacy of a request from another pharmacy to fill or refill a prescription drug order or to perform processing functions

such as dispensing, drug utilization review, claims adjudication, refill authorizations and therapeutic interventions.

"Chain pharmacy distribution center" means a distribution facility or warehouse owned by and operated for the primary use of a group of pharmacies that are under common or affiliated control or ownership.

"Commissioner" means the Commissioner of Health and Senior Services.

"Contraband" with respect to a prescription drug means: counterfeit; stolen; misbranded; obtained by fraud; purchased by a nonprofit institution for its own use and placed in commerce in violation of the own use agreement; or the existing documentation or pedigree, if required, for the prescription drug has been forged, counterfeited, falsely created, or contains any altered, false or misrepresented information.

"Counterfeit prescription drug" means a prescription drug, or the container, shipping container, seal or labeling thereof, which, without authorization, bears the trademark, trade name or other identifying mark, imprint, or any likeness thereof, of a manufacturer, processor, packer or distributor other than the person or persons who in fact manufactured, processed, packed or distributed such prescription drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other manufacturer, processor, packer or distributor.

"DEA" means the federal Drug Enforcement Administration.

"Department" means the Department of Health and Senior Services.

"Designated representative" means an individual who is designated by a wholesale prescription

drug distributor to serve as the primary contact person for the wholesale distributor with the department, and who is responsible for managing the company's operations at that licensed location.

"Distribute" means to sell, offer to sell, deliver, offer to deliver, broker, give away or transfer a prescription drug, whether by passage of title, physical movement, or both. The term does not mean to: dispense or administer; deliver or offer to deliver in the usual course of business as a common carrier or logistics provider; or provide a sample to a patient by a licensed practitioner, a health care professional acting at the direction and under the supervision of a practitioner, or the pharmacist of a health care facility licensed pursuant to P.L.1971, c. 136 (C.26:2H-1 et seq.) acting at the direction of a practitioner.

"Drug" means: a. an article or substance recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States or official National Formulary, or any supplement to any of them; b. an article or substance intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; c. an article or substance, other than food, intended to affect the structure of any function of the body of man or animals; and d. an article or substance intended for use as a component of any article or substance specified in clause a., b. or c.; but does not include devices or their components, parts or accessories. Drug includes a prefilled syringe or needle.

"Immediate container" means a container but does not include package liners.

"Logistics provider" means an entity that receives drugs from the original manufacturer and delivers them at the direction of that manufacturer, and does not purchase, sell, trade or take title to the drugs.

"Misbranded" means a prescription drug with respect to which the label is: false or misleading in any particular; does not bear the name and address of the manufacturer, packer or distributor and does not have an accurate statement of the quantities of the active ingredients; or does not show

an accurate monograph for legend drugs; or is misbranded based upon other considerations as provided in the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. s.301 et seq.

"Pedigree" means a statement or record identifying each previous sale of a prescription drug, from the sale by a manufacturer through acquisition and sale by a wholesale distributor, including each distribution to an authorized distributor, starting with the last authorized distributor, or the manufacturer if the prescription drug has not been purchased previously by an authorized distributor or is a prescription drug on the specified list of susceptible products. A pedigree shall include the following information: the proprietary and established name of the prescription drug; the dosage; container size; number of containers; the date, business name and address of all parties to each prior transaction involving the prescription drug starting with the last authorized distributor or the manufacturer if the prescription drug has not been purchased previously by an authorized distributor or is a prescription drug on the specified list of susceptible products.

"Repackage" means changing the container, wrapper, quantity or labeling of a prescription drug to further its distribution.

"Sales unit" means the unit of measure that the manufacturer uses to invoice its customer for the particular product.

"Specified list of susceptible products" means a specific list of prescription drugs, to be determined by the commissioner, that are considered to be potential targets for adulteration, counterfeiting or diversion, which the commissioner shall provide to wholesale distributors as prescription drugs are added to or removed from the list, along with notification of those changes.

"Wholesale distribution" means the distribution of prescription drugs in or into the State by a wholesale distributor to a person other than a consumer or patient, and includes transfers of prescription drugs from one pharmacy to another pharmacy if the value of the goods transferred

exceeds 5% of total prescription drug sales revenue of either the transferor or transferee pharmacy during any consecutive 12-month period. The term excludes:

a. the sale, purchase or trade of a prescription drug, an offer to sell, purchase, or trade a prescription drug, or the dispensing of a prescription drug pursuant to a prescription;

b. the sale, purchase or trade of a prescription drug, or an offer to sell, purchase or trade a prescription drug for emergency medical reasons;

c. the sale, purchase or trade of a prescription drug, or an offer to sell, purchase or trade a prescription drug by pharmacies, chain pharmacy distribution centers, and the associated transfer of goods between chain pharmacy distribution centers and their servicing wholesale distributors or manufacturers;

d. intracompany transactions or sales among wholesale distributors, chain pharmacy distribution centers, and pharmacies, and which are limited to those sales or transfers of a prescription drug among members of an affiliated group, even if the members of the affiliated group are separate legal entities;

e. the sale, purchase or trade of a prescription drug, or an offer to sell, purchase or trade a prescription drug among hospitals or other health care entities licensed pursuant to P.L.1971, c. 136 (C.26:2H-1 et seq.) that are under common control;

f. the sale, purchase or trade of a prescription drug, or offer to sell, purchase or trade a prescription drug by a charitable organization exempt from taxation pursuant to section 501(c)(3) of the Internal Revenue Code of 1986 (26 U.S.C. s.501(c)(3)) to a nonprofit affiliate of the organization;

g. the purchase or other acquisition by a hospital or other similar health care entity licensed pursuant to P.L.1971, c. 136 (C.26:2H-1 et seq.) that is a member of a group purchasing organization of a prescription drug for its own use from the group purchasing organization or from other hospitals or similar health care entities that are members of these organizations;

h. the transfer of prescription drugs between pharmacies pursuant to a centralized prescription processing agreement;

i. the distribution of prescription drug samples by manufacturers' representatives or wholesale distributors' representatives;

j. the sale, purchase or trade of blood and blood components intended for transfusion;

k. prescription drug returns, when conducted by a pharmacy, chain pharmacy distribution center, hospital, health care entity licensed pursuant to P.L.1971, c. 136 (C.26:2H-1 et seq.) or charitable institution in accordance with regulations established by the commissioner;

l. the sale of minimal quantities of prescription drugs by retail pharmacies to licensed practitioners for office use;

m. the stockpiling and distribution of drugs under the authorization of a State agency for the purpose of providing those products in an emergency situation; or

n. 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.

"Wholesale distributor" means any person, other than the manufacturer, pharmacy, logistics provider, or chain pharmacy distribution center, engaged in wholesale distribution of prescription drugs in or into the State and includes repackagers, own-label distributors, private-label distributors, jobbers, brokers, warehouses including distributors' warehouses, independent prescription drug traders, and retail pharmacies that conduct wholesale distribution.

New Mexico Statutes Annotated

Chapter 26. Drugs and Cosmetics
Article 1. Drugs and Cosmetics
§ 26-1-18. Promulgating regulations; procedure

A. The board may promulgate regulations for the efficient enforcement of the New Mexico Drug, Device and Cosmetic Act. The board shall conform the regulations promulgated under the New Mexico Drug, Device and Cosmetic Act, insofar as practical, with regulations promulgated under the federal act as defined in Section 26-1-2 NMSA 1978.

B. The board shall, by regulation, declare a substance a "dangerous drug" when necessary, and notification shall be sent to all registered pharmacies in the state within sixty days of the adoption of the regulation.

C. The board shall promulgate the requirements for a pedigree.

D. All regulations promulgated by the board shall be in accordance with the Uniform Licensing Act.

New Mexico Statutes Annotated

Chapter 26. Drugs and Cosmetics
Article 1. Drugs and Cosmetics
§ 26-1-2. Definitions

As used in the New Mexico Drug, Device and Cosmetic Act:

