TITLE 25 HEALTH SERVICES
PART 1 DEPARTMENT OF STATE HEALTH SERVICES
CHAPTER 229 FOOD AND DRUG
SUBCHAPTER W LICENSING OF WHOLESALE DISTRIBUTORS OF PRESCRIPTION DRUGS--INCLUDING GOOD MANUFACTURING PRACTICES

§229.419. Purpose.

This subchapter provides the minimum licensing requirements necessary to ensure the safety and efficacy of prescription drugs offered for sale by wholesale distributors.

§229.420. Applicable Laws and Regulations.

(a) The department adopts by reference the following laws and regulations:

(1) Federal Food, Drug, and Cosmetic Act, 21 United States Code (USC) §301 et seq., as amended;

(2) 9 Code of Federal Regulations (CFR) Part 113, Standard Requirements, as amended;

(3) 21 CFR Part 70, Color Additives, as amended;

(4) 21 CFR Part 71, Color Additive Petitions, as amended;

(5) 21 CFR Part 73, Listing of Color Additives Exempt From Certification, as amended;

(6) 21 CFR Part 74, Listing of Color Additives Subject to Certification, as amended;

(7) 21 CFR Part 80, Color Additive Certification, as amended;

(8) 21 CFR Part 81, General Specifications and General Restrictions for Provisional Color Additives for Use in Foods, Drugs, and Cosmetics, as amended;

(9) 21 CFR Part 82, Listing of Certified Provisionally Listed Colors and Specifications, as amended;

(10) 21 CFR Part 200, General, as amended;

(11) 21 CFR Part 201, Labeling, as amended;

(12) 21 CFR Part 202, Prescription Drug Advertising, as amended;

(13) 21 CFR Part 203, Prescription Drug Marketing, as amended;

(14) 21 CFR Part 205, Guidelines for State Licensing of Wholesale Prescription Drug Distributors, as amended;

(15) 21 CFR Part 206, Imprinting of Solid Oral Dosage Form Drug Products for Human Use, as amended;

(16) 21 CFR Part 207, Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs, and the National Drug Code, as amended;

(17) 21 CFR Part 210, Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General, as amended;

(18) 21 CFR Part 211, Current Good Manufacturing Practice for Finished Pharmaceuticals, as amended;

(19) 21 CFR Part 212, Current Good Manufacturing Practice for Positron Emission Tomography Drugs, as amended;

(20) 21 CFR Part 216, Human Drug Compounding, as amended;

(21) 21 CFR Part 225, Current Good Manufacturing Practice for Medicated Feeds, as amended;

(22) 21 CFR Part 226, Current Good Manufacturing Practice for Type A Medicated Articles, as amended;

(23) 21 CFR Part 250, Special Requirements For Specific Human Drugs, as amended;

(24) 21 CFR Part 251, §804, Importation Program, as amended;

(25) 21 CFR Part 290, Controlled Drugs, as amended;

(26) 21 CFR Part 299, Drugs; Official Names and Established Names, as amended;

(27) 21 CFR Part 300, General, as amended;

(28) 21 CFR Part 310, New Drugs, as amended;

(29) 21 CFR Part 312, Investigational New Drug Application, as amended;

(30) 21 CFR Part 314, Applications for FDA Approval to Market a New Drug, as amended;

(31) 21 CFR Part 315, Diagnostic Radiopharmaceuticals, as amended;

(32) 21 CFR Part 316, Orphan Drugs, as amended;

(33) 21 CFR Part 320, Bioavailability and Bioequivalence Requirements, as amended;

(34) 21 CFR Part 361, Prescription Drugs for Human Use Generally Recognized as Safe and Effective and Not Misbranded: Drugs Used in Research, as amended;

(35) 21 CFR Part 500, General, as amended;

(36) 21 CFR Part 510, New Animal Drugs, as amended;

(37) 21 CFR Part 511, New Animal Drugs for Investigational Use, as amended;

(38) 21 CFR Part 514, New Animal Drug Applications, as amended;

(39) 21 CFR Part 515, Medicated Feed Mill License, as amended;

(40) 21 CFR Part 516, New Animal Drugs for Minor Use and Minor Species, as amended;

(41) [(@] 21 CFR Part 520, Oral Dosage Form New Animal Drugs, as amended;

(42) 21 CFR Part 522, Implantation or Injectable Dosage Form New Animal Drugs, as amended;

(43) 21 CFR Part 524, Ophthalmic and Topical Dosage Form New Animal Drugs, as amended;

(44) 21 CFR Part 526, Intramammary Dosage Form New Animal Drugs, as amended;

(45) 21 CFR Part 528, New Animal Drugs in Genetically Engineered Animals, as amended;

(46) 21 CFR Part 529, Certain Other Dosage Form New Animal Drugs, as amended;

(47) 21 CFR Part 530, Extralabel Drug Use in Animals, as amended;

(48) 21 CFR Part 556, Tolerances for Residues of New Animal Drugs in Food, as amended;

(49) 21 CFR Part 558, New Animal Drugs for Use in Animal Feeds, as amended;

(50) 21 CFR Part 589, Substances Prohibited From Use in Animal Food or Feed, as amended;

(51) 21 CFR Part 600, Biological Products: General, as amended;

(52) 21 CFR Part 601, Licensing, as amended;

(53) 21 CFR Part 610, General Biological Products Standards, as amended;

(54) 21 CFR Part 660, Additional Standards for Diagnostic Substances for Laboratory Tests, as amended;

(55) 21 CFR Part 680, Additional Standards for Miscellaneous Products, as amended;

(56) 21 CFR Part 700, General, as amended;

(57) 21 CFR Part 701, Cosmetic Labeling, as amended;

(58) 21 CFR Part 740, Cosmetic Product Warning Statements, as amended;

(59) 21 CFR Part 1271, Human Cells, Tissues, and Cellular and Tissue-Based Products, as amended;

(60) 21 CFR Part 1300, Definitions, as amended;

(61) 21 CFR Part 1301, Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances, as amended;

(62) 21 CFR Part 1302, Labeling and Packaging Requirements For Controlled Substances, as amended;

(63) 21 CFR Part 1304, Records and Reports of Registrants, as amended;

(64) 21 CFR Part 1305, Orders for Schedule I and Schedule II Controlled Substances, as amended;

(65) 21 CFR Part 1306, Prescriptions, as amended;

(66) 21 CFR Part 1307, Miscellaneous; and

(67) 21 CFR Part 1317, Disposal, as amended.

(b) Copies of these laws and regulations are indexed and filed at the Texas Department of State Health Services, 1100 West 49th Street, Austin, Texas 78756, and are available for inspection during normal working hours. Electronic copies of these laws and regulations are available online at www.dshs.texas.gov.

(c) Nothing in this subchapter relieves any person of the responsibility for complying with other applicable Texas and federal laws and regulations.

§229.421. Definitions.

The following words and terms, when used in this subchapter, have the following meanings, unless the context clearly indicates otherwise.

