

Title 25. Health Services
Part 1. Department of State Health Services
Chapter 229. Food and Drug
Subchapter B. Donation of Unused Drugs
Amendments §§229.21 – 229.26
Subchapter W. Licensing of Wholesale Distributors of Prescription Drugs--Including Good
Manufacturing Practices
Amendments §§229.419 - 229.430

Adoption Preamble

The Executive Commissioner of the Health and Human Services Commission (commission) on behalf of the Department of State Health Services (department) adopts amendments to §§229.21 - 229.26, concerning the donation of unused drugs; and §§229.419 - 229.430, concerning the licensing of wholesale distributors of prescription drugs, including good manufacturing practices. The amendments to §§229.22, 229.421 and §§229.429 are adopted with changes to the proposed text as published in the July 23, 2010 issue of the *Texas Register* (35 TexReg 6460). Sections 229.21, 229.23 - 229.26, 229.419, 229.420, 229.422 - 229.428, and 229.430 are adopted without changes, and the sections will not be republished.

BACKGROUND AND PURPOSE

The amendments to Subchapter B, §§229.21 – 229.26, and Subchapter W, §§229.419 – 229.430, of the department's food and drug rules are necessary to implement legislative changes to the Health and Safety Code, Chapter 431, and to satisfy the required four-year review of agency rules previously adopted. The Health and Safety Code, Chapter 431, was amended by Senate Bill (SB) 943 and SB 1896, 80th Legislature, Regular Session, 2007, and SB 1645, 81st Legislature, Regular Session, 2009, to address charitable drug donations (Subchapter B) and new challenges to the integrity of the prescription drug distribution system (Subchapter W) as a result of the threat of counterfeit and adulterated drugs. The primary purpose for amending Subchapter B is to expand the definition of "charitable medical clinics" to include "a licensed pharmacy that is a community pharmaceutical access program provider." The primary purposes for the proposed rule changes under Subchapter W are to implement more stringent licensing requirements applicable to prescription drug wholesalers and to outline the steps necessary for the passing of prescription drug pedigrees. Current law requires licensing wholesalers and tracking drugs through commerce by means of "pedigree" documentation in certain instances. Texas law requires further change to Subchapter W to mirror newly clarified U.S. Food and Drug Administration (FDA) requirements in 21 Code of Federal Regulations (CFR), Parts 203 and 205, the regulations that implement the Prescription Drug Marketing Act of 1987 (PDMA), as modified by the Prescription Drug Amendments of 1992. Other amendments to this subchapter include updating mailing addresses and agency names, and making minor grammatical or format changes.

Government Code, §2001.039, requires that each state agency review and consider for re-adoption each rule adopted by that agency pursuant to the Government Code, Chapter 2001 (Administrative Procedure Act). Sections 229.21 - 229.26 (Subchapter B), and §§229.419 -

229.430 (Subchapter W), have been reviewed and the department has determined that reasons for adopting the sections continue to exist because rules on this subject are needed.

SECTION-BY-SECTION SUMMARY

Subchapter B amendments: The amendment to §229.21 expands the definition of "charitable medical clinic" by inserting the words "including a licensed pharmacy that is a community pharmaceutical access program provider" after the word "clinic." A new definition, "community pharmaceutical access program" is added at §229.21(3). The new definition, which states "A program offered by a licensed pharmacy under which the pharmacy assists financially disadvantaged persons to access prescription drugs at no charge or at a substantially reduced charge," is added as a specific type of business that engages in drug donation for charitable purposes. The preceding amendments are new in the statute. The definition of "wholesale distribution" of donated drugs in §229.21(13) is amended to reflect the new definition of "wholesale distributor" of prescription drugs added to Subchapter W at §229.421(29). Thus, "wholesale distribution" is amended by substituting the last term, "or wholesaler," and adding after the word "jobber" the following list of firm types: "private label distributor, broker, manufacturer warehouse, distributor warehouse, or other warehouse, manufacturer's exclusive distributor, 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." The name of the department is updated and the rule is also renumbered.

Additional amendments to Subchapter B were necessary to reflect the expanded definition of charitable medical clinic, to update mailing addresses, the agency name, and to correct minor grammatical or format changes, and revise rule references.

Subchapter W amendments: Amendments to §229.419 clarified the purpose of the rules by substituting the word "requirements" for "standards" as a term that is more commonly used throughout the rules, as well as correcting grammar.

Section 229.420 is renumbered and updates references to add and remove certain parts of CFR Title 21 which the department adopts and incorporates by reference. The new reference sections being added are: 21 CFR, Part 1300, Definitions; 21 CFR, Part 1301, Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances; 21 CFR, Part 1304, Records and Reports of Registrants; 21 CFR, Part 1305, Orders for Schedule I and Schedule II Controlled Substances; 21 CFR, Part 1306, Prescriptions; and, 21 CFR, Part 1307, Miscellaneous.