A. "board" means the board of pharmacy or its duly authorized agent;
B. "person" includes an individual, partnership, corporation, association, institution or establishment;
C. "biological product" means a virus, therapeutic serum, toxin, antitoxin or analogous product applicable to the prevention, treatment or cure of diseases or injuries of humans and domestic animals and, as used within the meaning of this definition:
(1) a "virus" is interpreted to be a product containing the minute living cause of an infectious disease and includes filterable viruses, bacteria, rickettsia, fungi and protozoa;
(2) a "therapeutic serum" is a product obtained from blood by removing the clot or clot components and the blood cells;
(3) a "toxin" is a product containing a soluble substance poisonous to laboratory animals or humans in doses of one milliliter or less of the product and having the property, following the injection of nonfatal doses into an animal, or causing to be produced therein another soluble substance that specifically neutralizes the poisonous substance and that is demonstrable in the serum of the animal thus immunized; and
(4) an "antitoxin" is a product containing the soluble substance in serum or other body fluid of an immunized animal that specifically neutralizes the toxin against which the animal is immune;
D. "controlled substance" means a drug, substance or immediate precursor enumerated in Schedules I through V of the Controlled Substances Act;
E. "drug" means articles:
(1) recognized in an official compendium;
(2) intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or other animals and includes the domestic animal biological products regulated under the federal Virus-Serum-Toxin Act, 37 Stat 832-833, 21 U.S.C. 151-158, and the biological products applicable to humans regulated under Federal 58 Stat 690, as amended, 42 U.S. C. 216, Section 351, 58 Stat 702, as amended, and 42 U.S.C. 262;
(3) other than food, that affect the structure or any function of the human body or the bodies of other animals; and
(4) intended for use as a component of Paragraph (1), (2) or (3) of this subsection, but does not include devices or their component parts or accessories;
F. "dangerous drug" means a drug, other than a controlled substance enumerated in Schedule I of the Controlled Substances Act, that because of a potentiality for harmful effect or the method of

its use or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such drug and hence for which adequate directions for use cannot be prepared. "Adequate directions for use" means directions under which the layperson can use a drug or device safely and for the purposes for which it is intended. A drug shall be dispensed only upon the prescription of a practitioner licensed by law to administer or prescribe the drug if it:
(1) is a habit-forming drug and contains any quantity of a narcotic or hypnotic substance or a chemical derivative of such substance that has been found under the federal act and the board to be habit forming;
(2) because of its toxicity or other potential for harmful effect or the method of its use or the collateral measures necessary to its use is not safe for use except under the supervision of a practitioner licensed by law to administer or prescribe the drug;
(3) is limited by an approved application by Section 505 of the federal act to the use under the professional supervision of a practitioner licensed by law to administer or prescribe the drug;
(4) bears the legend: "Caution: federal law prohibits dispensing without prescription.";
(5) bears the legend: "Caution: federal law restricts this drug to use by or on the order of a licensed veterinarian."; or
(6) bears the legend "RX only";
G. "counterfeit drug" means a drug that is deliberately and fraudulently mislabeled with respect to its identity, ingredients or sources. Types of such pharmaceutical counterfeits may include:
(1) "identical copies", which are counterfeits made with the same ingredients, formulas and packaging as the originals but not made by the original manufacturer;
(2) "look-alikes", which are products that feature high-quality packaging and convincing appearances but contain little or no active ingredients and may contain harmful substances;
(3) "rejects", which are drugs that have been rejected by the manufacturer for not meeting quality standards; and
(4) "relabels", which are drugs that have passed their expiration dates or have been distributed by unauthorized foreign sources and may include placebos created for late-phase clinical trials;
H. "device", except when used in Subsection P of this section and in Subsection G of Section 26-1-3, Subsection L and Paragraph (4) of Subsection A of Section 26-1-11 and Subsection C of Section 26-1-24 NMSA 1978, means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including any component, part or accessory, that is:
(1) recognized in an official compendium;
(2) intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment or prevention of disease in humans or other animals; or
(3) intended to affect the structure or a function of the human body or the bodies of other animals and that does not achieve any of its principal intended purposes through chemical action within or on the human body or the bodies of other animals and that is not dependent on being metabolized for achievement of any of its principal intended purposes;

I. "prescription" means an order given individually for the person for whom prescribed, either directly from a licensed practitioner or the practitioner's agent to the pharmacist, including by means of electronic transmission, or indirectly by means of a written order signed by the prescriber, and bearing the name and address of the prescriber, the prescriber's license classification, the name and address of the patient, the name and quantity of the drug prescribed, directions for use and the date of issue;
J. "practitioner" means a certified advanced practice chiropractic physician, physician, doctor of oriental medicine, dentist, veterinarian, euthanasia technician, certified nurse practitioner, clinical nurse specialist, pharmacist, pharmacist clinician, certified nurse-midwife, physician assistant, prescribing psychologist or other person licensed or certified to prescribe and administer drugs that are subject to the New Mexico Drug, Device and Cosmetic Act;
K. "cosmetic" means:
(1) articles intended to be rubbed, poured, sprinkled or sprayed on, introduced into or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness or altering the appearance; and
(2) articles intended for use as a component of any articles enumerated in Paragraph (1) of this subsection, except that the term shall not include soap;
L. "official compendium" means the official United States pharmacopoeia national formulary or the official homeopathic pharmacopoeia of the United States or any supplement to either of them;
M. "label" means a display of written, printed or graphic matter upon the immediate container of an article. A requirement made by or under the authority of the New Mexico Drug, Device and Cosmetic Act that any word, statement or other information appear on the label shall not be considered to be complied with unless the word, statement or other information also appears on the outside container or wrapper, if any, of the retail package of the article or is easily legible through the outside container or wrapper;
N. "immediate container" does not include package liners;
O. "labeling" means all labels and other written, printed or graphic matter:
(1) on an article or its containers or wrappers; or
(2) accompanying an article;
P. "misbranded" means a label to an article that is misleading. In determining whether the label is misleading, there shall be taken into account, among other things, not only representations made or suggested by statement, word, design, device or any combination of the foregoing, but also the extent to which the label fails to reveal facts material in the light of such representations or material with respect to consequences that may result from the use of the article to which the label relates under the conditions of use prescribed in the label or under such conditions of use as are customary or usual;
Q. "advertisement" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or that are likely to induce, directly or indirectly, the purchase of drugs, devices or cosmetics;

R. "antiseptic", when used in the labeling or advertisement of an antiseptic, shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be or represented as an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder or such other use as involves prolonged contact with the body;
S. "new drug" means a drug:
(1) the composition of which is such that the drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and efficacy of drugs, as safe and effective for use under the conditions prescribed, recommended or suggested in the labeling thereof; or
(2) the composition of which is such that the drug, as a result of investigation to determine its safety and efficacy for use under such conditions, has become so recognized, but that has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions;
T. "contaminated with filth" applies to a drug, device or cosmetic not securely protected from dirt, dust and, as far as may be necessary by all reasonable means, from all foreign or injurious contaminations, or a drug, device or cosmetic found to contain dirt, dust, foreign or injurious contamination or infestation;
U. "selling of drugs, devices or cosmetics" shall be considered to include the manufacture, production, processing, packing, exposure, offer, possession and holding of any such article for sale and the sale and the supplying or applying of any such article in the conduct of a drug or cosmetic establishment;
V. "color additive" means a material that:
(1) is a dye, pigment or other substance made by a process of synthesis or similar artifice or extracted, isolated or otherwise derived, with or without intermediate or final change of identity, from a vegetable, mineral, animal or other source; or
(2) when added or applied to a drug or cosmetic or to the human body or a part thereof, is capable, alone or through reaction with other substances, of imparting color thereto; except that such term does not include any material that has been or hereafter is exempted under the federal act;
W. "federal act" means the Federal Food, Drug and Cosmetic Act; [FN1]
X. "restricted device" means a device for which the sale, distribution or use is lawful only upon the written or oral authorization of a practitioner licensed by law to administer, prescribe or use the device and for which the federal food and drug administration requires special training or skills of the practitioner to use or prescribe. This definition does not include custom devices defined in the federal act and exempt from performance standards or premarket approval requirements under Section 520(b) of the federal act;
Y. "prescription device" means a device that, because of its potential for harm, the method of its use or the collateral measures necessary to its use, is not safe except under the supervision of a practitioner licensed in this state to direct the use of such device and for which "adequate directions for use" cannot be prepared, but that bears the label: "Caution: federal law restricts this

device to sale by or on the order of a _____", the blank to be filled with the word "physician", "physician assistant", "certified advanced practice chiropractic physician", "doctor of oriental medicine", "dentist", "veterinarian", "euthanasia technician", "certified nurse practitioner", "clinical nurse specialist", "pharmacist", "pharmacist clinician" or "certified nurse-midwife" or with the descriptive designation of any other practitioner licensed in this state to use or order the use of the device;

Z. "valid practitioner-patient relationship" means a professional relationship, as defined by the practitioner's licensing board, between the practitioner and the patient; and

AA. "pedigree" means the recorded history of a drug.

Oklahoma Statutes Annotated

Title 59. Professions and Occupations
Chapter 8. Pharmacy
Oklahoma Pharmacy Act
§ 353.18. Sale, manufacturing or packaging of dangerous drugs, medicines, chemicals or poisons--License or permit required--Violations--Penalties-- Renewal--Late fees

A. 1. It shall be unlawful for any person, including, but not limited to, Internet, website or online pharmacies, to engage in selling at retail, or offering for sale, dangerous drugs, medicines, chemicals or poisons for the treatment of disease, excluding agricultural chemicals and drugs, or to accept prescriptions for same, without first procuring a license from the State Board of Pharmacy. This applies whether such sale, offer for sale or acceptance of prescriptions occurs from this state, or such sale, offer for sale, or acceptance of prescription occurs and is to be delivered, distributed or dispensed to patients or customers in this state. The provisions of this subsection shall not apply to medical gas suppliers or medical gas distributors regulated pursuant to the provisions of subsection B of this section.

2. A license shall be issued to such person as the Board shall deem qualified upon evidence satisfactory to the Board that:

a. the place for which the license is sought will be conducted in full compliance with the law and the rules of the Board,
b. the location, appointments and physical characteristics of the place are reasonably consistent with the maintenance of professional surroundings and constitute no known danger to the public health and safety,
c. the place will be under the management and control of a licensed pharmacist, and
d. a licensed pharmacist will be present and on duty at all hours the pharmacy is open for business; provided, however, the provisions of this subparagraph shall not apply to a hospital drug room.