(1) Act--The Texas Food, Drug, and Cosmetic Act, Texas Health and Safety Code Chapter 431.

(2) Adulterated drug--Has the meaning specified in the Act.

(3) Authorized agent--An employee of the department who is designated by the commissioner to enforce the provisions of the Act.

(4) Broker--A person engaged in the offering or contracting for wholesale distribution; sale or transfer of a prescription drug into, within, or out of Texas; and, who does not take title to or physical possession of the prescription drug.

(5) Change of ownership--A sole proprietor who transfers all or part of the facility's ownership to another person or persons; the removal, addition, or substitution of a person or persons as a partner in a facility owned by a partnership; a corporate sale, transfer, reorganization, or merger of the corporation

which owns the facility if sale, transfer, reorganization, or merger causes a change in the facility's ownership to another person or persons; or if any other type of association, the removal, addition, or substitution of a person or persons as a principal of such association.

(6) Co-licensed product partner--One of two or more parties having the right to engage in the manufacturing or marketing of a prescription drug consistent with the United States Food and Drug Administration's (FDA) regulations and guidance implementing the Prescription Drug Marketing Act of 1987 (Pub. L. No. 100 - 293).

(7) Commissioner--Commissioner of the Texas Department of State Health Services.

(8) Component--Any ingredient intended for use in the manufacture of a drug product, including those that might not appear in such drug product.

(9) Department--The Texas Department of State Health Services.

(10) Device--An instrument apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory:

(A) recognized in the official United States Pharmacopoeia National Formulary or any supplement to it;

(B) 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

(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 is not dependent on metabolization for the achievement of any of its principal intended purposes.

(11) Drop shipment--The sale of a prescription drug to a wholesale distributor by the manufacturer of the prescription drug, or by the manufacturer's co-licensed product partner, third-party logistics provider, or exclusive distributor, in which:

(A) the wholesale distributor takes title but not physical possession of the prescription drug;

(B) the wholesale distributor invoices the pharmacy, pharmacy warehouse, or other person authorized by law to dispense or administer the drug to a patient; and

(C) the pharmacy, pharmacy warehouse, or other authorized person receives delivery of the prescription drug directly from the manufacturer or the manufacturer's third-party logistics provider or exclusive distributor.

(12) Drug--Articles recognized in the official United States Pharmacopoeia National Formulary, or any supplement to it; articles designated or intended for use

in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; articles, other than food, intended to affect the structure or any function of the body of humans or other animals; and articles intended for use as a component of any such article. The term does not include devices or their components, parts, or accessories. A food for which a claim is made in accordance with the Federal Food, Drug, and Cosmetic Act, §403(r) and 21 United States Code (USC) §301, et seq., and for which the claim is approved by the FDA, is not a drug solely because the label or labeling contains such a claim.

(13) Emergency medical reasons--Includes transfers of a prescription drug between a wholesale distributor or pharmacy to alleviate a temporary shortage of a prescription drug arising from delays in or interruption of regular distribution schedules; sales to nearby emergency medical services, i.e., ambulance companies and firefighting organizations in the same state or same marketing or service area, or nearby licensed practitioners of drugs for use in the treatment of acutely ill or injured persons; provision of minimal emergency supplies of drugs to nearby nursing homes for use in emergencies or during hours of the day when necessary drugs cannot be obtained; and transfers of prescription drugs by a retail pharmacy to alleviate a temporary shortage.

(14) Federal Act--Federal Food, Drug, and Cosmetic Act, 21 USC, §301, et seq., as amended.

(15) Flea market--A location at which booths or similar spaces are rented or otherwise made available temporarily to two or more persons and at which the persons offer tangible personal property for sale.

(16) Inactive ingredient--Any component, other than an active ingredient, including excipient, flavor, fragrance, and color.

(17) Labeling--All labels and other written, printed, or graphic matter:

(A) upon any drug or any of its containers or wrappers; or

(B) accompanying such drug.

(18) Manufacturer--A person who manufactures, prepares, propagates, compounds, processes, packages, or repackages prescription drugs, or a person who changes the container, wrapper, or labeling of any prescription drug package. A person licensed or approved by the FDA to engage in the manufacture of drugs or devices, consistent with the federal agency's definition of manufacturer under the agency's regulations and guidance implementing the Prescription Drug Marketing Act of 1987 (Pub. L. No. 100 - 293). The term does not include a pharmacist engaged in compounding done within the practice of pharmacy and pursuant to a prescription drug order or initiative from a practitioner for a patient or prepackaging done in accordance with Texas Occupations Code §562.154.

(19) Manufacturer's exclusive distributor--A person who holds a wholesale distributor license under this subchapter, who contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of the

manufacturer, and who takes title to, but does not have general responsibility to direct the sale or disposition of, the manufacturer's prescription drug. A manufacturer's exclusive distributor must be an authorized distributor of record to be considered part of the normal distribution channel.

(20) Misbranded drug--Has the meaning specified in the Act at §431.112.

(21) Nonprescription drug--Any drug that is not a prescription drug, including the terms Over-the-Counter Drug and Non-legend Drug.

(22) Normal distribution channel--A chain of custody for a prescription drug, either directly or by drop shipment, from the manufacturer of the prescription drug, the manufacturer to the manufacturer's co-licensed product partner, the manufacturer to the manufacturer's third-party logistics provider, or the manufacturer to the manufacturer's exclusive distributor, to:

(A) a pharmacy to:

(i) a patient; or

(ii) another designated person authorized by law to dispense or administer the drug to a patient;

(B) an authorized distributor of record to:

(i) a pharmacy to a patient; or

(ii) another designated person authorized by law to dispense or administer the drug to a patient;

(C) an authorized distributor of record to a wholesale distributor licensed under this subchapter to another designated person authorized by law to administer the drug to a patient;

(D) an authorized distributor of record to a pharmacy warehouse to the pharmacy warehouse's intracompany pharmacy;

(E) a pharmacy warehouse to the pharmacy warehouse's intracompany pharmacy or another designated person authorized by law to dispense or administer the drug to a patient;

(F) a person authorized by law to prescribe a prescription drug that by law may be administered only under the supervision of the prescriber; or

(G) an authorized distributor of record to one other authorized distributor of record to a licensed practitioner for office use.

(23) Person--An individual, corporation, business trust, estate, trust, partnership, association, or any other public or private legal entity.

(24) Pharmacy warehouse--A location for which a person holds a wholesale drug distribution license under this subchapter, serving as a central warehouse for drugs

or devices, and from which intracompany sales or transfers of drugs or devices are made to a group of pharmacies under common ownership and control.

(25) Prescription drug--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 the Federal Act, §503(b).

(26) Repackage--Repackaging or otherwise changing the container, wrapper, or labeling of a drug to further the distribution of a prescription drug. The term does not include repackaging by a pharmacist to dispense a drug to a patient or prepackaging in accordance with Texas Occupations Code §562.154.