Adopted and incorporated sections of 21 CFR Sections that are deleted from §229.420 are: 21 CFR, Part 429, Drugs Composed Wholly or Partly of Insulin; 21 CFR, Part 430, Antibiotic Drugs; 21 CFR, Part 431, Certification of Antibiotic Drugs; 21 CFR, Part 432, Packaging and Labeling of Antibiotic Drugs; 21 CFR, Part 433, Exemptions from Antibiotic Certification and Labeling Requirements; 21 CFR, Part 436, Tests and Methods of Assay of Antibiotic and Antibiotic-containing Drugs; 21 CFR, Part 440, Penicillin Antibiotic Drugs; 21 CFR, Part 441, Penem Antibiotic Drugs; 21 CFR, Part 442, Cepha Antibiotic Drugs; 21 CFR, Part 444,

Oligosaccharide Antibiotic Drugs; 21 CFR, Part 446, Tetracycline Antibiotic Drugs; 21 CFR, Part 448, Peptide Antibiotic Drugs; 21 CFR, Part 449, Antifungal Antibiotic Drugs; 21 CFR, Part 450, Antitumor Antibiotic Drugs; 21 CFR, Part 452, Macrolide Antibiotic Drugs; 21 CFR, Part 453, Lincomycin Antibiotic Drugs; 21 CFR, Part 455, Certain Other Antibiotic Drugs; 21 CFR, Part 460, Antibiotic Drugs Intended for Use in Laboratory Diagnosis of Disease; and 21 CFR, Part 650, Additional Standards for Diagnostic Substances Dermal Test. In addition, §229.420 makes minor grammatical or format changes.

Section 229.421 has new, amended and deleted definitions and, therefore, is renumbered. New definitions are included to facilitate the purpose of the legislative amendments: to help protect the integrity of the prescription drug distribution system. For clarification purposes, the term "broker" is now defined and included in the definition of wholesale distributor. "Co-licensed product partner" is added as a type of firm that can be considered a manufacturer or a participant in the manufacturing process and will be regulated as such. The definition "drop shipment" is necessary to clarify this particular method of wholesale drug distribution. The new definition of "manufacturer's exclusive distributor" defines a type of wholesale drug distribution. A definition of "normal distribution channel" provides exemptions from the requirement of a firm to pass a document identifying the movement of a prescription drug from manufacturer to the final recipient for certain entities engaged in specific transactions listed. The definition of "pharmacy warehouse" is added to describe a particular type of wholesale drug distributor. The definition "third party logistics provider" is added as a specific description of a type of wholesale drug distributor. The definition of "verification" is added to specify what a firm must do in order to determine if a document that traces a prescription drug from manufacturer to final recipient is true and correct. "Wholesale distributor" is added to provide specific examples of persons engaged in the practice of wholesale distribution.

Definitions that are amended in §229.421 include the following: "adulterated drug" is amended by deleting the phrase "Chapter 431" because that term is considered redundant when the specific citation, §431.111, is listed. The definition of "manufacturer" is amended by adding the sentence "A person licensed or approved by the United States Food and Drug Administration to engage in the manufacture of drugs or devices, consistent with the federal agency's definition of "manufacturer" under the agency's regulations and guidances implementing the Prescription Drug Marketing Act of 1987 (Pub. L. No. 100 - 293)" for additional clarification. The term "pharmacist engaged in" is added before the word "compounding" to correct the applicability of the term "manufacturer" to a person rather than to an action.

The amendment of §229.421(28), the definition of "wholesale distribution," not only reflects that Subchapter W pertains to the distribution of prescription drugs only, but also defines and clarifies which transactions are excluded from this definition. Intra-company sales now include transactions between co-licensed product partners, one of the new definitions listed previously. Transferring a prescription drug between pharmacies to alleviate a temporary shortage is now excluded or exempt from the definition of wholesale distribution. Sales of reasonable quantities of prescription drugs by a pharmacy to a licensed practitioner for office use are exempt. However, sales of reasonable quantities of prescription drugs by a pharmacy to a patient or patient's representative are no longer excluded from the definition. The act of selling, purchasing, offering, or trading a drug, under the authority of a prescription, is now exempt. The

sale, transfer, merger, or consolidation of all or part of the business of a pharmacy from or with another pharmacy is now exempt. 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, is now exempt. 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 Title 21, CFR, §203.23(a)(1) - (5), for other returns is now exempt. The purchase or other acquisition by a hospital or other health care entity that is a member of a purchasing group is exempt under certain scenarios. The transfer or offer of transfer of a drug by a charitable organization described in §501(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law is exempt. The offer or sale of a drug among hospitals or other health care entities that are under common control is exempt. The definition of common control also is clarified under this exemption. The sale, purchase, or trade of blood and blood components intended for transfusion is now exempt. The definition of "place of business," previously §229.421(17), is deleted because the term is not universally applicable to those firms engaged in the wholesale drug distribution channel regulated under Subchapter W.