3. a. An application for a license issued pursuant to the provisions of this subsection shall:
(1) be submitted to the Board in writing, and
(2) contain the name or names of persons owning the pharmacy.
b. An application for each initial or renewal license shall be accompanied by a licensing fee not to exceed Three Hundred Dollars ($300.00) for each period of one (1) year. Prior to opening for business, all applicants for an initial license or permit shall be inspected. Applicants shall pay an inspection fee not to exceed Two Hundred Dollars ($200.00); provided however, that no charge shall be made for the licensing of any Federal Veterans Hospital in the State of Oklahoma.

c. A license issued pursuant to the provisions of this subsection shall be valid for a period set by the Board and shall contain the name of the licensee and the address of the place at which such business shall be conducted.

4. A retail pharmacy that prepares sterile therapeutic preparations that shall be free from living microorganisms (aseptic) shall obtain a pharmacy license, and shall also obtain a parenteral permit at a fee set by the Board, not to exceed Seventy-five Dollars ($75.00). Such pharmacy shall meet requirements set by the Board by rule for parenteral permits.

B. 1. It shall be unlawful for any person to manufacture, package, or wholesale any dangerous drugs, or to engage in selling, or offering for sale at retail, medical gases, except under the management and control of a licensed pharmacist or such other persons as may be approved by the Board after an investigation and determination of such person's qualifications. No person shall sell medical gases, or manufacture, package, or wholesale dangerous drugs offered for sale in this state without first obtaining a permit from the Board.

2. a. An application for an initial or renewal permit issued pursuant to the provisions of this subsection shall be:
(1) made in writing, and
(2) accompanied by a permit fee not to exceed Three Hundred Dollars ($300. 00) for each period of one (1) year.
b. Prior to opening for business, all applicants for an initial permit shall be inspected. Applicants shall pay an inspection fee not to exceed Two Hundred Dollars ($200.00).

3. A permit issued pursuant to the provisions of this subsection shall be valid for a period determined by the Board and shall contain the name of the permittee and the address of the place at which such business shall be conducted.

C. A licensee or permittee who, pursuant to the provisions of this section, fails to complete an application for a renewal license or permit by the fifteenth day after the expiration of the license or permit shall pay a late fee to be fixed by the Board.

D. 1. The Board shall promulgate rules regarding the issuance and renewal of licenses and permits pursuant to the Oklahoma Pharmacy Act which shall include, but need not be limited to:

a. provisions for new or renewal application requirements for both in- and out-of-state wholesale distributors, chain pharmacy warehouses and repackagers that ship into Oklahoma. Requirements

for new and renewal applications, if such information has not been previously provided to the Board, may include, but need not be limited to, the following:

(1) type of ownership, whether individual, partnership, limited liability company or corporation,
(2) names of principal owners or officers and their Social Security numbers,
(3) names of designated managers and their Social Security numbers,
(4) applicant's and designated managers' fingerprints,
(5) criminal background check information for the applicants and designated managers as required by rule,
(6) a copy of the license from the applicant's or designated managers' home state, and
(7) bond requirements, and

b. provisions for the establishment of a pedigree or electronic file to be used by wholesale distributors, chain pharmacy warehouses and repackagers for the purpose of ensuring the integrity of drugs owned, purchased, distributed, returned, transferred and sold when the products leave the normal distribution channel.

2. The Board shall be authorized to use an outside agency, such as the National Association of Boards of Pharmacy (NABP) or the Verified-Accredited Wholesale Distributors (VAWD), to accredit wholesale distributors and repackagers.

3. The Board may exempt by rule wholesalers accredited by VAWD from the provisions of subparagraphs a and b of paragraph 1 of this subsection.

4. The Board shall exempt from the provisions of this subsection logistics providers that receive prescription drugs from original sponsors or manufacturers, deliver the drug products in commerce at the direction of the original sponsor or manufacturer, and do not purchase, sell, trade, or take title to any prescription drug.

5. In promulgating such rules, the Board shall seek input from manufacturers, wholesale distributors, chain pharmacy warehouses, logistics providers and repackagers.

E. A wholesale distributor shall accept prescription drug returns pursuant to the terms and conditions of the agreement between the wholesale distributor and a hospital, pharmacy, chain pharmacy warehouse or other healthcare entity and these returns shall not be subject to any

pedigree or electronic file requirement unless the returns appear suspicious or are greater than the purchases from the wholesale distributor. Wholesale distributors shall be held accountable for maintaining their return process and ensuring that items returned originated from their operations, that the return process is secure, and that the return process does not permit the entry of adulterated and counterfeit product.

F. The Oklahoma Pharmacy Act shall not be construed to prevent the sale of nonprescription drugs in original packages by any merchant or dealer.

South Dakota Codified Laws

Title 36. Professions and Occupations
Chapter 36-11A. Wholesale Drug Distributors
36-11A-34. Returns or exchanges of prescription drugs

A wholesale distributor shall receive prescription drug returns or exchanges from a pharmacy or chain pharmacy warehouse pursuant to the terms and conditions of the agreement between the wholesale distributor and the pharmacy or chain pharmacy warehouse. Returns of expired, damaged, recalled, or otherwise nonsaleable pharmaceutical products shall be distributed by the receiving wholesale distributor only to either the original manufacturer or a third party returns processor. The returns or exchanges of prescription drugs, saleable or otherwise, including any redistribution by a receiving wholesaler, are not subject to the pedigree requirement of § 36-11A-39, so long as they are exempt from pedigree under the Federal Food and Drug Administration's currently applicable Prescription Drug Marketing Act guidance. Wholesale distributors and pharmacies shall be held accountable for administering their returns process and ensuring that the aspects of this operation are secure and do not permit the entry of adulterated and counterfeit product.

South Dakota Codified Laws

Title 36. Professions and Occupations
Chapter 36-11A. Wholesale Drug Distributors
36-11A-39. Pedigrees to be provided for prescription drugs that leave normal distribution channel

Each person who is engaged in wholesale distribution of prescription drugs, including repackagers, but excluding the original manufacturer of the finished form of the prescription drug that leave, or have ever left, the normal distribution channel shall, before each wholesale distribution of such drug, provide a pedigree to the person who receives such drug.

A retail pharmacy or chain pharmacy warehouse shall comply with the requirements of this section only if the pharmacy or chain pharmacy warehouse engages in wholesale distribution of prescription drugs, as defined in § 36- 11A-26.

South Dakota Codified Laws

Title 36. Professions and Occupations
Chapter 36-11A. Wholesale Drug Distributors
36-11A-40. Electronic track and trace pedigree technology

The board shall determine by July 1, 2009, a targeted implementation date for electronic track and trace pedigree technology. Such a determination shall be based on consultation with manufacturers, distributors, and pharmacies responsible for the sale and distribution of prescription drug products in this state. After consultation with interested stakeholders and prior to implementation of the electronic pedigree, the board shall determine that the technology is universally available across the entire prescription pharmaceutical supply chain. The implementation date for the mandated electronic track and trace pedigree technology shall be no sooner than July 1, 2010, and may be extended by the board in one year increments if it appears the technology is not universally available across the entire prescription pharmaceutical supply chain.

South Dakota Codified Laws

Title 36. Professions and Occupations
Chapter 36-11A. Wholesale Drug Distributors
36-11A-41. Verification of transactions listed on pedigree

Each person who is engaged in the wholesale distribution of a prescription drug including repackagers, but excluding the original manufacturer of the finished form of the prescription drug, who is provided a pedigree for a prescription drug and attempts to further distribute that prescription drug, shall affirmatively verify before any distribution of a prescription drug occurs that each transaction listed on the pedigree has occurred.

South Dakota Codified Laws

Title 36. Professions and Occupations
Chapter 36-11A. Wholesale Drug Distributors
36-11A-42. Chain of distribution information to be included on pedigree

The pedigree shall include all necessary identifying information concerning each sale in the chain of distribution of the product from the manufacturer, or the manufacturer's third party logistics provider, co-licensed product partner, manufacturer's exclusive distributor, through acquisition and sale by any wholesale distributor or repackager, until final sale to a pharmacy or other person dispensing or administering the drug. At minimum, the necessary chain of distribution information shall include:

(1) Name, address, telephone number, and if available, the e-mail address, of each owner of the prescription drug, and each wholesale distributor of the prescription drug;
(2) Name and address of each location from which the product was shipped, if different from the owner's;
(3) Transaction dates; and
(4) Certification that each recipient has authenticated the pedigree.

South Dakota Codified Laws

Title 36. Professions and Occupations
Chapter 36-11A. Wholesale Drug Distributors
36-11A-43. Additional information to be included on pedigree

In addition to the requirements of § 36-11A-42, the pedigree shall also include the following minimum requirements:

(1) Name and national drug code number of the prescription drug;
(2) Dosage form and strength of the prescription drug;
(3) Size of the container;
(4) Number of containers;
(5) Lot number of the prescription drug; and
(6) Name of the manufacturer of the finished dosage form.