(27) Repackager--A person who engages in repackaging.

(28) Third-party logistics provider--A person who holds a wholesale distributor license under this subchapter, who contracts with a prescription drug manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of the manufacturer, and who 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 an authorized distributor of record to be considered part of the normal distribution channel.

(29) Verification--A person who is engaged in the wholesale distribution of a prescription drug, and who is in possession of a pedigree for a prescription drug must , before distributing the prescription drug, authenticate and certify, in accordance with the Act at Texas Food, Drug, and Cosmetic Act, Health and Safety Code §431.412 and §431.413, and §229.429(f)(3)(G) of this subchapter (relating to Minimum Standards of Licensure), each transaction listed on the pedigree has occurred.

(30) Wholesale distribution--Distribution of prescription drugs to a person other than a consumer or patient. The term does not include:

(A) intracompany sales of prescription drugs, which means transactions or transfers of prescription drugs between a division, subsidiary, parent, or affiliated or related company under common ownership and control or any transaction or transfer between co-license holders of a co-licensed product;

(B) the sale, purchase, trade, or transfer of prescription drugs or the offer to sell, purchase, trade, or transfer a prescription drug for emergency medical reasons including a transfer of a prescription drug by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage;

(C) the distribution of prescription drug samples by a representative of a manufacturer;

(D) the return of drugs by a hospital, health care entity, or charitable institution in accordance with 21 Code of Federal Regulations (CFR) §203.23;

(E) the sale of reasonable quantities by a retail pharmacy of a prescription drug to a licensed practitioner 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 under 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 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;

(I) 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 in accordance with the procedures set out in 21 CFR §203.23(a)(1) - (5) for other returns;

(J) the purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of such organizations;

(K) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in the Internal Revenue Code of 1986, 26 USC §501(c)(3), to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(L) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities under common control; for purposes of this subchapter, 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, voting rights, by contract, or otherwise; or

(M) the sale, purchase, or trade of blood and blood components intended for transfusion.

(31) Wholesale distributor--A person engaged in the wholesale distribution of prescription drugs, including a manufacturer, repackager, own-label distributor, private-label distributor, jobber, broker, manufacturer warehouse, distributor warehouse, or other warehouse, manufacturer's exclusive distributor, authorized distributor of record, drug wholesaler or distributor, independent wholesale drug trader, specialty wholesale distributor, third-party logistics provider, retail pharmacy that conducts wholesale distribution, and pharmacy warehouse that conducts wholesale distribution.

§229.422. Sale of a Prescription Drug.

Any reference in this subchapter to the sale of a prescription drug must be

considered to include the manufacture, packaging, exposure, offer, possession, and holding of any prescription drug for sale; the sale, dispensing, and providing of any prescription drug; and supplying or applying of any prescription drug in the operation of any prescription drug place of business.

§229.423. Exemptions.

(a) General. A person who engages in the wholesale distribution of prescription drugs in this state for use in humans is exempt from this subchapter if the person is exempt under:

(1) the Prescription Drug Marketing Act of 1987 (PDMA Act), (21 United States Code (USC) §353(c)(3)(B));

(2) the regulations adopted by the secretary to administer and enforce the PDMA Act;

(3) the interpretations of the PDMA Act set forth in the compliance policy manual of the United States Food and Drug Administration; or

(4) the Texas Occupations Code §562.154.

(b) Exemptions from licensing. Persons who engage in the following types of distribution of prescription drugs are exempt from the licensing requirements of this subchapter, to the extent it does not violate provisions of the Texas Controlled Substances Act, Texas Health and Safety Code Chapter 481, or the Texas Dangerous Drug Act, Texas Health and Safety Code Chapter 483:

(1) intracompany sales of prescription drugs, which means transactions or transfers of prescription drugs between a division, subsidiary, parent, or affiliated or related company under common ownership and control, or any transaction or transfer between co-license holders of a co-licensed product;

(2) the sale, purchase, trade, or transfer of prescription drugs or the offer to sell, purchase, trade, or transfer a prescription drug for emergency medical reasons; including a transfer of a prescription drug by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage;

(3) the distribution of prescription drug samples by a representative of a manufacturer;

(4) the return of drugs by a hospital, health care entity, or charitable institution in accordance with Title 21, Code of Federal Regulations (CFR) §203.23;

(5) the sale of reasonable quantities by a retail pharmacy of a prescription drug to a licensed practitioner 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 under a prescription;

(7) 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;

(8) 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;

(9) 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 in accordance with procedures set out in 21 CFR §203.23(a)(1) - (5) for returns;

(10) the purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of such organizations;

(11) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in the Internal Revenue Code of 1986, 26 USC §501(c)(3), to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(12) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control; for purposes of this subchapter, 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, voting rights, contract, or otherwise; or

(13) the sale, purchase, or trade of blood and blood components intended for transfusion.

(c) Applicability of other requirements. An exemption from the licensing requirements granted in subsection (b) of this section does not constitute an exemption from other applicable requirements for prescription drugs under this subchapter or under the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431.

(d) Exemption from certain requirements for certain wholesale distributors.

(1) A wholesale distributor that distributes only prescription drugs that are medical gases is exempt from the following requirements: §229.424(d) of this subchapter (relating to Licensure Requirements), §229.425(b)(4) - (5), (c) and (d) of this subchapter (relating to Licensing Procedures); and §229.424(n) and §229.425(h) of this subchapter concerning bonds.

(2) A wholesale distributor that is a manufacturer or a third-party logistics provider on behalf of a manufacturer is exempt from the following requirements: §229.424(d) of this title; §229.425(b)(4) - (5), (c) and (d) of this subchapter; and

§229.424(n) and §229.425(h) of this subchapter concerning bonds.

(3) A state agency or a political subdivision of this state that distributes prescription drugs using federal or state funding to nonprofit health care facilities or local intellectual and developmental disability authorities, referred to as local mental health or mental retardation authorities, for distribution to a pharmacy, practitioner, or patient is exempt from §229.424(d) and (n) and §229.425(d) and (h) of this subchapter concerning bonds, and §229.429(f) of this subchapter (relating to Minimum Standards of Licensure) concerning pedigree.

(4) The executive commissioner of the Texas Health and Human Services Commission by rule may exempt specific purchases of prescription drugs by state agencies and political subdivisions of this state if the executive commissioner determines the requirements of this subchapter would result in a substantial cost to the state or a political subdivision of the state.

§229.424. Licensure Requirements.

(a) General. Except as provided in §229.423 of this subchapter (relating to Exemptions), a person may not engage in the wholesale distribution of prescription drugs in Texas, as defined in §229.421(30) - (31) of this subchapter (relating to Definitions), unless the person has a valid license from the commissioner of the department for each place of business.

(b) Out-of-state place of business.

(1) Except as provided by §229.423 of this subchapter, a person who engages in the wholesale distribution of prescription drugs from outside this state may only engage in the wholesale distribution of prescription drugs in this state if the person holds a license as required in subsection (a) of this section.