Section 229.422 is amended by substituting the word "drug" for "drugs;" and correcting minor grammatical errors.

The phrase "for use in humans" is deleted from the first sentence of §229.423(b) because distributors of veterinary drugs are regulated under Subchapter W. Additional amendments to §229.423(b) expand certain exemptions from licensing under Subchapter W as provided by the new amendments to the Health and Safety Code, Chapter 431, and to mirror the exemptions from licensing that the U.S. Food and Drug Administration also allows. Existing exemptions are deleted and replaced with new, clarified exemptions which include the following: those engaged in intra-company sales are exempt from the requirement to license and the term "intracompany sales" is specifically defined under new §229.423(b)(1). A hospital, health care entity, or charitable institution that returns drugs in accordance with Title 21, CFR, §203.23 is now exempt from the requirement to license. Pharmacies that sell reasonable quantities of prescription drugs to practitioners for office use are now exempt. Persons, who sell, transfer, merge, or consolidate all or part of the business of a pharmacy from or with another pharmacy are now exempt. Common carriers that deliver or offer to deliver, a prescription drug in the usual course of business are exempt if the common carrier does not store, warehouse, or take legal ownership of the prescription drug. Pharmacies and pharmacy warehouses that sell or transfer 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 Title 21, CFR, §203.23(a)(1) - (5) are exempt. Hospitals or health care entities that are members of a group purchasing organization that purchase a drug for their own use from the group purchasing organization or from other hospitals or health care entities that are members of such organizations are exempt. In addition, amendments to §229.423(d) provide exemptions from certain, specified licensing requirements and procedures before receiving a license to those wholesale drug distributors described in the rule itself. The entities that are defined under this exemption include: wholesale distributors that are manufacturers or third-party logistics providers on behalf of the manufacturers; and 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 mental health or mental retardation authorities for distribution to a pharmacy, practitioner, or patient. In addition, the Executive Commissioner of the Health and Human Services Commission may exempt by rule specific purchases of prescription drugs by state agencies and political subdivisions under certain circumstances. Additional amendments to §229.423 include other minor grammatical or format changes.

Amendments to §229.424, "Licensure Requirements," include the following: the phrase "as defined in §229.421(29)-(30) of this title" is added after the word "Texas" to link the term "person" back to the definition of wholesale distributor and to link the act of wholesale distribution back to the definition of wholesale distribution. Section 229.424(d)(6) is amended by adding the phrase "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 §1504, Internal Revenue Code of 1986." This amendment was made at the request of stakeholders for whom this situation applies. Section 229.424(m)(1) is amended by deleting the phrase "prior to the expiration date of the current license" and substituting the phrase "not later than the 30th day after the date the wholesale distributor receives a renewal notification form from the department." Bonding requirements and details are set out in §229.424(n), including: setting the amount of the bond or other equivalent security at \$100,000; the purpose of the bond, to secure payment of fines or penalties imposed in connection with any enforcement actions; and the time period during which the department may stake a claim against the bond. Pharmacy warehouses that are not engaged in wholesale distribution are exempt from the requirement to provide a bond; and a single bond may be submitted to cover all places of business operated by a wholesale drug distributor in this state.

Certain phrases in §229.425, "Licensing Procedures," are deleted and amended to modify the contents of an application for a wholesale license to distribute prescription drugs, and, therefore, the paragraphs and subparagraphs of this rule are renumbered. The reworded requirements of §229.425(b) include the following: the applicant must provide the name, full business address, and telephone number; the applicant must provide the name of a contact person for each of the applicant's places of business; the applicant must describe the type of business entity, whether the business is a person, sole proprietorship, partnership or corporation; and the name of each person, partner, officer and director must be provided. The following provision has been deleted: managers of a business are no longer required to supply information showing whether they meet the qualifications to represent the business. Additional requirements that a person must meet under §229.425(c) to become a designated representative of a firm include: whether the designated representative has been involved in a criminal proceeding; whether the designated representative, as an officer or director of a pharmaceutical related business, has been involved in a lawsuit; and a description of any misdemeanor offense for which the designated representative was found guilty.

Section 229.425(e) amends the requirement for license renewal by adding the phrase "Not later than the 30th day after the date the wholesale distributor receives the form, the wholesale distributor shall identify and state under oath to the department any change in or correction to the

information." A new procedure for obtaining a replacement license is included under §229.425(f) because of the need for consistency in handling such requests. Section 229.425(g) sets out the method by which applications may be submitted to the department. Lastly, a bond requirement is added under §229.425(h) which is required to be submitted with the application for a wholesale drug distributor license.

In addition, §229.425 substitutes references to Texas Online to texas.gov, and makes other minor grammatical or format changes.