South Dakota Codified Laws

Title 36. Professions and Occupations
Chapter 36-11A. Wholesale Drug Distributors
36-11A-44. Pedigrees and electronic files to be maintained and available for inspection

Each pedigree or electronic file shall be:

(1) Maintained by the purchaser and the wholesale distributor for three years from the date of sale or transfer; and
(2) Available for inspection or use within two business days upon a request of an authorized officer of the law.

South Dakota Codified Laws

Title 36. Professions and Occupations
Chapter 36-11A. Wholesale Drug Distributors
36-11A-45. Cease and desist order for violation--Hearing

The board shall issue an order requiring the appropriate person including any distributor or retailer of the drug to immediately cease distribution of the drug within this state if the board finds that there is a reasonable probability that:

(1) A wholesale distributor, other than a manufacturer, has:
(a) Violated a provision of §§ 36-11A-20 to 36-11A-46, inclusive; or
(b) Falsified a pedigree, or sold, distributed, transferred, manufactured, repackaged, handled, or held a counterfeit prescription drug intended for human use;
(2) The prescription drug at issue as a result of a violation in subdivision (1) could cause serious, adverse health consequences or death; and
(3) Other procedures would result in unreasonable delay.

An order under this section shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than ten days after the date of the issuance of the order, on the actions required by the order. If, after providing an opportunity for such a hearing, the board determines that inadequate grounds exist to support the actions required by the order, the board shall vacate the order.

South Dakota Codified Laws

Title 36. Professions and Occupations
Chapter 36-11A. Wholesale Drug Distributors
36-11A-46. Prohibited acts--Misdemeanor or felony

It is unlawful for a person to perform or cause the performance of or aid and abet any of the following acts in this state:

(1) Failure to obtain a license in accordance with §§ 36-11A-20 to 36- 11A-46, inclusive, or operating without a valid license when a license is required by §§ 36-11A-20 to 36-11A-46, inclusive;
(2) If the requirements of § 36-11A-34 are applicable and are not met, the purchasing or otherwise receiving a prescription drug from a pharmacy;
(3) If a state license is required pursuant to § 36-11A-35, the sale, distribution, or transfer of a prescription drug to a person that is not authorized under the law of the jurisdiction in which the person receives the prescription drug to receive the prescription drug;
(4) Failure to deliver prescription drugs to specified premises, as required by § 36-11A-36;
(5) Accepting payment or credit for the sale of prescription drugs in violation of § 36-11A-38;
(6) Failure to maintain or provide pedigrees as required by §§ 36-11A-20 to 36-11A-46, inclusive;
(7) Failure to obtain, pass, or authenticate a pedigree, as required by §§ 36-11A-20 to 36-11A-46, inclusive;
(8) Providing the state or any of its representatives or any federal official with false or fraudulent records or making false or fraudulent statements regarding any matter within the provisions of §§ 36-11A-20 to 36-11A-46, inclusive;
(9) Obtaining or attempting to obtain a prescription drug by fraud, deceit, misrepresentation or engaging in misrepresentation or fraud in the distribution of a prescription drug;
(10) Except for the wholesale distribution by manufacturers of a prescription drug that has been delivered into commerce pursuant to an application approved under federal law by the Food and Drug Administration, the manufacture, repacking, sale, transfer, delivery, holding, or offering for sale any prescription drug that is adulterated, misbranded, counterfeit, suspected of being counterfeit, or has otherwise been rendered unfit for distribution;
(11) Except for the wholesale distribution by manufacturers of a prescription drug that has been delivered into commerce pursuant to an application approved under Federal law by the Food and Drug Administration, the adulteration, misbranding, or counterfeiting of any prescription drug;
(12) The receipt of any prescription drug that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit, or suspected of being counterfeit, and the delivery or proffered delivery of such drug for pay or otherwise; and

(13) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of a prescription drug or the commission of any other act with respect to a prescription drug that results in the prescription drug being misbranded.

Any person who violates this section is guilty of a Class 1 misdemeanor for the first conviction and a Class 6 felony for any subsequent conviction.

Vernon's Texas Statutes and Codes Annotated

Health and Safety Code
Title 6. Food, Drugs, Alcohol, and Hazardous Substances
Subtitle A. Food and Drug Health Regulations
Chapter 431. Texas Food, Drug, and Cosmetic Act
Subchapter N. Wholesale Distributors of Prescription Drugs
§ 431.413. Pedigree Contents

(a) A pedigree must include all necessary identifying information concerning each sale in the product's chain of distribution from the manufacturer, through acquisition and sale by a wholesale distributor or repackager, until final sale to a pharmacy or other person dispensing or administering the drug. At a minimum, the chain of distribution information must include:

(1) the name, address, telephone number, and, if available, the e-mail address of each person who owns the prescription drug and each wholesale distributor of the prescription drug;
(2) the name and address of each location from which the product was shipped, if different from the owner's name and address;
(3) the transaction dates; and
(4) certification that each recipient has authenticated the pedigree.

(b) The pedigree must include, at a minimum, the:

(1) name of the prescription drug;
(2) dosage form and strength of the prescription drug;
(3) size of the container;
(4) number of containers;
(5) lot number of the prescription drug; and
(6) name of the manufacturer of the finished dosage form.

(c) Each pedigree statement must be:

(1) maintained by the purchaser and the wholesale distributor for at least three years; and
(2) available for inspection and photocopying not later than the second business day after the date a request is submitted by the department or a peace officer in this state.

(d) The executive commissioner of the Health and Human Services Commission shall adopt rules to implement this section.

(e) Expired.

(e-1) If, after consulting with manufacturers, distributors, and pharmacies responsible for the sale and distribution of prescription drugs in this state, the department determines that electronic track and trace pedigree technology is universally available across the entire prescription pharmaceutical supply chain, the department shall establish a targeted implementation date for electronic track and trace pedigree technology. After the department has established a targeted implementation date, the department may revise the date. The targeted implementation date may not be earlier than July 1, 2010.

(f) Expired.

Vernon's Texas Statutes and Codes Annotated

Health and Safety Code
Title 6. Food, Drugs, Alcohol, and Hazardous Substances
Subtitle A. Food and Drug Health Regulations
Chapter 431. Texas Food, Drug, and Cosmetic Act
Subchapter N. Wholesale Distributors of Prescription Drugs
§ 431.412. Pedigree Required

(a) A person who is engaged in the wholesale distribution of a prescription drug, including a repackager but excluding the original manufacturer, shall provide a pedigree for each prescription drug for human consumption that leaves or at any time has left the normal distribution channel and is sold, traded, or transferred to any other person.

(b) Repealed by Acts 2007, 80th Leg., ch. 980, § 14.

(b-1) A retail pharmacy or pharmacy warehouse is required to comply with this section only if the pharmacy or warehouse engages in the wholesale distribution of a prescription drug.

(c) Repealed by Acts 2007, 80th Leg., ch. 980, § 14.

(d) A person who is engaged in the wholesale distribution of a prescription drug, including a repackager, but excluding the original manufacturer of the finished form of a prescription drug, and who is in possession of a pedigree for a prescription drug must verify before distributing the prescription drug that each transaction listed on the pedigree has occurred.

Vernon's Texas Statutes and Codes Annotated

Health and Safety Code
Title 6. Food, Drugs, Alcohol, and Hazardous Substances
Subtitle A. Food and Drug Health Regulations
Chapter 431. Texas Food, Drug, and Cosmetic Act
Subchapter B. Prohibited Acts
§ 431.021. Prohibited Acts

The following acts and the causing of the following acts within this state are unlawful and prohibited:

(a) the introduction or delivery for introduction into commerce of any food, drug, device, or cosmetic that is adulterated or misbranded;

(b) the adulteration or misbranding of any food, drug, device, or cosmetic in commerce;

(c) the receipt in commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise;

(d) the distribution in commerce of a consumer commodity, if such commodity is contained in a package, or if there is affixed to that commodity a label that does not conform to the provisions of this chapter and of rules adopted under the authority of this chapter; provided, however, that this prohibition shall not apply to persons engaged in business as wholesale or retail distributors of consumer commodities except to the extent that such persons:

(1) are engaged in the packaging or labeling of such commodities; or
(2) prescribe or specify by any means the manner in which such commodities are packaged or labeled;

(e) the introduction or delivery for introduction into commerce of any article in violation of Section 431.084, 431.114, or 431.115;

(f) the dissemination of any false advertisement;

(g) the refusal to permit entry or inspection, or to permit the taking of a sample or to permit access to or copying of any record as authorized by Sections 431.042-431.044; or the failure to establish or maintain any record or make any report required under Section 512(j), (l), or (m) of the federal Act, or the refusal to permit access to or verification or copying of any such required record;

(h) the manufacture within this state of any food, drug, device, or cosmetic that is adulterated or misbranded;

(i) the giving of a guaranty or undertaking referred to in Section 431.059, which guaranty or undertaking is false, except by a person who relied on a guaranty or undertaking to the same effect signed by, and containing the name and address of the person residing in this state from whom the person received in good faith the food, drug, device, or cosmetic; or the giving of a guaranty or undertaking referred to in Section 431.059, which guaranty or undertaking is false;

(j) the use, removal, or disposal of a detained or embargoed article in violation of Section 431.048;