(2) The department may accept reports from authorities in other jurisdictions to determine the extent of compliance with the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431 and this subchapter.

(3) The department may issue a license to a person who engages in the wholesale distribution of prescription drugs outside this state to engage in the wholesale distribution of prescription drugs in this state if, after an examination of the reports of the person's compliance history and current compliance record, the department determines the person is in compliance with the Act and this subchapter.

(4) The department considers each license application and any related documents or reports filed by or in connection with a person who wishes to engage in the wholesale distribution of prescription drugs in this state on an individual basis.

(c) Combination product. If the United States Food and Drug Administration determines, with respect to a product that is a combination of a prescription drug and a device, the primary mode of action of the product is as a prescription drug, a

wholesale distributor of such a product is subject to licensure as described in this section.

(d) Applicant qualifications. To qualify for the issuance or renewal of a wholesale distributor license under this subchapter, the designated representative of an applicant or license holder must:

(1) be at least 21 years of age;

(2) have been employed full-time for at least three years by a pharmacy or a wholesale distributor in a capacity related to the dispensing or distributing of prescription drugs, including recordkeeping for the dispensing or distributing of prescription drugs;

(3) be employed by the applicant full-time in a managerial-level position;

(4) be actively involved in and aware of the actual daily operation of the wholesale distributor;

(5) be physically present at the applicant's place of business during regular business hours, except when the absence of the designated representative is authorized, including sick leave and vacation leave;

(6) serve as a designated representative for only one applicant at any one time, except in a circumstance, as the department determines reasonable, in which more than one licensed wholesale distributor is co-located in the same place of business at the same address and the wholesale distributors are members of an affiliated group, as defined by the Internal Revenue Code of 1986, 26 USC §1504;

(7) not have been convicted of a violation of any federal, state, or local laws relating to wholesale or retail prescription drug distribution or the distribution of controlled substances; and

(8) not have been convicted of a felony under a federal, state, or local law.

(e) Proof of licensure. The license holder must show proof of licensure in a format readily available to the public and at each place of business.

(f) New place of business. Each person acquiring or establishing a place of business for the purpose of wholesale distribution of prescription drugs must apply to the department for a license of such business before beginning operation.

(g) Two or more places of business. If the wholesale distributor of prescription drugs operates more than one place of business, the wholesale distributor of prescription drugs must license each place of business separately.

(h) Pre-licensing inspection. The applicant must cooperate with any pre-licensing inspection by the department of the applicant's place of business.

(i) Issuance of license. In accordance with §229.281 of this chapter (relating to Processing License/Permit Applications Relating to Food and Drug Operations), the

department may license a wholesale distributor of prescription drugs who meets the requirements of this subchapter and pays all license fees under §229.427 of this subchapter (relating to Licensure Fees).

(j) Transfer of license. Licenses are not transferable from one person to another or from one place of business to another.

(k) License term. Unless the license is amended as provided in subsection (l) of this section or suspended or revoked as provided in §229.428 of this subchapter (relating to Refusal, Cancellation, Suspension, or Revocation of License), the license is valid for two years.

(l) Amendment of license. A license that is amended, including a change of name, or a notification of a change in the location of a licensed place of business will require submission of an application as outlined in §229.425 of this subchapter (relating to Licensing Procedures) and submission of fees as outlined in §229.427 of this subchapter.

(m) Renewal of license.

(1) The license application as outlined in §229.425 of this subchapter and nonrefundable licensing fees as outlined in §229.427 of this subchapter for each place of business must be submitted to the department not later than the 30th day after the date the wholesale distributor receives a renewal notification form from the department. A person who files a renewal application after the expiration date must pay an additional $100 as a delinquency fee.

(2) A license holder who fails to submit a renewal application before the current licensure expiration date and continues operations may be subject to the enforcement and penalty provisions in §229.430 of this subchapter (relating to Enforcement and Penalties), and the refusal, cancellation, suspension, and revocation provisions in §229.428 of this subchapter.

(3) A renewal license is only issued when all past due license fees and delinquency fees are paid.

(n) Bond.

(1) A wholesale distributor applying for or renewing a license must submit, payable to this state, a bond or other equivalent security acceptable to the department, including an irrevocable letter of credit or a deposit in a trust account or financial institution, in the amount of $100,000.

(2) The bond or equivalent security submitted under paragraph (1) of this subsection must secure payment of any fines or penalties imposed by the department or imposed in connection with an enforcement action by the attorney general, any fees or other enforcement costs, including attorney's fees payable to the attorney general, and any other fees and costs incurred by this state related to that license holder, authorized under the laws of this state and not paid by the license holder before the 30th day after the date a fine, penalty, fee, or cost is

assessed.

(3) The department or this state may make a claim against a bond or security submitted under paragraph (1) of this subsection before the first anniversary of the date a license expires or is revoked under this subchapter.

(4) The department must deposit the bonds and equivalent securities received under this section in a separate account.

(5) A pharmacy warehouse not engaged in wholesale distribution is exempt from the bond requirement under paragraph (1) of this subsection.

(6) A single bond is sufficient to cover all places of business operated by a wholesale distributor in this state.

§229.425. Licensing Procedures.

(a) License application forms. License application forms may be obtained from the Texas Department of State Health Services, 1100 West 49th Street, Austin, Texas, 78756, or online at www.dshs.texas.gov.

(b) Contents of license application. The application for licensure as a wholesale distributor of prescription drugs must be signed and verified, submitted on a license application form furnished by the department, and contain the following information:

(1) the name, full business address, and telephone number of the applicant;

(2) all trade or business names under which the business is conducted;

(3) the address, telephone number, and name of a contact person for each of the applicant's places of business;

(4) the type of business entity:

(A) if a person, the name of the person;

(B) if the business is a sole proprietorship, the name of the proprietor;

(C) if the business is a partnership, the name of the partnership and each of the partners; or

(D) if the business is a corporation, the name of the corporation, the place of incorporation, and the name and title of each corporate office and director;

(5) the name, date of birth, residence address, telephone number, and any information necessary to complete a criminal history record check on a designated representative of each place of business;

(6) a list of all licenses and permits issued to the applicant by any other state under which the applicant is permitted to purchase or possess prescription drugs;

(7) the name of the manager, if different from the designated representative,

for each place of business;

(8) a list of categories which must be marked and adhered to in the determination and paying of the fee; and

(9) a statement verified by the applicant's signature acknowledging the applicant read, understood, and agrees to abide by the provisions of this subchapter and those of the Texas Food, Drug, and Cosmetic Act, Texas Health and Safety Code Chapter 431.

(c) Designated representatives.

