TEXAS DEPARTMENT OF STATE HEALTH SERVICES

DRUGS AND MEDICAL DEVICES GROUP WEB SITE:
http://www.dshs.state.tx.us/dmd/

LICENSING OF WHOLESALE DISTRIBUTORS OF PRESCRIPTION DRUGS— INCLUDING GOOD MANUFACTURING PRACTICES
(25 Texas Administrative Code, §§229.419 – 229.430)

§229.419. Purpose. These sections provide for the minimum licensing standards 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, 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, Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution, 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 216, Pharmacy Compounding, as amended;

(20) 21 CFR, Part 225, Current Good Manufacturing Practice for Medicated Feeds, as amended;

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

(22) 21 CFR, Part 250, Special Requirements For Specific Human Drugs, as amended;

(23) 21 CFR, Part 290, Controlled Drugs, as amended;

(24) 21 CFR, Part 299, Drugs; Official Names and Established Names, as amended;

(25) 21 CFR, Part 300, General, as amended;

(26) 21 CFR, Part 310, New Drugs, as amended;

(27) 21 CFR, Part 312, Investigational New Drug Application, as amended;

(28) 21 CFR, Part 314, Applications for FDA Approval to Market a New Drug or

an Antibiotic Drug, as amended;

(29) 21 CFR, Part 315, Diagnostic Radiopharmaceuticals, as amended;

(30) 21 CFR, Part 316, Orphan Drugs, as amended;

(31) 21 CFR, Part 320, Bioavailability and Bioequivalence Requirements, as amended;

(32) 21 CFR, Part 361, Prescription Drugs for Human Use Generally Recognized as Safe and Effective and Not Misbranded: Drugs Used In Research, as amended;

(33) 21 CFR, Part 429, Drugs Composed Wholly or Partly of Insulin, as amended;

(34) 21 CFR, Part 430, Antibiotic Drugs; General, as amended;

(35) 21 CFR, Part 431, Certification of Antibiotic Drugs, as amended;

(36) 21 CFR, Part 432, Packaging and Labeling of Antibiotic Drugs, as amended;

(37) 21 CFR, Part 433, Exemptions from Antibiotic Certification and Labeling Requirements, as amended;

(38) 21 CFR, Part 436, Tests and Methods of Assay of Antibiotic and Antibiotic-containing Drugs, as amended;

(39) 21 CFR, Part 440, Penicillin Antibiotic Drugs, as amended;

(40) 21 CFR, Part 441, Penem Antibiotic Drugs, as amended;

(41) 21 CFR, Part 442, Cepha Antibiotic Drugs, as amended;

(42) 21 CFR, Part 444, Oligosaccharide Antibiotic Drugs, as amended;

(43) 21 CFR, Part 446, Tetracycline Antibiotic Drugs, as amended;

(44) 21 CFR, Part 448, Peptide Antibiotic Drugs, as amended;

(45) 21 CFR, Part 449, Antifungal Antibiotic Drugs, as amended;

(46) 21 CFR, Part 450, Antitumor Antibiotic Drugs, as amended;

(47) 21 CFR, Part 452, Macrolide Antibiotic Drugs, as amended;

(48) 21 CFR, Part 453, Lincomycin Antibiotic Drugs, as amended;

(49) 21 CFR, Part 455, Certain Other Antibiotic Drugs, as amended;

(50) 21 CFR, Part 460, Antibiotic Drugs Intended for Use in Laboratory Diagnosis of Disease, as amended;

(51) 21 CFR, Part 500, General, as amended;

(52) 21 CFR, Part 510, New Animal Drugs, as amended;

(53) 21 CFR, Part 511, New Animal Drugs for Investigational Use, as amended;

(54) 21 CFR, Part 514, New Animal Drug Applications, as amended;

(55) 21 CFR, Part 515, Medicated Feed Mill License, as amended;

(56) 21 CFR, Part 520, Oral Dosage Form New Animal Drugs, as amended;