(k) the alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to a food, drug, device, or cosmetic, if such act is done while such article is held for sale after shipment in commerce and results in such article being adulterated or misbranded;

(l)(1) forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by rules adopted under this chapter or the regulations promulgated under the provisions of the federal Act;

(2) making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing on any drug or container or labeling thereof so as to render such drug a counterfeit drug;
(3) the doing of any act that causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug;

(m) the using by any person to the person's own advantage, or revealing, other than to the commissioner, an authorized agent, a health authority or to the courts when relevant in any judicial proceeding under this chapter, of any information acquired under the authority of this chapter concerning any method or process that as a trade secret is entitled to protection;

(n) the using, on the labeling of any drug or device or in any advertising relating to such drug or device, of any representation or suggestion that approval of an application with respect to such drug or device is in effect under Section 431.114 or Section 505, 515, or 520(g) of the federal Act, as the case may be, or that such drug or device complies with the provisions of such sections;

(o) the using, in labeling, advertising or other sales promotion of any reference to any report or analysis furnished in compliance with Sections 431.042-431.044 or Section 704 of the federal Act;

(p) in the case of a prescription drug distributed or offered for sale in this state, the failure of the manufacturer, packer, or distributor of the drug to maintain for transmittal, or to transmit, to any practitioner licensed by applicable law to administer such drug who makes written request for information as to such drug, true and correct copies of all printed matter that is required to be included in any package in which that drug is distributed or sold, or such other printed matter as is approved under the federal Act. Nothing in this subsection shall be construed to exempt any person from any labeling requirement imposed by or under other provisions of this chapter;

(q)(1) placing or causing to be placed on any drug or device or container of any drug or device, with intent to defraud, the trade name or other identifying mark, or imprint of another or any likeness of any of the foregoing;

(2) selling, dispensing, disposing of or causing to be sold, dispensed, or disposed of, or concealing or keeping in possession, control, or custody, with intent to sell, dispense, or dispose of, any drug, device, or any container of any drug or device, with knowledge that the trade name or other identifying mark or imprint of another or any likeness of any of the foregoing has been placed thereon in a manner prohibited by Subdivision (1) of this subsection; or
(3) making, selling, disposing of, causing to be made, sold, or disposed of, keeping in possession, control, or custody, or concealing with intent to defraud any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying

mark, imprint, or device of another or any likeness of any of the foregoing on any drug or container or labeling of any drug or container so as to render such drug a counterfeit drug;

(r) dispensing or causing to be dispensed a different drug in place of the drug ordered or prescribed without the express permission in each case of the person ordering or prescribing;

(s) the failure to register in accordance with Section 510 of the federal Act, the failure to provide any information required by Section 510(j) or (k) of the federal Act, or the failure to provide a notice required by Section 510(j)(2) of the federal Act;

(t)(1) the failure or refusal to:

(A) comply with any requirement prescribed under Section 518 or 520(g) of the federal Act; or
(B) furnish any notification or other material or information required by or under Section 519 or 520(g) of the federal Act;
(2) with respect to any device, the submission of any report that is required by or under this chapter that is false or misleading in any material respect;

(u) the movement of a device in violation of an order under Section 304(g) of the federal Act or the removal or alteration of any mark or label required by the order to identify the device as detained;

(v) the failure to provide the notice required by Section 412(b) or 412(c), the failure to make the reports required by Section 412(d)(1)(B), or the failure to meet the requirements prescribed under Section 412(d)(2) of the federal Act;

(w) except as provided under Subchapter M of this chapter and Section 562.1085, Occupations Code, the acceptance by a person of an unused prescription or drug, in whole or in part, for the purpose of resale, after the prescription or drug has been originally dispensed, or sold;

(x) engaging in the wholesale distribution of drugs or operating as a distributor or manufacturer of devices in this state without obtaining a license issued by the department under Subchapter I, L, or N, as applicable;

(y) engaging in the manufacture of food in this state or operating as a warehouse operator in this state without having a license as required by Section 431.222 or operating as a food wholesaler in this state without having a license under Section 431.222 or being registered under Section 431. 2211, as appropriate;

(z) unless approved by the United States Food and Drug Administration pursuant to the federal Act, the sale, delivery, holding, or offering for sale of a self-testing kit designed to indicate whether a person has a human immunodeficiency virus infection, acquired immune deficiency syndrome, or a related disorder or condition;

(aa) making a false statement or false representation in an application for a license or in a statement, report, or other instrument to be filed with or requested by the department under this chapter;

(bb) failing to comply with a requirement or request to provide information or failing to submit an application, statement, report, or other instrument required by the department;

(cc) performing, causing the performance of, or aiding and abetting the performance of an act described by Subdivision (x);

(dd) purchasing or otherwise receiving a prescription drug from a pharmacy in violation of Section 431.411(a);

(ee) selling, distributing, or transferring a prescription drug to a person who is not authorized under state or federal law to receive the prescription drug in violation of Section 431.411(b);

(ff) failing to deliver prescription drugs to specified premises as required by Section 431.411(c);

(gg) failing to maintain or provide pedigrees as required by Section 431.412 or 431.413;

(hh) failing to obtain, pass, or authenticate a pedigree as required by Section 431.412 or 431.413;

(ii) the introduction or delivery for introduction into commerce of a drug or prescription device at a flea market;

(jj) the receipt of a prescription drug that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit, or suspected of being counterfeit, and the delivery or proffered delivery of such a drug for payment or otherwise; or

(kk) the alteration, mutilation, destruction, obliteration, or removal of all or any part of the labeling of a prescription drug or the commission of any other act with respect to a prescription drug that results in the prescription drug being misbranded.

Annotated Code of Virginia

Title 54.1. Professions and Occupations
Subtitle III. Professions and Occupations Regulated by Boards Within the Department of Health Professions
Chapter 33. Pharmacy
Article 2. Board of Pharmacy
§ 54.1-3307. Specific powers and duties of Board

A. The Board shall regulate the practice of pharmacy and the manufacturing, dispensing, selling, distributing, processing, compounding, or disposal of drugs and devices. The Board shall also control the character and standard of all drugs, cosmetics and devices within the Commonwealth, investigate all complaints as to the quality and strength of all drugs, cosmetics, and devices and take such action as may be necessary to prevent the manufacturing, dispensing, selling, distributing, processing, compounding and disposal of such drugs, cosmetics and devices that do not conform to the requirements of law.

The Board's regulations shall include criteria for:

1. Maintenance of the quality, quantity, integrity, safety and efficacy of drugs or devices distributed, dispensed or administered.

2. Compliance with the prescriber's instructions regarding the drug, its quantity, quality and directions for use.

3. Controls and safeguards against diversion of drugs or devices.

4. Maintenance of the integrity of, and public confidence in, the profession and improving the delivery of quality pharmaceutical services to the citizens of Virginia.

5. Maintenance of complete records of the nature, quantity or quality of drugs or substances distributed or dispensed, and of all transactions involving controlled substances or drugs or devices so as to provide adequate information to the patient, the practitioner or the Board.

6. Control of factors contributing to abuse of legitimately obtained drugs, devices, or controlled substances.

7. Promotion of scientific or technical advances in the practice of pharmacy and the manufacture and distribution of controlled drugs, devices or substances.

8. Impact on costs to the public and within the health care industry through the modification of mandatory practices and procedures not essential to meeting the criteria set out in subdivisions 1 through 7 of this section.

9. Such other factors as may be relevant to, and consistent with, the public health and safety and the cost of rendering pharmacy services.

B. The Board's regulations to implement the criteria set forth in subsection A shall include, but shall not be limited to, the establishment and implementation of a pedigree system, as defined in subsection D. The Board shall structure the implementation of the pedigree with limited application to certain schedules or certain drugs, upon finding that such drugs are more subject to counterfeiting. In order to maintain a current and appropriate list of drugs susceptible to counterfeiting, the Board may amend such list in its regulations. Such amendments to the list shall be exempt from the requirements of Article 2 (§ 2.2-4006 et seq.) of the Administrative Process Act. The Board shall establish in regulation a process for amending such list that provides notice and opportunity for public comment. The Board shall limit the implementation of a pedigree system to those drugs that have left the normal distribution channel as defined in subsection D. The pedigree shall also satisfy the requirements of 21 U.S.C. § 353(e), regarding requirements for wholesale distributors of drugs in interstate commerce. The Board may provide

for exceptions to the pedigree requirements of this section for emergency medical reasons as defined in regulation.

C. The Board may collect and examine specimens of drugs, devices and cosmetics that are manufactured, distributed, stored or dispensed in the Commonwealth.

D. For the purposes of this section:

"Normal distribution channel" means a chain of custody for a prescription drug from initial sale by a pharmaceutical manufacturer, through acquisition and sale by one wholesale distributor as defined in § 54.1-3401, that is not exempted pursuant to § 54.1-3401.1, until sale to a pharmacy or other person dispensing or administering the controlled substance; or a chain of custody for a prescription drug from initial sale by a pharmaceutical manufacturer, through acquisition and sale by one wholesale distributor as defined in § 54.1-3401, that is not exempted pursuant to § 54.1-3401.1, to a chain pharmacy warehouse to its intracompany pharmacies; or a chain of custody for a prescription drug from initial sale by a pharmaceutical manufacturer to a chain pharmacy warehouse to its intracompany pharmacies.