(1) For each person who is a designated representative of each place of business, the applicant must provide the following to the department:

(A) the person's places of residence for the past seven years;

(B) the person's date and place of birth;

(C) the person's occupations, positions of employment, and offices held during the past seven years;

(D) the business name and address of any business, corporation, or other organization in which the person held an office under subsection (b)(4) of this section or in which the person conducted an occupation or held a position of employment;

(E) a statement of whether, during the preceding seven years, the person was the subject of a proceeding to revoke a license or a criminal proceeding and the nature and disposition of the proceeding;

(F) a statement of whether, during the preceding seven years, the person has been enjoined, either temporarily or permanently, by a court from violating any federal or state law regulating the possession, control, or distribution of prescription drugs, including the details concerning the event;

(G) a written description of any involvement by the person as an officer or director 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, that manufactured, administered, prescribed, distributed, or stored pharmaceutical products and any lawsuits in which the businesses were named as a party;

(H) a description of any misdemeanor or felony offense for which the person, as an adult, was found guilty, regardless of whether adjudication of guilt was withheld or whether the person pled guilty or nolo contendere;

(I) a description of any criminal conviction of the person under appeal, a copy of the notice of appeal for that criminal offense, and a copy of the final written order of an appeal not later than the 15th day after the date of the appeal's disposition; and

(J) a photograph of the person taken not earlier than 180 days before the date the application was submitted.

(2) The information submitted under paragraph (1) of this subsection must be attested to under oath.

(d) Criminal history. The department will obtain an applicant's criminal history record information and may forward the fingerprints to the Federal Bureau of Investigation for a federal criminal history check.

(e) Renewal license application. The renewal application for licensure as a wholesale distributor of prescription drugs must be made on a license application form furnished by the department. Not later than the 30th day after the date the wholesale distributor receives the form, the wholesale distributor must identify and state under oath to the department any change in or correction to the information.

(f) Replacement license. In the event a current and valid license is lost, stolen, or destroyed, the license holder must request a replacement license from the department by submitting an application and non-refundable fee as outlined in §229.427 of this subchapter (relating to Licensing Fees). A replacement license is only issued if the lost, stolen, or destroyed license was current and valid at the time of the request, and no changes in business name, location, or ownership have occurred.

(g) Texas.gov. Applicants may submit initial and renewal license applications under this subchapter electronically through texas.gov. The department is authorized to collect fees, in amounts determined by §229.427(a) of this subchapter to recover costs associated with application and renewal application processing through texas.gov.

(h) Bond. Applicants will submit a bond in a manner prescribed by the department.

§229.426. Report of Changes.

(a) Change in the content of a license application. The license holder must notify the department in writing within 10 days of any change which would render the information contained in the application for the license, reported pursuant to §229.425 of this subchapter (relating to Licensing Procedures), no longer accurate. Failure to inform the department no later than 10 days of a change in the information required in the application for a license may result in an enforcement action, including suspension or revocation of the license.

(b) Change in location of place of business. The license holder must notify the department at least 30 days in advance of an intended change of address of the licensed place of business. The notice must include the address of the new location and the name of the individual in charge of the business at the new location. Within 10 days of beginning operations at the new location, the license holder must notify the department in writing to confirm the move, and provide verification or correction of the information provided on the notice of intent. The notice and confirmation required by this subchapter will be deemed adequate if the license

holder submits the notices by certified mail, return receipt requested, to the Texas Department of State Health Services, 1100 West 49th Street, Austin, Texas, 78756, or electronically through texas.gov.

§229.427. Licensure Fees

(a) License fee. Except as provided by §229.423 of this subchapter (relating to Exemptions), no person may operate or conduct business as a wholesale distributor of prescription drugs without first obtaining a license from the department. All applicants for an initial wholesale distributor of prescription drugs license or a renewal license must pay a licensing fee unless otherwise exempt as provided by subsection (c) of this section. All fees are nonrefundable. Licenses are issued for two-year terms. A license shall only be issued when all past due license fees and delinquency fees are paid.

(1) In-state and out-of-state wholesale distributors of prescription drugs who are not manufacturers must pay a two-year license fee based on the gross annual sales of all drugs.

(A) For a wholesale distributor of only medical gases, the fees are:

(i) $675 for a two-year license;

(ii) $675 for a two-year license issued to a change of ownership; and

(iii) $337 for a license amended during the current licensure period due to minor changes.

(B) For a wholesale distributor with gross annual drug sales of $0 - $199,999.99, the fees are:

(i) $1,080 for a two-year license;

(ii) $1,080 for a two-year license issued due to a change of ownership; and

(iii) $540 for a license amended during the current licensure period due to minor changes.

(C) For a wholesale distributor with gross annual drug sales of $200,000 - $19,999,999.99, the fees are:

(i) $1,755 for a two-year license;

(ii) $1,755 for a two-year license issued due to a change of ownership; and

(iii) $877 for a license amended during the current licensure period due to minor changes.

(D) For a wholesale distributor with gross annual drug sales greater than or equal to $20 million, the fees are:

(i) $2,295 for a two-year license;

(ii) $2,295 for a two-year license issued due to a change of ownership; and

(iii) $1,147 for a license amended during the current licensure period due to minor changes.

(2) In-state and out-of-state wholesale distributors of medical gases who are not manufacturers and who also are required to be licensed as a device distributor under §229.439(a) of this chapter (relating to Licensure Fees) or as a wholesale food distributor under §229.182(a)(3) of this chapter (relating to Licensing/Registration Fee and Procedures) must pay a combined two-year license fee for each place of business. License fees are based on the combined gross annual sales of these regulated products (medical gases, foods, drugs, and devices) as follows:

(A) For combined gross annual sales of $0 - $199,999.99, the fees are:

(i) $540 for a two-year license;

(ii) $540 for a two-year license issued due to a change of ownership; and

(iii) $270 for a license amended during the current licensure period due to minor changes.

(B) For combined gross annual sales of $200,000 - $499,999.99, the fees are:

(i) $810 for a two-year license;

(ii) $810 for a two-year license issued due to a change of ownership; and

(iii) $405 for a license amended during the current licensure period due to minor changes.

(C) For combined gross annual sales of $500,000 - $999,999.99, the fees are:

(i) $1,080 for a two-year license;

(ii) $1,080 for a two-year license issued due to a change of ownership; and

(iii) $540 for a license amended during the current licensure period due to minor changes.

(D) For combined gross annual sales of $1 million - $9,999,999.99, the fees are:

(i) $1,350 for a two-year license;

(ii) $1,350 for a two-year license issued due to a change of ownership;

and

(iii) $675 for a license issued during the current licensure period due to minor changes.

(E) For combined gross annual sales greater than or equal to $10 million, the fees are:

(i) $2,025 for a two-year license;

(ii) $2,025 for a two-year license issued due to a change of ownership; and

(iii) $1,012 for a license amended during the current licensure period due to minor changes.

(3) In-state and out-of-state manufacturers of only medical gases must pay a two-year license fee based on the gross annual sales of all prescription drugs as follows.

(A) For gross annual drug sales of $0 - $199,999.99, the fees are:

(i) $1,080 for a two-year license;

(ii) $1,080 for a two-year license issued due to a change of ownership; and

(iii) $540 for a license amended during the current licensure period due to minor changes.