(57) 21 CFR, Part 522, Implantation or Injectable Dosage Form New Animal Drugs, as amended;

(58) 21 CFR, Part 524, Opthalmic and Topical Dosage Form New Animal Drugs, as amended;

(59) 21 CFR, Part 526, Intramammary Dosage Forms, as amended;

(60) 21 CFR, Part 529, Certain Other Dosage Form New Animal Drugs, as amended;

(61) 21 CFR, Part 530, Extralabel Drug Use in Animals, as amended;

(62) 21 CFR, Part 556, Tolerances for Residues of New Animal Drugs in Food, as amended;

(63) 21 CFR, Part 558, New Animal Drugs for Use in Animal Feeds, as amended;

(64) 21 CFR, Part 589, Substances Prohibited From Use in Animal Food or Feed, as amended;

(65) 21 CFR, Part 600, Biological Products: General, as amended;

(66) 21 CFR, Part 601, Licensing, as amended;

(67) 21 CFR, Part 610, General Biological Products Standards, as amended;

(68) 21 CFR, Part 650, Additional Standards for Diagnostic Substances Dermal Test, as amended;

(69) 21 CFR, Part 660, Additional Standards for Diagnostic Substances for Laboratory Tests, as amended;

(70) 21 CFR, Part 680, Additional Standards for Miscellaneous Products, as amended; and

(71) 21 CFR, Part 1302, Labeling and Packaging Requirements For Controlled Substances, as amended.

(b) Copies of these laws and regulations are indexed and filed at the department, 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 http://www.dshs.state.tx.us/license.shtm.

(c) Nothing in these sections shall relieve any person of the responsibility for compliance with other applicable Texas and federal laws and regulations.

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

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

(2) Adulterated drug -- Has the meaning specified in the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431, §431.111.

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

(4) 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.

(5) Commissioner -- Commissioner of the Department of State Health Services.

(6) Department -- The Department of State Health Services.

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

(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 man or other animals; or

(C) intended to affect the structure or any function of the body of man or other animals and that does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and is not dependent on metabolization for the achievement of any of its principal intended purposes.

(8) 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 man or other animals, articles, other than food, intended to affect the structure or any function of the body of man 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 Act, §403(r), and for which the claim is approved by the U.S. Food and Drug Administration, is not a drug solely because the label or labeling contains such a claim.

(9) 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.

(10) Federal Act -- Federal Food, Drug, and Cosmetic Act, 21 United States Code, et seq., as amended.

(11) 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.

(12) 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.

(13) 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. The term does not include compounding

that is done within the practice of pharmacy and pursuant to a prescription drug order or initiative from a practitioner for a patient or prepackaging that is done in accordance with Occupations Code, §562.154.

(14) Misbranded drug -- Has the meaning specified in the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431, §431.112.

(15) Nonprescription drug -- Any drug that is not a prescription drug.

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

(17) Place of business -- Each location at which a prescription drug for wholesale distribution is located.

(18) 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).

(19) 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 Occupations Code, §562.154.

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

(21) Wholesale distribution -- Distribution to a person other than a consumer or patient, and includes distribution by a manufacturer, repackager, own label distributor, broker, jobber, warehouse, retail pharmacy that conducts wholesale distribution, or wholesaler. 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 that is under common ownership and control of a corporate entity;

(B) the sale, purchase, distribution, trade, or transfer of prescription drugs or the offer to sell, purchase, distribute, trade, or transfer a prescription drug for emergency medical reasons;

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

(D) the return of drugs by a hospital, health care entity, retail pharmacy, chain pharmacy warehouse, or charitable institution in accordance with 21 CFR, §203.23; or

(E) the delivery by a retail pharmacy of a prescription drug to a patient or a patient's agent under the lawful order of a licensed practitioner.