"Pedigree" means a paper document or electronic file recording each distribution of a controlled substance from sale by a pharmaceutical manufacturer through acquisition and sale by any wholesale distributor, as defined in § 54.1-3401 and not exempted pursuant to § 54.1-3401.1, until sale to a pharmacy or other person dispensing or administering the controlled substance. Returns from a pharmacy to the originating wholesale distributor or pharmaceutical manufacturer shall not be subject to the pedigree requirements of this section.

Wisconsin Statutes Annotated

Regulation and Licensing (Ch. 440 to 480)
Chapter 450. Pharmacy Examining Board
450.072. Wholesale distributors; restrictions on transactions

(1) A wholesale distributor shall receive prescription drug returns or exchanges from a pharmacy, a person authorized to administer or dispense drugs, or a pharmacy's intracompany warehouse pursuant to the terms and conditions of the agreement between the wholesale distributor and the pharmacy or chain pharmacy warehouse. A wholesale distributor that receives returns of expired, damaged, recalled, or otherwise nonsaleable prescription drugs may distribute the prescription drugs only to the original manufacturer of the products or to a 3rd party returns processor. Notwithstanding s. 450.073, returns or exchanges of saleable or nonsaleable prescription drugs, including any redistribution by a receiving wholesaler, are not subject to pedigree requirements under s. 450.073 if the returns or exchanges are exempt from the pedigree requirement under the federal food and drug administration's current guidance on the federal prescription drug marketing act. A person licensed under s. 450.071 or a pharmacy or other person authorized to administer or dispense drugs shall ensure that the person or pharmacy's return process is secure and does not permit the entry of adulterated and counterfeit products.

(2)(a) A manufacturer or wholesale distributor may not deliver prescription drugs to a person unless the person is licensed under s. 450.071 or 450.06 or by the appropriate licensing authority of another state. A manufacturer or wholesale distributor may not deliver prescription drugs to a person that is not known to the manufacturer or wholesale distributor unless the manufacturer or wholesale distributor has verified with the board or with the licensing authority of the state in which the person in located that the person is licensed to receive prescription drugs.

(b) A manufacturer or wholesale distributor may distribute a prescription drug only to the premises listed on the person's license or authorization, except that a manufacturer or wholesale distributor may distribute the prescription drugs to an authorized agent of the person at the premises of the manufacturer or wholesale distributor if all of the following are true:

1. The manufacturer or wholesale distributor documents the authorized agent's name and address.

2. Distribution to an authorized agent is necessary to promote or protect the immediate health or safety of the authorized agent's patient.

(c) A manufacturer or wholesale distributor may distribute a prescription drug to a hospital pharmacy receiving area if a licensed pharmacist or another authorized recipient signs, at the time of the distribution, a receipt that shows the type and quantity of prescription drugs distributed. If there is a discrepancy between the type and quantity of prescription drugs indicated on the receipt and the type and quantity of prescription drugs received at the hospital pharmacy receiving area, the discrepancy shall be reported to the manufacturer or wholesale distributor that distributed the prescription drugs no later than the day immediately following the date on which the prescription drugs were distributed to the hospital pharmacy receiving area.

(d) No manufacturer or wholesale distributor may accept payment for, or allow the use of, a person's credit to establish an account for the purchase of a prescription drug from any person other than the owner of record, the chief executive officer, or the chief financial officer identified on the license or authorization of a person who may receive prescription drugs. Any account established for the purchase of prescription drugs shall bear the name of the licensed or authorized person.

Wisconsin Statutes Annotated

Regulation and Licensing (Ch. 440 to 480)
Chapter 450. Pharmacy Examining Board
450.073. Wholesale distributors; pedigree

(1) A wholesale distributor shall establish and maintain a pedigree for each prescription drug that leaves, or has ever left, the normal distribution channel. Before a wholesale distribution of a prescription drug leaves the normal distribution channel, a wholesale distributor shall provide a copy of the pedigree to the person receiving the drug. This section does not apply to a retail pharmacy or pharmacy intracompany warehouse unless the pharmacy or pharmacy intracompany warehouse engages in the wholesale distribution of prescription drugs.

(2) A pedigree shall contain all necessary identifying information concerning each sale in the chain of the distribution of the prescription drug from the manufacturer of the prescription drug or the manufacturers 3rd-party logistics provider, colicensed product partner, or exclusive distributor until final sale or distribution to a pharmacy or a person dispensing or distributing the prescription drug. The pedigree shall include all of the following:

(a) The name, address, telephone number, and, if available, electronic mail address of each recipient or distributor of the prescription drug in the chain of distribution, until the final sale or distribution described in sub. (2).

(b) The name and address of each facility from which the prescription drug was distributed, if different from the address provided in par. (a).

(c) The date of each distribution.

(d) A certification that every recipient has authenticated the pedigree before distribution of the prescription drug to the next point in the chain of distribution.

(e) The name, dosage strength, size and number of containers, lot number, and name of the manufacturer for each prescription drug.

(3) The board shall promulgate rules implementing an electronic track and trace pedigree system. Not later than July 1, 2010, the board shall determine the date on which the system will be implemented. The system may not be implemented before July 1, 2011, and the board may delay the implementation date in increments if the board determines that the technology to implement the system is not yet universally available across the prescription drug supply chain or is not capable of adequately protecting patient safety.

(4) A person who is engaged in the wholesale distribution of a prescription drug, including a repackager but not including the original manufacturer of the prescription drug, who possesses a pedigree for the prescription drug, and who intends to further distribute the prescription drug, shall verify that each transaction recorded on the pedigree has occurred before the person may distribute the prescription drug.

(5)(a) A pedigree shall be maintained by a person who purchases prescription drugs identified in the pedigree and by a wholesale distributor who distributes prescription drugs identified in the pedigree for not less than 3 years from the date of sale or distribution.

(b) A person maintaining a pedigree under par. (a) shall make the pedigree available for inspection or use by a law enforcement officer within 7 days after the law enforcement officer's request.

Wisconsin Statutes Annotated

Regulation and Licensing (Ch. 440 to 480)
Chapter 450. Pharmacy Examining Board
450.074. Wholesale distributors; prohibited actions, enforcement, penalties

(1) If the board finds that there is a reasonable probability that a wholesale distributor, other than a manufacturer, has done any of the following, that continued distribution of a prescription drug involved in the occurrence could cause death or serious adverse health consequences, and that additional procedures would result in an unreasonable delay, the board shall issue an order requiring that distribution of a prescription drug in this state cease immediately:

(a) Violated a provision of ss. 450.071 to 450.073.

(b) Falsified a pedigree or sold, distributed, transferred, manufactured, repackaged, handled, or held a counterfeit prescription drug intended for human use.

(2) If the board issues an order under sub. (1), the board shall provide the person who is the subject of the order an opportunity for an informal hearing not more than 10 days after the date on which the order is issued. If, after a hearing, the board determines that the order was issued without sufficient grounds, the board shall vacate the order.

(3) Any person who knowingly does any of the following is guilty of a Class H felony:

(a) Fails to obtain a license required under s. 450.071.

(b) Purchases or otherwise receives a prescription drug from a pharmacy in violation of s. 450.072(1).

(c) Violates s. 450.072(2)(a), if the person is required to obtain a license under s. 450.071.

(d) Violates s. 450.072(2)(b).

(e) Violates s. 450.072(2)(d).

(f) Violates s. 450.073.

(g) Provides false or fraudulent records to, or makes a false or fraudulent statement to, the board, a representative of the board, or a federal official.

(h) Obtains or attempts to obtain a prescription drug by fraud, deceit, or misrepresentation, or engages in misrepresentation or fraud in the distribution of a prescription drug.

(i) Manufactures, repackages, sells, transfers, delivers, holds, or offers for sale a prescription drug that is adulterated, misbranded, counterfeit, suspected of being counterfeit, or otherwise unfit for distribution, except for wholesale distribution by a manufacturer of a prescription drug that has been delivered into commerce pursuant to an application approved by the federal food and drug administration.

(j) Adulterates, misbrands, or counterfeits a prescription drug, except for wholesale distribution by a manufacturer of a prescription drug that has been delivered into commerce pursuant to an application approved by the federal food and drug administration.

(k) Receives a prescription drug that has been adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeited, or suspected of being counterfeited, and delivers or proffers such a drug.

(L) Alters, mutilates, destroys, obliterates, or removes any part of the labeling of a prescription drug or commits another act that results in the misbranding of a prescription drug.

(4) Subsection (3) does not apply to a prescription drug manufacturer or an agent of a prescription drug manufacturer, if the manufacturer or agent is obtaining or attempting to obtain a prescription drug for the sole purpose of testing the authenticity of the prescription drug.

Wisconsin Statutes Annotated

Regulation and Licensing (Ch. 440 to 480)
Chapter 450. Pharmacy Examining Board
450.01. Definitions

In this chapter:

(1) "Administer" means the direct application of a vaccine or a prescribed drug or device, whether by injection, ingestion or any other means, to the body of a patient or research subject by any of the following:

(a) A practitioner or his or her authorized agent.