(B) For gross annual drug sales of $200,000 - $19,999,999.99, the fees are:

(i) $1,755 for a two-year license;

(ii) $1,755 for a two-year license issued due to a change of ownership; and

(iii) $877 for a license amended during the current licensure period due to minor changes.

(C) For gross annual drug sales greater than or equal to $20 million, the fees are:

(i) $2,295 for a two-year license;

(ii) $2,295 for a two-year license issued due to a change of ownership; and

(iii) $1,147 for a license amended during the current licensure period due to minor changes.

(4) In-state and out-of-state manufacturers of prescription drugs must pay a two-year license fee based on the gross annual sales of all drugs as follows.

(A) For gross annual drug sales of $0 - $199,999.99, the fees are:

(i) $1,080 for a two-year license;

(ii) $1,080 for a two-year license issued due to a change of ownership; and

(iii) $540 for a license amended during the current licensure period due to minor changes.

(B) For gross annual drug sales of $200,000 - $1,999,999.99, the fees are:

(i) $1,350 for a two-year license;

(ii) $1,350 for a two-year license issued due to a change of ownership; and

(iii) $697 for a license amended during the current licensure period due to minor changes.

(C) For gross annual drug sales of $2 million - $9,999,999.99, the fees are:

(i) $1,620 for a two-year license;

(ii) $1,620 for a two-year license issued due to a change of ownership; and

(iii) $847 for a license amended during the current licensure period due to minor changes.

(D) For gross annual drug sales of $10 million to $19,999,999.99, the fees are:

(i) $1,890 for a two-year license;

(ii) $1,890 for a two-year license issued due to a change of ownership; and

(iii) $997 for a license amended during the current licensure period due to minor changes.

(E) For gross annual drug sales greater than or equal to $20 million, the fees are:

(i) $2,295 for a two-year license;

(ii) $2,295 for a two-year license issued due to a change of ownership; and

(iii) $1,147 for a license amended during the current licensure period due to minor changes.

(b) Replacement license fee. The replacement license fee is $100.

(c) Proration of license fees. A person having more than one place of business may request a one-time proration of the license fees when applying for a license for each new place of business. Upon approval by the department, the license for the new place of business will have a renewal date the same as the firm's other licensed places of business.

(d) Exemption from license fees. A person is exempt from the license fees required by this section if the person is a charitable organization, as described in the Internal Revenue Code of 1986, 26 USC §501(c)(3), or a nonprofit affiliate of the organization, to the extent otherwise permitted by law.

§229.428. Refusal, Cancellation, Suspension, or Revocation of License.

(a) The commissioner may refuse an application for a wholesale distributor of prescription drugs license or may suspend or revoke such a license if the applicant or license holder:

(1) has been convicted of a felony or misdemeanor involving moral turpitude;

(2) is an association, partnership, or corporation and the managing officer or any officer or director of a corporation has been convicted of a felony or misdemeanor involving moral turpitude;

(3) is an association, partnership, or corporation and the managing officer or any officer or director of a corporation has been convicted of a felony or misdemeanor involving the illegal use, sale, or transportation of intoxicating liquors, narcotic drugs, barbiturates, amphetamines, desoxyephedrine, their compounds or derivatives, or any other dangerous or habit-forming drugs;

(4) has violated any of the provisions of the Texas, Food, Drug, and Cosmetic Act, Texas Health and Safety Code Chapter 431 (Act) or this subchapter;

(5) has violated the Texas Health and Safety Code §431.021(l)(3), (jj), and (kk), concerning the counterfeiting of a drug or the sale or holding for sale of a counterfeit drug;

(6) has violated the Texas Controlled Substances Act, Texas Health and Safety Code Chapter 481, or the Texas Dangerous Drug Act, Texas Health and Safety Code Chapter 483;

(7) has violated the rules of the director of the Department of Public Safety, including being responsible for a significant discrepancy in the records that state law requires the applicant or license holder to maintain;

(8) fails to complete a license application or submits an application containing false, misleading, or incorrect information or containing information not verifiable by the department;

(9) has furnished false or fraudulent information in any application made in connection with drug manufacturing or distribution;

(10) has failed to pay a license fee or a renewal fee for a license; or

(11) has obtained or attempted to obtain a license by fraud or deception.

(b) The department may, after providing opportunity for hearing, refuse to license a wholesale distributor of prescription drugs, or may suspend or revoke a license for violations of the requirements in this subchapter or for any of the reasons described in the Act.

(c) Any hearings for the refusal, suspension, or revocation of a license are governed by §§1.21, 1.23, 1.25, and 1.27 of this title (relating to Formal Hearing Procedures).

(d) If the department suspends a license, the suspension remains in effect until the department determines the reason for the suspension no longer exists. If the suspension overlaps a renewal date, the suspended license holder must comply with the renewal procedures in §229.425 of this subchapter (relating to Licensing Procedures); however, the department may choose not to renew the license until the department determines the reason for suspension no longer exists.

(e) If the department revokes or does not renew a license, a person may reapply for a license by complying with the requirements and procedures in §229.425 of this subchapter at the time of reapplication. The department may refuse to issue a license if the reason for revocation or non-renewal continues to exist.

(f) A license issued under this subchapter must be returned to the department if the person's place of business:

(1) ceases business or otherwise ceases operation on a permanent basis;

(2) relocates; or

(3) changes name or ownership. For a corporation, an ownership change is deemed to have occurred, resulting in the necessity to return the license to the department, when 5.0 percent or more of the share of stock of a corporation is transferred from one person to another.

(g) The commissioner may suspend or revoke a license if the license holder no longer meets the qualification for obtaining a license under Texas Health and Safety Code §431.405.

§229.429. Minimum Standards for Licensure.

(a) General requirements.

(1) All persons engaged in the wholesale distribution of prescription drugs must comply with the applicable minimum standards in this section, in addition to the statutory requirements contained in the Texas Food, Drug, and Cosmetic Act, Health and Safety Code Chapter 431 (Act) and the requirements in §229.420 of this subchapter (relating to Applicable Laws and Regulations).

(2) For the purpose of this section, the policies described in the United States Food and Drug Administration (FDA) Compliance Policy Guides as they apply to prescription drugs are the policies of the department.

(3) Prescription drug wholesalers must not purchase or receive drugs in this state other than from drug distributors licensed by the department.

(b) Federal establishment registration and drug listing. All persons who operate as prescription drug manufacturers in Texas must meet the requirements in 21 Code of Federal Regulations (CFR) Part 207, titled Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs That are Regulated Under a Biologics License Application, and Animal Drugs, and the National Drug Code. New prescription drugs offered for sale by wholesale distributors must meet, if applicable, the requirements of 21 CFR Part 314, Applications for FDA Approval to Market a New Drug.