§229.422. Sale of Prescription Drugs. Any reference in these sections to the sale of prescription drugs shall be considered to include the manufacture, packaging, exposure, offer, possession, and holding of any prescription drug for sale; the sale, dispensing, and giving 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 these sections if the person is exempt under:

(1) the Prescription Drug Marketing Act of 1987 (Act), (21 U.S.C., §353(c)(3)(B));

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

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

(4) the Occupations Code, §562.154.

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

(1) intracompany sales;

(2) the purchase or 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;

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

(4) 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 the purpose of this subsection, "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;

(5) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons. For purposes of this section, "emergency medical reasons" includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage;

(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 distribution of drug samples by manufacturers' representatives or distributors' representatives; or

(8) 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 these sections or under the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431.

(d) Exemption from certain requirements for certain wholesale distributors. A wholesale distributor that distributes only prescription drugs that are medical gases is exempt from the requirements in §229.424(d) of this title (relating to Licensure Requirements), §229.425(c) and (d) of this title (relating to Licensing Procedures).

§229.424. Licensure Requirements.

(a) General. Except as provided in §229.423 of this title (relating to Exemptions), a person may not engage in the wholesale distribution of prescription drugs in Texas 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 title, 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 Act and these sections.

(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 that the person is in compliance with the Act and these sections.

(4) The department shall consider 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, that 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 these sections, 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;

(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) Display of license. The license shall be displayed in an open public area 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 after the effective date of these sections shall apply to the department for a license of such business prior to 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 shall license each place of business separately.

(h) Pre-licensing inspection. The applicant shall 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 title (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 these sections, and pays all license fees in compliance with §229.427 of this title (relating to Licensure Fees).

(j) Transfer of license. Licenses shall not be 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 (m) of this section or suspended or revoked as provided in §229.428 of this title (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, ownership, 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 title (relating to Licensing Procedures) and submission of fees as outlined in §229.427 of this title.

(m) Renewal of license.

(1) The license application as outlined in §229.425 of this title and nonrefundable licensing fees as outlined in §229.427 of this title for each place of business shall be submitted to the department prior to the expiration date of the current license. A person who files a renewal application after the expiration date must pay an additional $100 as a delinquency fee.

(2) A licensee who fails to submit a renewal application prior to the current licensure expiration date and continues operations may be subject to the enforcement and penalty provisions in §229.431 of this title (relating to Enforcement and Penalties), and/or the refusal, cancellation, suspension and revocation provisions in §229.428 of this title.

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

§229.425. Licensing Procedures.

(a) License application forms. License application forms may be obtained from the department, 1100 West 49th Street, Austin, Texas, 78756, or online at http://www.dshs.state.tx.us/license.shtm.

(b) Contents of license application. The application for licensure as a wholesale

distributor of prescription drugs shall be signed and verified, submitted on a license application form furnished by the department, and contain the following information:

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

(2) the address and telephone number of each place of business that is licensed;

(3) the type of business and the name, residence address, and valid driver's license number of:

(A) the proprietor, if the business is a proprietorship;

(B) all partners, if the business is a partnership; or

(C) all principals, if the business is an association;

(4) the date and place of incorporation, if the business is a corporation;

(5) the names and business addresses of the individuals in an administrative capacity showing:

(A) the managing proprietor, if the business is a proprietorship;

(B) the managing partner, if the business is a partnership;

(C) the officers and directors, if the business is a corporation; or

(D) the persons in a managerial capacity, if the business is an association;

(6) 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;

(7) the state of incorporation, if the business is a corporation;

(8) 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;

(9) the name of the manager for each place of business;

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

(11) a statement verified by the applicant's signature that acknowledges the applicant has read, understood, and agrees to abide by the provisions of these sections and those of the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431.

(c) Designated representatives and managers.

(1) For each person who is a designated representative and/or a manager of each place of business, the applicant shall provide the following to the department:

(A) the person's place(s) 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 paragraph (3) of subsection (b) 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 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 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 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 30 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 shall be made on a license application form furnished by the department.