The amendment to §229.426, "Report of Changes," substitutes references to texas.gov for Texas Online and updates the department's mailing address.

Licensing fees are amended by §229.427 to consolidate and simplify the licensing categories and to ensure that out-of-state licensees pay the same fee as in-state licensees. An additional fee for requests for replacement permits is also added to compensate for the costs associated with handling such requests. Additionally, new §229.427(a)(3) is added to set out the fees to be paid by manufacturers of only medical gases. The term "compressed" is removed from every reference to medical gas because it is an unnecessary qualifier for that term.

Amendments to §229.428 add new provisions as grounds to refuse, suspend or revoke a license which include: the furnishing of false or fraudulent information in an application; and a licensee's failure to continue to meet the qualifications for obtaining a license under Health and Safety Code, §431.405. Additional amendments to §229.428 include other minor grammatical or format changes.

Amendments to §229.429 clarify the requirements for returns of prescription drugs, and set out the requirements for those returns to be exempt from the tracking requirements of a pedigree. The amendments to this section also clarify when a pedigree is required, what the pedigree must contain, and how a pedigree may be verified. Under §229.429(f)(1), returns must be conducted in the manner described by these new amendments which include: non-saleable prescription drugs returned to the wholesale distributor may only be returned to either the original manufacturer or a third party returns processor; the process of returning drugs must be secure and prevent the introduction of adulterated or counterfeit drugs into the distribution channel; and all other returns must comply with the requirements of Title 21, CFR, §201.23(a)(1)-(5). A specific licensing exemption also is provided to certain pharmacies that engage in the sale or transfer of expired, damaged, returned, or recalled prescription drugs to the originating wholesale distributor or manufacturer under §229.429(f)(1)(C). Returns or exchanges of salable items, including redistribution of returns and exchanges, are exempt under §229.429(f)(1)(A) from the requirement to have a pedigree under only three conditions: if those returns or exchanges are exempt under §503, Prescription Drug Marketing Act of 1987 (21 U.S.C. §353(c)(3)(B)); or the regulations adopted by the Secretary of the U.S. Department of Health and Human Services to administer and enforce that Act; or the interpretations of that Act set out in the compliance policy guide of the United States Food and Drug Administration.

Amendments to §229.429(f)(2) clarify that out-of-state wholesale drug distributors shall verify, prior to purchasing or receiving product, that the suppliers of drugs are licensed in Texas and shall notify the department of unlicensed wholesale distributors.

Section 229.429(f)(3) addresses details and requirements concerning pedigree. Persons who are required to provide or pass a pedigree include: a person who is engaged in the wholesale distribution of a prescription drug, including a repackager (but excluding the original manufacturer), for any drug that leaves the normal channel of distribution. A pharmacy or pharmacy warehouse must offer a pedigree only if it is engaged in the wholesale distribution of a drug. After publication of the proposed rules, provisions previously set out in subsections (B) and (D) of §229.429(f)(3) were deleted in their entirety based on amendments to Health and Safety Code, §431.412; as a result, the remaining subsections of 229.429(f)(3) were relettered.

New §229.429(f)(3)(D) and (E) set forth the contents of a pedigree. A pedigree must include the following: enough information to identify each prior sale of the drug; 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; the name and address of each location from which the product was shipped, if different from the owner's name and address; the transaction dates; certification that each recipient has authenticated the pedigree; name of the prescription drug; dosage form and strength of the prescription drug; size of the container; number of containers; lot number of the prescription drug; and name of the manufacturer of the finished dosage form.

New section 229.429(f)(3)(G) sets the verification standard and describes the various procedures by which each transaction listed on the pedigree may be verified. The verification process requires authenticating that each prior transaction occurred prior to further wholesale distribution. Verification may be accomplished through confirmation by invoice review; telephone calls; emails; electronic web-based systems; notarized documents; exclusive purchasing; or any other method approved by the department.

Section 229.430, "Enforcement and Penalties," is amended by removing the phrase, "Administrative and civil penalties will be assessed using the Severity Levels contained in §229.251 of this title (relating to Minimum Standards for Licensure)" because the language was confusing and unnecessary.

COMMENTS

The department, on behalf of the commission, has reviewed comments received regarding the proposed rules during the comment period and prepared responses to them, responses which the commission has reviewed and accepts. The commenters were individuals, associations, and/or groups, including the following: Health Industry Distributors Association, Pharmaceutical Research and Manufacturers of America, National Association of Chain Drug Stores, and National Coalition of Pharmaceutical Distributors, Representative Ruth Jones McClendon, and Len Neeper with Advantage Medical Supply. The commenters were not against the rules in their entirety; however, the commenters suggested some changes. A summary of the comments as well as the department's responses to each are set out as follows.