(c) Good manufacturing practices. Manufacturers of prescription drug products must comply with the applicable requirements in:

(1) 21 CFR Part 210, Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General;

(2) 21 CFR Part 211, Current Good Manufacturing Practice for Finished Pharmaceuticals;

(3) 21 CFR Part 225, Current Good Manufacturing Practice for Medicated Feeds;

(4) 21 CFR Part 226, Current Good Manufacturing Practice for Type A Medicated Articles; and

(5) the regulations in this subsection governing the methods used in, and the facilities or controls used for, the manufacture, processing, packing, or holding of a drug to ensure each drug meets the requirements of the Federal Food, Drug, and Cosmetic Act, 21 United States Code (USC) §301, et seq., as amended, (Federal Act) as to safety, and has the identity and strength and meets the quality and purity characteristics it purports or is represented to possess.

(d) Buildings and facilities.

(1) All manufacturing, processing, packing, or holding of drugs by prescription drug manufacturers must take place in buildings and facilities described in subsection (c) of this section.

(2) Manufacturing, processing, packing, or holding of prescription drugs must not be conducted in any personal residence.

(3) Sale of prescription drugs must not be conducted in any flea market.

(4) Any place of business used by a wholesale distributor of prescription drugs who is not a manufacturer to store, warehouse, hold, offer, transport, or display drugs must:

(A) comply with §229.420(a)(14) of this subchapter;

(B) be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(C) have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, and space;

(D) be maintained in a clean and orderly condition;

(E) be free from infestation by insects, rodents, birds, or vermin of any kind; and

(F) have a quarantine area for storage of drugs that are outdated, damaged, deteriorated, misbranded, or adulterated.

(e) Storage of prescription drugs. All prescription drugs stored by wholesale distributors must be held at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs.

(f) Minimum restrictions on transactions.

(1) Returns.

(A) A wholesale distributor must receive prescription drug returns or exchanges from a pharmacy or pharmacy warehouse in accordance with the terms and conditions of the agreement between the wholesale distributor and the pharmacy or pharmacy warehouse. An expired, damaged, recalled, or otherwise nonsalable prescription drug returned to the wholesale distributor may be distributed by the wholesale distributor only to either the original manufacturer or a third party returns processor. The returns or exchanges, salable or otherwise, received by the wholesale distributor as provided by this subsection, including any redistribution of returns or exchanges by the wholesale distributor, are not subject to the pedigree requirement under Texas Health and Safety Code §431.412, if the returns or exchanges are exempt from pedigree under:

(i) §503, Prescription Drug Marketing Act of 1987 (21 USC §353(c)(3)(B));

(ii) the regulations adopted by the Secretary of the U.S. Department of Health and Human Services to administer and enforce the Act in clause (i) of this subsection; or

(iii) the interpretations of the Act in clause (i) of this subsection, set out in the compliance policy guide of the FDA.

(B) Each wholesale distributor and pharmacy must administer the process of drug returns and exchanges to ensure the process is secure and does not permit the entry of adulterated or counterfeit drugs into the distribution channel.

(C) Notwithstanding any provision of state or federal law to the contrary, a

person not otherwise required to obtain a wholesale license under this subchapter and that is a pharmacy engaging in the sale or transfer of expired, damaged, returned, or recalled prescription drugs to the originating wholesale distributor or manufacturer and pursuant to federal statute, rules, and regulations, including the FDA applicable guidance implementing the Prescription Drug Marketing Act of 1987 (Pub. L. No. 100 - 293), is exempt from wholesale licensure requirements under this subchapter.

(D) All other returns must comply with the requirements of 21 CFR §203.23(a)(1) - (5).

(2) Distributions. A manufacturer or wholesale distributor may distribute prescription drugs only to a person licensed under this subchapter, or the appropriate state licensing authorities, if an out-of-state wholesaler or retailer, or to a person authorized by federal law to receive the drug. Before furnishing prescription drugs to a person not known to the manufacturer or wholesale distributor, the manufacturer or wholesale distributor must verify the person is legally authorized by the department or the appropriate state licensing authority to receive the prescription drugs or is authorized by federal law to receive the drugs. Wholesale distributors physically located and conducting operations in another state must verify, before purchasing or receiving product, the suppliers of drugs are licensed under this subchapter and physically located in Texas; and must notify the department of unlicensed wholesale distributors.

(3) Pedigree.

(A) A person, who is engaged in the wholesale distribution of a prescription drug, including a repackager but excluding the original manufacturer, must provide a pedigree for each prescription drug for human consumption that leaves or at any time left the normal distribution channel and is sold, traded, or transferred to any other person.

(B) 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) 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.

(D) 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:

(i) 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;

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

(iii) the transaction dates; and

(iv) certification that each recipient has authenticated the pedigree.

(E) The pedigree must include, at a minimum, 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 of the prescription drug; and

(vi) name of the manufacturer of the finished dosage form.

(F) Each pedigree statement must be:

(i) maintained by the purchaser and the wholesale distributor for at least three years; and

(ii) available for inspection and duplication not later than the second business day after the date a request is submitted by the department or a peace officer in this state.

(G) Verification procedures.

(i) Each transaction listed on the pedigree must be affirmatively authenticated before any wholesale distribution of a prescription drug.

(ii) A person who is engaged in the wholesale distribution of a prescription drug, and who is in possession of a pedigree for a prescription drug must certify, using the following methods, each transaction listed on the pedigree has occurred.

(I) Invoice confirmation. Receipt of an invoice (or shipping document) from the seller to the purchaser, which may have the prices redacted. Documentation requirements include, at a minimum, a copy of the invoice or shipping document. If this method is used to authenticate a pedigree, the wholesaler must review the document received for signs of tampering, incompleteness, or inconsistency with other invoices or shipping documents from that manufacturer or wholesaler, and must randomly verify the authenticity of the invoice or shipping document with the seller or shipping point reflected on that document using one of the methods in the subsections below. Each wholesaler must establish policies and procedures for the random verification of the authenticity of the invoices or shipping documents according to statistically sound

standards. Each wholesaler must establish policies and procedures for verification with those wholesalers in the distribution chain with which the wholesaler performing the authentication does not have an established prescription drug vendor relationship.

(II) Telephonic confirmation. Documentation requirements include a signed statement by the person placing the telephone call identifying the person's name and position title representing the seller who provides the information, the date the information was provided, and verification of the sales transaction between the parties, including verification of the date of the transaction and the quantity of prescription drugs involved in the transaction.

(III) Electronic mail confirmation. Documentation requirements include a copy of the e-mail identifying the person's name and position title representing the seller who provides the information, the date the information was provided, and verification of the sales transaction between the parties, including verification of the date of the transaction and quantity of prescription drugs involved in the transaction.

(IV) Electronic web-based confirmation. Verification of the transaction per a web-based system established by the seller or an independent person secure from intentional or unintentional tampering or manipulation to conceal an accurate and complete history of the prescription drug transactions. Documentation requirements include a written representation from the seller or independent person that the seller or independent person, as applicable, is responsible for the information included on the website and has adequate security on the information posted to prevent unauthorized tampering, manipulation, or modification of the information and a copy of the dated website page confirming the sales transaction between the parties, including the date of the transaction and quantity of prescription drugs involved in the transaction.