(f) Texas Online. Applicants may submit initial and renewal license applications under these sections electronically by the Internet through Texas Online at www.texasonline.state.tx.us. The department is authorized to collect fees, in amounts determined by the Texas Online Authority, to recover costs associated with application and renewal application processing through Texas Online.

§229.426. Report of Changes.

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

(b) Change in location of place of business. Not fewer than 30 days in advance of the change, the licensee shall notify the department in writing of the licensee's intent to change the location of a licensed place of business. The notice shall include the address of the new location, and the name and residence address of the individual in charge of the business at the new location. Not more than 10 days after the completion of the change of location, the licensee shall notify the department in writing to confirm the completion of the change of location, and provide verification of the information previously provided or correct and confirm any information that has changed since providing the notice of intent. The notice and confirmation required by this subsection will be deemed adequate if the licensee sends the notices by certified mail, return receipt requested, to the department at 1100 West 49th Street, Austin, Texas 78756, or submits them electronically through the Texas Online Internet website.

§229.427. Licensure Fees.

(a) License fee. Except as provided by §229.423 of this title (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 shall 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 wholesale distributors of prescription drugs who are not manufacturers shall pay a two-year license fee based on the gross annual sales of all drugs.

(A) For a wholesale distributor of only compressed medical gases with gross annual drug sales of $0 - $20,000, the fees are:

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

(ii) $675 for a two-year license that is amended due to a change of ownership; and

(iii) $337 for a license that is 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 that is amended due to a change of ownership; and

(iii) $540 for a license that is 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 that is amended due to a change of ownership; and

(iii) $877 for a license that is 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 that is amended due to a change of ownership; and

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

(2) In-state wholesale distributors of only compressed medical gases who are not manufacturers and who also are required to be licensed as a device distributor under §229.439(a) of this title (relating to Licensure Fees) or as a wholesale food distributor under §229.182(a)(3) of this title (relating to Licensing/Registration Fee and Procedures) shall 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 (foods, drugs, and/or devices).

(A) For a wholesale distributor with 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 that is amended due to a change of ownership; and

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

(B) For a wholesale distributor with 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 that is amended due to a change of ownership; and

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

(C) For a wholesale distributor with 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 that is amended due to a change of ownership; and

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

(D) For a wholesale distributor with 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 that is amended due to a change of ownership; and

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

(E) For a wholesale distributor with 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 that is amended due to a change of ownership; and

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

(3) In-state wholesale distributors of prescription drugs who are manufacturers shall pay a two-year license fee based on the gross annual sales of all drugs.

(A) 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 that is amended due to a change of ownership; and

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

(B) 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 that is amended due to a change of ownership; and

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

(C) 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 that is amended due to a change of ownership; and

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

(4) Out-of-state wholesale distributors of prescription drugs shall pay a two-year license fee based on all gross annual sales of drugs delivered into Texas.

(A) For each wholesale distributor with gross annual drug sales of $0 – $19,999,999, the fees are:

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

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

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

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

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

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

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

(b) Proration of license fees. A person that has 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 that is the same as the firm's other licensed places of business.

(c) 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, §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 licensee:

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

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

(3) is an association, partnership, or corporation and the managing officer and/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, Health and Safety Code, Chapter 431 (Act) or these sections;

(5) has violated the Health and Safety Code, §431.021(l)(3), 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, Health and Safety Code, Chapter 481, or the Texas Dangerous Drug Act, 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 licensee to maintain;

(8) fails to complete a license application or submits an application that contains false, misleading, or incorrect information or contains information that cannot be verified by the department;

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

(10) 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 these sections 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 shall remain in effect until the department determines that the reason for the suspension no longer exists. If the suspension overlaps a renewal date, the suspended license holder shall comply with the renewal procedures in §229.425 of this title (relating to Licensing Procedures); however, the department may choose not to renew the license until the department determines that 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 title 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 these sections shall 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% or more of the share of stock of a corporation is transferred from one person to another.