(b) A patient or research subject at the direction of a practitioner.

(c) A pharmacist.

(1m) "Advanced practice nurse prescriber" means an advanced practice nurse who is certified under s. 441.16(2).

(1p) "Affiliated group" has the meaning given in section 1504 of the Internal Revenue Code.

(1t) "Authenticate" means to affirmatively verify, before wholesale distribution of a prescription drug occurs, that each transaction listed on a pedigree has occurred.

(1x) "Authorized distributor of record" means a wholesale distributor with whom a manufacturer

has established an ongoing relationship to distribute the manufacturer's prescription drug. For purposes of this subsection, an ongoing relationship exists between a wholesale distributor and a manufacturer if all of the following apply:

(a) The wholesale distributor, including any affiliated group of the wholesale distributor, has in effect a written agreement with the manufacturer evidencing the ongoing relationship.

(b) The wholesale distributor, including any affiliated group of the wholesale distributor, is included in the manufacturer's current list of authorized distributors of record.

(2) "Board" means the pharmacy examining board.

(2m) "Colicensed" means, with respect to a partner or product, that 2 or more parties have the right to engage in marketing or manufacturing of a product consistent with the federal food and drug administration's implementation of the federal prescription drug marketing act.

(3) "Compound" means to mix, combine or put together various ingredients or drugs for the purpose of dispensing.

(4) "Controlled substance" has the meaning designated in s. 961.01(4).

(5) "Deliver" or "delivery" means the actual, constructive or attempted transfer of a drug or device from one person to another.

(6) "Device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including any component, part or accessory, which does not achieve any of its principal intended purposes through chemical action within or on the

body of a person or other animal, is not dependent upon being metabolized for the achievement of any of its principal intended purposes and is:

(a) Recognized by the U.S. pharmacopoeia and national formulary or official homeopathic pharmacopoeia of the United States, or any supplement to either of them;

(b) Intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease or other conditions in persons or other animals; or

(c) Intended to affect the structure or any function of the body of persons or other animals.

(7) "Dispense" means to deliver a prescribed drug or device to an ultimate user or research subject by or pursuant to the prescription order of a practitioner, including the compounding, packaging or labeling necessary to prepare the prescribed drug or device for delivery.

(8) "Distribute" means to deliver, other than by administering or dispensing.

(9) "Distributor" means a person licensed by the board under s. 450.07(2).

(9m) "Drop shipment" means a sale of a prescription drug to a wholesale distributor by the manufacturer of the drug, by the manufacturer's colicensed product partner, by the manufacturer's 3rd party logistics provider, or by the manufacturer's exclusive distributor, to which all of the following apply:

(a) The wholesale distributor or chain pharmacy warehouse takes title to, but not physical possession of, the drug.

(b) The wholesale distributor invoices a pharmacy, a chain pharmacy warehouse, or a person authorized to dispense or administer the drug to a patient.

(c) The pharmacy, chain pharmacy warehouse, or person authorized to dispense or administer the drug receives delivery of the drug directly from the manufacturer, the manufacturer's 3rd party logistics provider, or the manufacturer's exclusive distributor.

(10) "Drug" means:

(a) Any substance recognized as a drug in the official U.S. pharmacopoeia and national formulary or official homeopathic pharmacopoeia of the United States or any supplement to either of them;

(b) Any substance intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease or other conditions in persons or other animals;

(c) Any substance other than a device or food intended to affect the structure or any function of the body of persons or other animals; or

(d) Any substance intended for use as a component of any article specified in pars. (a) to (c) but does not include gases or devices or articles intended for use or consumption in or for mechanical, industrial, manufacturing or scientific applications or purposes.

(11) "Drug product" means a specific drug or drugs in a specific dosage form and strength from a known source of manufacture.

(11m) "Facility" means a location where a wholesale distributor stores, handles, repackages, or offers for sale prescription drugs.

(11r) "Intracompany sales" means any transaction or transfer between any division, subsidiary, parent, or affiliated or related company under common ownership and control of a corporate entity or any transaction or transfer between colicensees of a colicensed product.

(12) "Manufacturer" means a person licensed or approved by the federal food and drug administration to engage in the manufacture of drugs or devices, consistent with the definition of "manufacturer" under the federal food and drug administration's regulations and interpreted guidances implementing the federal prescription drug marketing act.

(12m) "Manufacturer's exclusive distributor" means a person that contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of the 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 drug.

(13) "Manufacturing" means making, assembling, processing or modifying devices, or mixing, producing or preparing drugs in dosage forms by encapsulating, entableting or other process, or packaging, repackaging or otherwise changing the container, wrapper or label of any package containing a drug or device in furtherance of the distribution of the drug or device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer.

(13m) "Nonprescription drug product" means any nonnarcotic drug product which may be sold without a prescription order and which is prepackaged for use by consumers and labeled in accordance with the requirements of state and federal law.

(13r)(a) "Normal distribution channel" means a chain of custody for a prescription drug that runs,

directly or by drop shipment, from the manufacturer of a drug, from the manufacturer to the manufacturer's colicensed partner, from the manufacturer to the manufacturer's 3rd-party logistics provider, or from the manufacturer to the manufacturer's exclusive distributor, and continues as described in any of the following:

1. To a pharmacy or to a person authorized to dispense or administer a drug to a patient.

2. To an authorized distributor of record, and then to a pharmacy or to a person authorized to dispense or administer a drug to a patient.

3. To an authorized distributor of record, then to one other authorized distributor of record, then to an office-based practitioner.

4. To a pharmacy warehouse to the pharmacy warehouse's intracompany pharmacy, then to a patient or to a person authorized to dispense or administer a drug to a patient.

5. To an authorized distributor of record, then to a pharmacy warehouse, then to the pharmacy warehouse's intracompany pharmacy, then to a patient or to a person authorized to dispense or administer a drug to a patient.

(b) For purposes of this subsection, a distribution of a prescription drug to a warehouse or to another entity that redistributes the drug by intracompany sale to a pharmacy or to another person authorized to dispense or administer the drug constitutes a distribution to the pharmacy or to the person authorized to dispense or administer the drug.

(14) "Patient" means the person or other animal for whom drug products or devices are prescribed or to whom drug products or devices are dispensed or administered.

(14m) "Pedigree" means a document or electronic file containing information that records each distribution of a prescription drug.

(15) "Pharmacist" means a person licensed by the board under s. 450.03 or 450.05.

(15m) "Pharmacy warehouse" means a physical location for prescription drugs that acts as a central warehouse and performs intracompany sales.

(16) "Practice of pharmacy" means any of the following:

(a) Interpreting prescription orders.

(b) Compounding, packaging, labeling, dispensing and the coincident distribution of drugs and devices.

(c) Participating in drug utilization reviews.

(d) Proper and safe storage of drugs and devices and maintaining proper records of the drugs and devices.

(e) Providing information on drugs or devices which may include, but is not limited to, advice relating to therapeutic values, potential hazards and uses.

(f) Drug product substitution under s. 450.13.

(g) Supervision of pharmacist supportive personnel.

(h) Making therapeutic alternate drug selections, if made in accordance with written guidelines or procedures previously established by a pharmacy and therapeutics committee of a hospital and approved by the hospital's medical staff and use of the therapeutic alternate drug selection has been approved for a patient during the period of the patient's stay within the hospital by any of the following:

1. The patient's physician .

2. The patient's advanced practice nurse prescriber, if the advanced practice nurse prescriber has entered into a written agreement to collaborate with a physician.

(i) Drug regimen screening, including screening for therapeutic duplication, drug-to-drug interactions, incorrect dosage, incorrect duration of treatment, drug allergy reactions and clinical abuse or misuse.

(j) Performing any act necessary to manage a pharmacy.

(k) Administering prescribed drug products and devices under s. 450.035 (1r) and, pursuant to vaccination protocols, vaccines.

(17) "Practitioner" means a person licensed in this state to prescribe and administer drugs or licensed in another state and recognized by this state as a person authorized to prescribe and administer drugs.

(18) "Prescribed drug or device" means any drug or device prescribed by a practitioner.

(19) "Prescription" means a drug or device prescribed by a practitioner.

(20) "Prescription drug" means all of the following, but does not include blood, blood components intended for transfusion, or biological products that are also medical devices:

(a) A drug, drug product, or drug-containing preparation that is subject to 21 USC 353(b) or 21 CFR 201.105.

(b) A controlled substance included in schedules II to V of ch. 961, whether by statute or rule, except a substance that by law may be dispensed without the prescription order of a practitioner. Controlled substances are included within this definition for purposes of s. 450.11(3), (4)(a), and (8) only and for violations thereof punishable under s. 450.11(9).

(21) "Prescription order" means an order transmitted orally, electronically or in writing by a practitioner for a drug or device for a particular patient.

(21e) "Repackage" means to repack or otherwise change the container, wrapper, or label of a prescription drug, except that "repackage" does not include any of the following:

(a) An action by a pharmacist with respect to a prescription drug that the pharmacist is dispensing.

(b) An action by a pharmacist who receives a prescription drug or device that the pharmacist dispensed to a patient, if, after altering the packaging or labeling of the prescription drug or device, the pharmacist returns the prescription drug or device to the patient.