Comment: Concerning the definition of "Manufacturer's exclusive distributor" found in §229.421(17), two commenters stated that the new language requiring a manufacturer's exclusive distributor to also be an authorized distributor of record subsequently changes the definition "normal channel of distribution" to exclude licensed wholesale drug distributors that are not authorized distributors of record, but receive drugs directly from the manufacturer under an exclusive contract with that manufacturer.

Response: The commission acknowledges this comment. The proposed language was added to the definition of "manufacturer's exclusive distributor" in Health and Safety Code, §431.401(4-b) by Acts 2009, 81st Legislature, Regular Session, Chapter 1384, §3. No change was made to the rule as a result of this comment.

Comment: Concerning the definition of "normal channel of distribution" in §229.421(20)(C), one commenter expressed concern that the language which allows distribution of a prescription drug from a manufacturer to an authorized distributor of record to another licensed wholesale distributor to another person authorized by law to administer a drug to a patient might create a security problem.

Response: The commission acknowledges this comment. This specific language was added to the definition of "normal channel of distribution" in Health and Safety Code, §431.401(5)(C) by Acts 2009, 81st Legislature, Regular Session, Chapter 1384, §3. No change was made to the rule as a result of this comment.

Comment: Concerning the definition of "normal channel of distribution" in §229.421(20)(C), one commenter suggested that the exemption broadens federal law.

Response: The commission disagrees. The commenter did not provide a specific legal citation, and the commission is not aware of any conflict with federal law. No change was made to the rule as a result of this comment.

Comment: Concerning the definition of "third-party logistics provider" found in §229.421(26), one commenter stated that the new language requiring a third-party logistics provider to also be an authorized distributor of record changes the definition of normal channel of distribution to exclude non-authorized distributor of record licensed wholesalers who contract directly with a manufacturer to provide this service.

Response: The commission acknowledges this comment. The definition of "third-party logistics provider" was added to Health and Safety Code, §431.401(10-a), by Acts 2009, 81st Legislature, Regular Session, Chapter 1384, §3. No change was made to the rule as a result of this comment.

Comment: Concerning the definition of "verification" in §229.421(27) one commenter suggested that the phrase "engaging in wholesale distribution" be added in order to be consistent with the intent of the language in Health and Safety Code, §431.412(d), and §431.413(a)(4), which describes persons to whom verification and authentication requirements apply.

Response: The commission agrees that the definition of "verification" in §229.421(27) refers directly to Health and Safety Code, §431.412(d). Therefore, the language is changed to reflect the wording used in Health and Safety Code, §431.412(d).

Comment: Concerning §229.424(n), the requirements for applicants to submit a bond to the department, three commenters suggested that the bond amount be reduced or restructured in a manner that more objectively considers the size and revenues of the affected businesses.

Response: The commission disagrees. Health and Safety Code, §431.408(a), requires that a bond of \$100,000 be submitted to the department when a firm applies for or renews its license. No change was made to the rule as a result of this comment.

Comment: Concerning §229.429(f)(1)(D), one commenter requested that this section be removed because the citation references pediatric drug studies instead of prescription drug returns.

Response: The commission agrees to strike the reference to Title 21 CFR §201.23(a)(1)-(5) because it is a typographical error. The reference is corrected to read Title 21 CFR §203.23(a)(1)-(5).

Comment: Concerning §229.429(f)(1)(D) one commenter requested the section be stricken in its entirety. The commenter stated that applying further requirements on returns beyond what is required by state law and the federal government is inconsistent with existing statutory language and federal regulations.

Response: The commission disagrees. The reference to Title 21 CFR §201.23(a)(1)-(5) was determined to be a typographical error, and the corrected reference to Title 21 CFR §203.23(a)(1)-(5) pertains to returns of prescription drugs. The commission is simply adopting a section of the CFR which describes requirements for certain types of returns of prescription drugs. The commission interprets this to be consistent with the language crafted by the legislature. No change was made to the rule as a result of this comment.

Comment: Concerning §229.429(f)(3)(A), one commenter requested that the original manufacturer not be excluded from the requirement to pass a pedigree for each prescription drug that has left the normal distribution channel since it appears not to follow legislative intent.

Response: The commission disagrees. The exclusion of an original manufacturer from the requirement to pass pedigree is language added to Health and Safety Code, §431.412(a), by Acts 2005, 79th Legislature, Chapter 282, §3(g). No change was made to the rule as a result of this comment.

Comment: Concerning §229.429(f)(3)(B), the sale of a reasonable quantity of a drug to a practitioner for office use, one commenter noted that this language was deleted from Health and Safety Code, §431.412, by Acts 2007, 80th Legislature, Regular Session, Chapter 980, §14.

Response: The commission agrees. The language of this provision is deleted and the remaining sections of this rule relettered.

The following changes have been made to provide consistency of terms to further clarify the intent of the rule.