§229.429. Minimum Standards for Licensure.

(a) General requirements. 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 those requirements in §229.420 of this title (relating to Applicable Laws and Regulations). For the purpose of this section, the policies described in the United States Food and Drug Administration's (FDA's) Compliance Policy Guides as they apply to prescription drugs shall be the policies of the department.

(b) Federal establishment registration and drug listing. All persons who operate as prescription drug manufacturers in Texas shall meet the requirements in 21 Code of Federal Regulations (CFR), Part 207, titled "Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution." New prescription drugs offered for sale by wholesale distributors shall have met, if applicable, the requirements of 21 CFR, Part 314, titled "Applications for FDA Approval to Market a New Drug."

(c) Good manufacturing practices. Manufacturers of prescription drug products shall be in compliance with the applicable requirements in 21 CFR, Part 210, titled "Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs"; 21 CFR, Part 211, titled "Current Good Manufacturing Practice for Finished Pharmaceuticals; General"; 21 CFR, Part 225, titled "Current Good Manufacturing Practice for Medicated Feeds"; and 21 CFR, Part 226, titled "Current Good Manufacturing Practice for Type A Medicated Articles." The regulations in these parts govern the methods used in, and the facilities or controls used for, the manufacture, processing, packing, or holding of a drug to assure that each drug meets the requirements of the Federal Act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess.

(d) Buildings and facilities.

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

(2) No manufacturing, processing, packing, or holding of prescription drugs shall be conducted in any personal residence.

(3) No sale of prescription drugs shall 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 shall:

(A) be in compliance with the requirements adopted in §229.420(a)(14) of this title;

(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 shall 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 wholesale distributor shall receive prescription drug returns or exchanges from a pharmacy or chain pharmacy warehouse in accordance with the terms and conditions of the agreement between the wholesale distributor and the pharmacy or chain pharmacy warehouse. The returns or exchanges received by the wholesale distributor as provided by this subsection are not subject to the pedigree requirement under §431.412 of the Act. In connection with the returned goods process, a wholesale distributor shall establish appropriate business practices and exercise due diligence designed to prevent the entry of adulterated or counterfeit drugs into the distribution channel.

(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 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 that the person is legally authorized by the department or the appropriate state licensing authority to receive the prescription drugs or authorized by federal law to receive the drugs.

(3) 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 (4) 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.

(4) 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 shall 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 shall meet the labeling requirements of the Act and those adopted in §229.420 of this title (relating to Applicable Laws and Regulations).

(h) Prescription drugs that are combination products. Any prescription drug that is a combination product as described in §229.424(c) of this tile (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 shall be in compliance 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 these sections or the Texas Food, Drug, and Cosmetic Act, 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 these sections 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, in order 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 these sections or the Act.

(3) An inspection under paragraph (2) of this subsection may 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 Act; or

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

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

(b) Receipt for samples. An authorized agent or health authority who makes an inspection of 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, shall give to the owner, operator, or the owner's or operator's agent a receipt describing the sample.

(c) Access to records.

(1) A person who is required to maintain records referenced in these sections or under the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431 (Act) or Chapter V of the Federal Food, Drug, and Cosmetic Act (Federal Act) or a person who is in charge or custody of those records shall, 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 shall, 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 these sections shall be maintained at the place of business or other location that is 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 laws and regulations adopted in §229.420 of this title (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, but not limited to: detention, emergency order, recall, condemnation, destruction, injunction, civil penalties, criminal penalties, and/or administrative penalties. Administrative and civil penalties will be assessed

using the Severity Levels contained in §229.251 of this title (relating to Minimum Standards for Licensure).

(f) Order to cease distribution.

(1) The commissioner shall 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 that:

(A) a wholesale distributor has:

(i) violated these sections 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 with an opportunity for an informal hearing on the actions required by the order to be held not later than the 10th day after the date of issuance of the order.

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

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