(V) Notarized copy confirmation. Receipt of a legible and unaltered copy of a previous transaction's pedigree paper signed under oath at the time of the previous transaction to support the transaction to which the pedigree paper relates. If this method is used to authenticate a pedigree, the wholesaler must review the document received for signs of tampering, incompleteness, or inconsistency, and must randomly verify the authenticity of pedigrees using one of the methods in this subparagraph. Each wholesaler must establish policies and procedures for the random verification of the authenticity of these copies of pedigree according to statistically sound standards.

(VI) Exclusive purchasing. A wholesale distributor may use a written agreement between the wholesale distributor and an authorized distributor of record requiring all prescription drugs distributed to the wholesale distributor by the authorized distributor of record, be purchased by the authorized distributor of record from the manufacturer. If this method is used to authenticate a pedigree, the wholesale distributor must establish policies and procedures for the random verification of the authenticity of the pedigrees that disclose the authorized distributor of record purchased the prescription drug from the manufacturer

according to statistically sound standards.

(VII) Other methods. Any other method approved by the department.

(4) Premises. Prescription drugs distributed by a manufacturer or wholesale distributor may be delivered only to the premises listed on the license, except as listed in paragraph (5) of this subsection. A manufacturer or wholesale distributor may distribute 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) delivery is made only to meet the immediate needs of a particular patient of the authorized person.

(5) Delivery to hospital pharmacies. Prescription drugs may be distributed to a hospital pharmacy receiving area if a pharmacist or an authorized receiving person 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 must be reported to the delivering manufacturer or wholesale distributor not later than the next business day after the date of delivery to the pharmacy receiving area.

(g) Prescription drug labeling. Prescription drugs sold by wholesale distributors must meet the labeling requirements of the Act and those adopted in §229.420(a) of this subchapter.

(h) Prescription drugs that are combination products. Any prescription drug that is a combination product as described in §229.424(c) of this subchapter (relating to Licensure Requirements) is also subject to the applicable requirements in Subchapter X of this chapter (relating to Licensing of Device Distributors and Manufacturers).

(i) Prescription drugs that are also cosmetics. Any prescription drug that is also a cosmetic or component thereof is also subject to the applicable requirements of Subchapter D of this chapter (relating to Regulation of Cosmetics).

(j) Nonprescription drugs. Nonprescription drugs offered for sale by wholesale distributors of prescription drugs must comply with the applicable requirements of Subchapter O of this chapter (relating to Licensing of Wholesale Distributors of Nonprescription Drugs--Including Good Manufacturing Practices).

§229.430. Enforcement and Penalties.

(a) Inspection.

(1) To enforce this subchapter or the Texas Food, Drug, and Cosmetic Act, Texas Health and Safety Code Chapter 431 (Act), the commissioner, an authorized agent, or a health authority may, on presenting appropriate credentials to the owner, operator, or agent in charge of a place of business:

(A) enter at reasonable times a place of business, including a factory or warehouse, in which a prescription drug is manufactured, packed, or held for introduction into commerce or held after the introduction;

(B) enter a vehicle being used to transport or hold a prescription drug in commerce; or

(C) inspect at reasonable times, within reasonable limits, and in a reasonable manner, the place of business or vehicle and all equipment, finished and unfinished materials, containers, and labeling of any item and obtain samples necessary for the enforcement of this subchapter or the Act.

(2) The inspection of a place of business, including a factory, warehouse, or consulting laboratory, in which a prescription drug is manufactured, processed, packed, or held for introduction into commerce extends to any place or thing, including a record, file, paper, process, control, or facility, to determine whether the drug:

(A) is adulterated or misbranded;

(B) may not be manufactured, introduced into commerce, sold, or offered for sale under the Act; or

(C) is otherwise in violation of this subchapter or the Act.

(3) An inspection under paragraph (2) of this subsection does not extend to:

(A) financial data;

(B) sales data other than shipment data;

(C) pricing data;

(D) personnel data other than data relating to the qualifications of technical and professional personnel performing functions under the Act;

(E) research data other than data:

(i) relating to new drugs and antibiotic drugs; and

(ii) subject to reporting and inspection under regulations issued under §505(i) or (j) of the Federal Food, Drug, and Cosmetic Act, 21 United States Code (USC) §301, et seq., as amended, (Federal Act); or

(F) data relating to other drugs, in the case of a new drug, subject to reporting or inspection under regulations issued under §505(j) of the Federal Act.

(4) An inspection under paragraph (2) of this subsection must be started and completed with reasonable promptness.

(b) Receipt for samples. An authorized agent or health authority who inspects a place of business, including a factory or warehouse, and obtains a sample during or

on completion of the inspection and before leaving the place of business, must give the owner, operator, or the owner's or operator's agent a receipt describing the sample.

(c) Access to records.

(1) A person required to maintain records referenced in this subchapter or under the Act or Chapter V of the Federal Act or a person in charge or custody of those records must, at the request of an authorized agent or health authority, permit the authorized agent or health authority at all reasonable times, access to and to copy and verify the records.

(2) A person, including a carrier engaged in commerce, or other person receiving a prescription drug in commerce or holding a prescription drug received in commerce must, at the request of an authorized agent, permit the authorized agent at all reasonable times to have access to and to copy and verify all records showing:

(A) the movement in commerce of any prescription drug;

(B) the holding of any prescription drug after movement in commerce; and

(C) the quantity, shipper, and consignee of any prescription drug.

(d) Retention of records. Records required by this subchapter must be maintained at the place of business or other location reasonably accessible for a period of at least three years following disposition of the prescription drug unless a greater period of time is required by §229.420 of this subchapter (relating to Applicable Laws and Regulations).

(e) Adulterated or misbranded prescription drug. If the department identifies an adulterated or misbranded prescription drug, the department may impose the applicable enforcement provisions of Subchapter C of the Act including detention, emergency order, recall, and administrative penalties. The department may request the attorney general or local law enforcement institute an action for criminal penalties, collection of civil penalties, condemnation, destruction, and injunction under the Act.

(f) Order to cease distribution.

(1) The commissioner must issue an order requiring a person, including a manufacturer, distributor, or retailer of a prescription drug, to immediately cease distribution of the drug if the commissioner determines there is a reasonable probability:

(A) a wholesale distributor has:

(i) violated this subchapter or the Act; or

(ii) sold, distributed, transferred, manufactured, repackaged, handled, or held a counterfeit prescription drug intended for human use that could cause

serious adverse health consequences or death; and

(B) other procedures would result in unreasonable delay.

(2) An order under this subsection must provide the person subject to the order an opportunity for an informal hearing on the actions required by the order to be held not later than the 10th day after issuance of the order.

(3) If, after providing an opportunity for a hearing, the commissioner determines inadequate grounds exist to support the actions required by the order, the commissioner must vacate the order.