The rule reference in §229.22(15) was revised to reflect §229.251 of this title (relating to Minimum Standards for Licensure).

In §229.421(27), a rule referenced was revised; in §229.429(f)(2), language was added to clarify that suppliers of drugs must be physically located in Texas; and the word "electron" in §229.429(f)(3)(G)(ii)(III) was changed to "electronic."

Section 229.429(f)(3)(D), regarding sales between licensed firms under common ownership, was deleted and the remaining sections of this rule relettered because this language was deleted from Health and Safety Code, §431.412, by Acts 2007, 80th Legislature, Regular Session, Chapter 980, §14.

Concerning new §229.429(f)(3)(G)(ii), the phrase "who is engaged in the wholesale distribution of a prescription drug, and who is" was added which will mirror the wording used in Health and Safety Code, §431.412(d), which pertains to the verification and authentication process.

LEGAL CERTIFICATION

The Department of State Health Services General Counsel, Lisa Hernandez, certifies that the rules, as adopted, have been reviewed by legal counsel and found to be a valid exercise of the agencies' legal authority.

STATUTORY AUTHORITY

The amendments are adopted under Health and Safety Code, §431.241, which provides the department with authority to adopt rules to enforce the Texas Food, Drug and Cosmetic Act; and Government Code, §531.0055, and Health and Safety Code, §1001.075, which authorizes the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration and enforcement of the Health and Safety Code, Chapter 1001, including Chapter 431, the Texas Food, Drug, and Cosmetic Act. The amendment regarding fees for replacement licenses is adopted under Health and Safety Code, §12.0111, which requires the department to charge a fee for issuing or renewing a license in an amount to cover the costs to the department for administering its licensing programs; and Health and Safety Code, §12.0112, which requires that the term of each license issued by the department to be two years. Review of the rules implements Government Code, §2001.039.

Legend: (Final Amendments – With additional changes not proposed)

Double underline = new language not proposed

[Bold, underline, and brackets] = Proposed new language now being deleted

[Bold and Brackets] = Final language now being deleted

Regular print = Current language incorporating proposed changes for final adoption.

(No change) = No changes are being considered for the designated subdivision

SUBCHAPTER B. DONATION OF UNUSED DRUGS

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

(1) Charitable drug donor--A licensed convalescent or nursing home or related institution, licensed hospice, hospital, physician, pharmacy, or a pharmaceutical seller or manufacturer who donates drugs pursuant to a qualified patient assistance program, or that donates drugs to a charitable medical clinic. A charitable drug donor is a wholesale drug distributor.

(2) Charitable medical clinic--A clinic, including a licensed pharmacy that is a community pharmaceutical access program provider, that provides medical care or drugs without charge or for a substantially reduced charge, complies with the insurance requirements of Civil Practice and Remedies Code, Chapter 84, and is exempt from federal income tax under Internal Revenue Code of 1986, §501(a) by being listed as an exempt organization in §501(c)(3) or (4) of the Internal Revenue Code, and is operated exclusively for the promotion of social welfare by being primarily engaged in promoting the common good and general welfare of the people in a community.

(3) Community pharmaceutical access program--A program offered by a licensed pharmacy under which the pharmacy assists financially disadvantaged persons to access prescription drugs at no charge or at a substantially reduced charge.

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

(5) Dispense--To prepare, package, compound, or label in the course of professional practice, a prescription drug or device for delivery to an ultimate user or the user's agent under a practitioner's lawful order.

(6) Drug sample--A unit of a drug that is not intended to be sold and is intended to promote the sale of the drug.

(7) Manufacture--The process of preparing, propagating, compounding, processing, packaging, repackaging, labeling, testing, or quality control of a drug or drug product, but does not include compounding that is done within the practice of pharmacy and pursuant to a prescription from a practitioner for a patient.

(8) Manufacturer--A person, other than a charitable drug donor, as defined in Civil Practice and Remedies Code, Chapter 82.

(9) Patient assistance program--A qualified program offered by a pharmaceutical manufacturer under which the manufacturer provides drugs to financially disadvantaged persons at no charge or at a substantially reduced cost. The term does not include the provision of a drug as part of a clinical trial.

(10) Person--An individual, partnership, corporation, or association.

(11) Qualified program--Any program sponsored by a pharmaceutical manufacturer.

(12) Seller--A person, other than a charitable drug donor, as defined in Civil Practice and Remedies Code, Chapter 82, who is engaged in the business of distributing or otherwise placing, for any commercial purpose, in the stream of commerce for use or consumption, a product or any component part thereof.

(13) Wholesale distribution--Distribution to a person other than a consumer or patient including, but not limited to, distribution to any person by a manufacturer, repacker, own-label distributor, jobber, private label distributor, broker, manufacturer warehouse, distributor warehouse, or other warehouse, manufacturer's exclusive distributor, drug wholesaler or distributor, 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.