(21m) "Repackager" means a person that repackages.

(21s) "Third party logistics provider" means a person that contracts with a prescription drug manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of the manufacturer but that does not take title to the manufacturer's prescription drug or have general responsibility to direct the prescription drug's sale or disposition.

(22) "Vaccination protocol" means a written protocol agreed to by a physician, as defined in s. 448.01 (5), and a pharmacist that establishes procedures and record-keeping and reporting requirements for the administration of a vaccine by a pharmacist for a period specified in the protocol that may not exceed 2 years.

(23) "Wholesale distribution" means distribution of a prescription drug to a person other than a consumer or patient, but does not include any of the following:

(a) Intracompany sales of prescription drugs.

(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.

(c) The distribution of prescription drug samples, if the distribution is permitted under 21 CFR 353(d).

(d) Drug returns, when conducted by a hospital, health care entity, or charitable institution as provided in 21 CFR 203.23.

(e) The sale of minimal quantities, as defined by the board in an administrative rule, of prescription drugs by retail pharmacies to licensed practitioners for office use.

(f) The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription.

(g) The sale, transfer, merger, or consolidation of all or part of the business of a pharmacy from or with another pharmacy, whether accomplished as a purchase and sale of stock or business assets.

(h) The sale, purchase, distribution, trade, or transfer of a prescription drug from one authorized distributor of record to one additional authorized distributor of record, if the manufacturer states in writing to the receiving authorized distributor of record that the manufacturer is unable to supply the drug and the supplying authorized distributor of record states in writing that the drug has previously been exclusively in the normal distribution channel.

(i) The delivery of, or offer to deliver, a prescription drug by a common carrier solely in the common carrier's usual course of business of transporting prescription drugs, if the common carrier does not store, warehouse, or take legal ownership of the drug.

(j) A transaction excluded from the definition of "wholesale distribution" under 21 CFR 203.3(cc).

(k) The donation or distribution of a prescription drug under s. 255.056 or under 21 CFR 203.39.

(L) The transfer from a retail pharmacy or pharmacy warehouse of an expired, damaged, returned, or recalled prescription drug to the original manufacturer or original wholesale

distributor or to a 3rd-party returns processor or reverse distributor.

(m) The return of a prescription drug, if the return is authorized by the law of this state.

(24) "Wholesale distributor" means a person engaged in the wholesale distribution of prescription drugs, including manufacturers, repackagers, own-label distributors, private label distributors, jobbers, brokers, warehouses, including manufacturers' and distributors' warehouses, manufacturers' exclusive distributors, manufacturers' authorized distributors of record, prescription drug wholesalers and distributors, independent wholesale prescription drug traders, 3rd party logistics providers, retail pharmacies that conduct wholesale distribution, and chain pharmacy warehouses that conduct wholesale distribution.

Wyoming Statutes Annotated

Title 33. Professions and Occupations
Chapter 24. Pharmacy
Article 1. In General
§ 33-24-153. Manufacturer or wholesaler registration; requirements for registration; bonds or other security; fees; renewal; denial, revocation or suspension; record keeping; summary orders; administrative penalties; definitions

(a) Every wholesale distributor who engages in the distribution of prescription drugs in this state shall obtain from the board a drug distributor's license for each distribution location. In addition, every nonresident wholesale distributor who ships prescription drugs into this state shall be licensed by the licensing authority in the state in which the distributor resides. For manufacturers engaged in wholesale distribution of prescription drugs in this state, the provisions of this section that are more stringent than those required by the United States food and drug administration shall not apply. This section shall not apply to resident pharmacies registered under W.S. 33-24-113, nonresident pharmacies registered under W.S. 33-24-152 or to individuals practicing medicine as defined by W.S. 33-26-102(a)(xi)(B) and (E).

(b) Applications for a drug distributor's license under this section shall be made on a form furnished by the board. By January 1, 2009, current license holders and applicants for licensure under this section shall provide the board with fingerprints, necessary fees and other information required to perform a criminal history record background check as provided for by W.S. 7-19-201 for the designated representative for each wholesale drug distributor site.

(c) The fee for a drug distributor's license shall be the fee specified in W.S. 33-24-112(a)(iii).

(d) Repealed by Laws 2007, ch. 211, § 2.

(e) Every drug distributor's license shall be renewed annually on or before the first day of July.

(f) Any administrative penalty assessed under this section shall be paid to the board who shall remit the monies to the county treasurer to the credit of the public school fund of the county in which the violation occurred.

(g) By January 1, 2009, the board shall require every drug distributor license holder and applicant to submit a bond in the amount of one hundred thousand dollars ($100,000.00), or other security acceptable to the board such as an irrevocable letter of credit or deposit in a trust account or financial institution, payable to a fund established by the board pursuant to paragraph (h) of this section. The purpose of the bond or other security shall be to secure payment of any fines or penalties imposed by the board and any fees and costs incurred by the board regarding the drug distributor's license which are authorized under state law and which remain unpaid thirty (30) days after liability for the payment is final. The board shall release the bond or security one (1) year after the distributor's license ceases to be valid. The bond or security shall cover all facilities operated by the applicant and licensed by the board. The board may waive the requirement of a bond or other security if:

(i) The drug distributor has previously obtained a comparable bond or other security for the purpose of licensure in another state where the wholesaler possesses a valid license in good standing; or
(ii) The drug distributor is a publicly held company.

(h) The board shall establish a fund, separate from its other accounts, for the deposit of amounts submitted in lieu of a bond pursuant to subsection (g) of this section.

(j) The board shall require each person engaged in wholesale distribution of prescription drugs to establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of the drugs. The records shall include pedigrees for all prescription drugs that are or ever have been distributed outside the normal distribution channel as established by board regulations.

(k) The board shall issue an order to cease distribution of a prescription drug if the board finds that there is probable cause that:

(i) A drug distributor has:
(A) Violated a provision of this section; or
(B) Falsified a pedigree or sold, distributed, transferred, manufactured, repackaged, handled or held a counterfeit prescription drug intended for human or animal use.
(ii) The prescription drug at issue as a result of a violation in paragraph (k)(i)(B) of this section could cause serious adverse health consequences or death; and
(iii) Other procedures would result in unreasonable delay in responding to the dangers posed by the prescription drug at issue.

(m) An order issued by the board pursuant to subsection (k) of this section shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than ten (10) working days after the date of the issuance of the order, on the actions required by the order. If, after providing an opportunity for a hearing, the board determines that inadequate grounds exist to support the actions required by the order, the board shall vacate the order.

(n) The board may deny, suspend, revoke or refuse to renew a license issued under this section, may issue a letter of admonition and may assess an administrative penalty not to exceed those penalties established in paragraph (o) of this section for any of the following acts:

(i) Failure to obtain a license in accordance with this section or operating without a valid license when a license is required;
(ii) The sale, distribution or transfer of a prescription drug to a person who is not authorized to receive the prescription drug under the law of the jurisdiction in which the person receives the prescription drug;
(iii) Failure to obtain, pass or authenticate a pedigree as required by this section or board rules;
(iv) Providing the board with false or fraudulent records or making false or fraudulent statements regarding the provisions of this section or board rules;
(v) Obtaining or attempting to obtain a prescription drug by fraud, deceit or misrepresentation, or engaging in fraud or misrepresentation in the distribution of a prescription drug;
(vi) Except for the wholesale distribution by manufacturers of a prescription drug that has been delivered into commerce pursuant to an application approved by the United States food and drug administration, the adulteration, misbranding or counterfeiting of any prescription drug;
(vii) The receipt of any prescription drug that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit or suspected of being counterfeit, or the delivery or proffered delivery of such drug whether for pay or otherwise; and
(viii) The adulteration, mutilation, destruction, obliteration or removal of all or any part of the labeling of a prescription drug or the commission of any other act with respect to a prescription drug that results in the prescription drug being misbranded.

(*o*) The board may assess an administrative penalty for a violation of subsection (n) of this section as follows:

(i) If a person unknowingly engages in the wholesale distribution of prescription drugs and acts in violation of subsection (n) of this section, the person may be assessed an administrative penalty not to exceed fifty thousand dollars ($50,000.00);
(ii) If a person knowingly engages in wholesale distribution of prescription drugs in violation of subsection (n) of this section, the person may be assessed an administrative penalty not to exceed five hundred thousand dollars ($500,000.00).

(p) The board is authorized to contract with a private person or entity to inspect and accredit drug distributors. Any proprietary information obtained during the accreditation process shall remain confidential and privileged. The board shall provide by rule and regulation for the administrative review of any decision denying accreditation.

(q) The board may license by reciprocity a drug distributor that is licensed in another state if:

(i) The requirements of the distributor's domiciliary state are determined by the board to be substantially equivalent to the requirements of this state for licensing of drug distributors; or
(ii) The applicant is accredited by a third party approved by the board.

(r) For purposes of this section:

(i) "Designated representative" means an individual designated by a wholesale drug distributor and who is actively involved in and aware of the actual daily operation of the wholesale drug distributor at the wholesaler's licensed location;
(ii) "Pedigree" means a document or electronic file containing recorded information regarding each distribution of any given prescription drug.