§229.22. Donation of Drugs to Charitable Medical Clinics.

A charitable medical clinic may receive a drug donated by a charitable drug donor for dispensing to a patient of the charitable medical clinic, provided that the following requirements are met.

(1) The charitable drug donor must be licensed with the department as a wholesale drug distributor. Manufacturers who participate in a patient assistance program and physicians who donate samples will not be required to license with the department.

(2) The donated drugs must be dangerous drugs as defined in Health and Safety Code, Chapter 483, entitled "Texas Dangerous Drug Act."

(3) Donated drugs may not be controlled substances as defined in Health and Safety Code, Chapter 481, entitled "Texas Controlled Substances Act."

(4) All donated drugs must be approved by the Food and Drug Administration (FDA) and intended for human use.

(5) Donation of drug samples must comply with Title 21, Code of Federal Regulations (CFR), §203.39.

(6) Previously dispensed drugs shall not be donated.

(7) The charitable drug donor must verify that the requesting charity is legitimate.

(A) Verification shall include copies of documents proving the charitable medical clinic's status as exempt from federal income tax; address, telephone number, and name of contact person at the charitable medical clinic.

(B) Documentation of verification must be retained by the charitable drug donor for three years.

(8) A drug donated by a charitable drug donor shall be received by a charitable medical clinic in the manufacturer's unopened original tamper-evident packaging with its labeling intact.

(9) Delivery of a donated drug to a recipient charitable medical clinic shall be completed by an authorized agent or employee of the recipient charitable medical clinic or by the charitable drug donor. All deliveries shall be made in person. The authorized agent or employee shall present his or her official state identification to the recipient upon delivery.

(10) The recipient charitable medical clinic shall prepare at the time of collection or delivery of drugs a complete and accurate donation record, a copy of which shall be retained by the recipient charitable medical clinic for at least three years, containing the following information:

(A) a signed written statement from the charitable drug donor that the drugs have been properly stored in accordance with the manufacturer's instructions;

(B) a verifiable name, address, and telephone number of the charitable drug donor;

(C) the manufacturer, brand name, quantity, and lot or control number of the drugs donated;

(D) the date of the donation; and

(E) a copy of official state identification of the authorized agent or employee of the charitable drug donor.

(11) A donated drug shall not be dispensed to a patient until it has been examined by a registered pharmacist at the recipient charitable medical clinic to confirm that the donation record accurately describes the drug delivered, and to confirm in his or her professional judgment that no drug is adulterated or misbranded for any reason including, but not limited to, the following:

(A) the drug is out of date;

(B) the labeling has become mutilated, obscured, or detached from the drug packaging;

(C) the drug shows evidence of having been stored or shipped under conditions that might adversely affect its stability, integrity, or effectiveness;

(D) the drug has been recalled or is no longer marketed; or

(E) the drug is otherwise possibly contaminated, deteriorated, or adulterated.

(12) Documentation of the examination of the drug and the drug donation record by the registered pharmacist shall be retained by the charitable medical clinic for three years after the date of examination.

(13) The recipient charitable medical clinic shall dispose of any drug found to be adulterated/misbranded by destroying it. The charitable medical clinic shall retain complete records of the disposition of all destroyed drugs for three years from the date of destruction.

(14) Each recipient charitable medical clinic shall conduct, at least annually, an inventory of drug stocks and shall prepare a report reconciling the results of each inventory with the most recent prior inventory. Drug inventory discrepancies and reconciliation problems shall be investigated by the charitable medical clinic and outcomes documented. All reports of reconciliation, investigation, and outcome shall be retained by the charitable medical clinic for three years.

(15) All charitable drug donors shall comply with the existing statutory standards contained in the Texas Health and Safety Code, Chapter 431 and the requirements of §229.251 [§229.253] of this title (relating to Minimum Standards for Licensure [Licensing]) for "Licensing of Wholesale Distributors of Drugs - Including Good Manufacturing Practices."

(16) A charitable medical clinic shall immediately notify the Drugs and Medical Devices Group at (512) 834-6755, of becoming aware of a significant loss or theft of drugs; and a copy of the inventory reconciliation, investigation, and outcome report shall be forwarded to the Drugs and Medical Devices Group, Mail Code 1987, P.O. Box 149347, Austin, TX 78714-9347 within five days of the telephone notification.

(17) A charitable drug donor shall promptly notify in writing a charitable medical clinic to which donations have been made, if the donor becomes aware of a recall or other situation pertaining to the safety and efficacy of the previously donated drugs. Documentation of this notice shall be retained for three years after the date of notification.

§229.23. Donation of Drugs From Nursing Homes to Foreign Countries.

A nursing home may donate certain drugs or drug samples, due for destruction, to a foreign country provided the following requirements are met.

(1) The drugs to be donated are in the manufacturer's unopened original tamper-evident packaging with its labeling intact.

(2) Previously dispensed drugs shall not be donated.

(3) Controlled substances as defined in Health and Safety Code, Chapter 481, entitled "Texas Controlled Substances Act," shall not be donated.

(4) A drug shall not be shipped to a foreign country until it has been examined by a registered pharmacist at the nursing home to confirm, in his or her professional judgment, that it is not adulterated or misbranded for any reason including, but not limited to, the following:

(A) the drug is out of date;

(B) the labeling has become mutilated, obscured, or detached from the drug packaging;

(C) the drug shows evidence of having been stored or shipped under conditions that might adversely affect its stability, integrity, or effectiveness;

(D) the drug has been recalled or is no longer marketed; or

(E) the drug is otherwise possibly contaminated, deteriorated, or adulterated.

(5) The nursing home shall destroy any drug or drug sample found to be unsuitable, and retain documentation for three years from the date of destruction.

(6) Shipment. A drug described in this section may be exported to any country, if the drug complies with the laws of that country and if the nursing home has documented the prior consent of the foreign recipient. Documentation of consent shall be retained by the nursing home for three years after the date of consent. All drug donations should be packed in accordance with international shipping regulations, and be accompanied by a detailed packing list which specifies the contents of each carton and any special storage conditions. Drugs should not be mixed with other supplies in the same carton.

(7) Eligible countries for export. The nursing home shall make a good faith effort to determine that shipment of drugs to a selected foreign country is not prohibited. If no evidence of prohibition is found, then shipment may proceed. Documentation of this effort shall be retained for three years from the date of shipment. The nursing home shall contact the following:

(A) the Office of Foreign Assets Control (OFAC) of the U.S. Department of the Treasury, and the Bureau of Export Administration of the United States Department of Commerce at or (202) 622-1260; or

(B) any other agency that provides information about the prohibition of certain shipments to foreign countries.

(8) The nursing home shall prepare a complete and accurate donation record, a copy of which shall be retained by the nursing home for at least three years, containing the following information:

(A) the name, address, city, country, and telephone number of the licensed practitioner, charitable medical clinic, or foreign recipient receiving the donation;

(B) documentation of prior consent from the foreign recipient;

(C) the manufacturer, brand name, quantity, and lot or control number of the drugs to be donated; and

(D) the date of the donation.

(9) All nursing homes who donate drugs to foreign recipients shall comply with the existing statutory standards contained in the Health and Safety Code, Chapter 431, and the requirements of §229.251 of this title (relating to Minimum Standards for Licensure) for "Licensing of Wholesale Distributors of Nonprescription Drugs--Including Good Manufacturing Practices," and §229.429 of this title (relating to Minimum Standards for Licensure) for "Licensing of Wholesale Distributors of Prescription Drugs--Including Good Manufacturing Practices."

(10) A nursing home shall notify a foreign recipient to whom donations have been made, if the nursing home becomes aware of a recall or other situation pertaining to the safety and efficacy of the previously donated drugs. Documentation of this notice shall be retained for three years after the date of notification.

§229.24. Dispensing of Drugs from Charitable Medical Clinics.

All charitable medical clinics (including licensed pharmacies that are a community pharmaceutical access program provider as defined at §229.21(3) of this title (relating to Definitions) shall comply with the laws and rules pertaining to dispensing of prescription drugs as contained in the Occupations Code, Chapters 551 – 566, and 569 (relating to the Texas Pharmacy Act); and 22 Texas Administrative Code, Chapters 281 – 311 (relating to the Texas State Board of Pharmacy).

§229.25. Minimum Requirements for Licensing as a Charitable Drug Donor.

(a) All charitable drug donors in Texas shall obtain a wholesale drug distributor license annually with the department.

(b) Charitable drug donors are exempt from the license fee, but otherwise are subject to and must comply with the requirements of this chapter.

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

product is as a drug, a person who engages in donation of the product is subject to licensing as described in this section.

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

(e) License statement. The charitable drug donors' licensing statement shall be signed and verified by the owner, partner, president, or corporate designee (authorized person), shall be made on the department furnished license form, and shall contain the following information:

(1) the legal name under which the business is conducted;

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

(3) if a proprietorship, the name and residence address of the proprietor; if a partnership, the names and residence addresses of all partners; if a corporation, the date and place of incorporation and name and address of its registered agent in the state; or if any other type of association, then the names of the principals of such association;

(4) the names, residence addresses, and valid driver's license of those individuals in an actual administrative capacity which, in the case of proprietorship, shall be the managing proprietor, partnership, the managing partner, corporation, the officers and directors, or those in a managerial capacity in any other type of association; and

(5) for each place of business, the residence addresses of the individuals in charge thereof.

(f) Two or more places of business. If the charitable drug donor operates more than one place of business, the charitable drug donor shall license each place of business separately.

(g) Pre-licensing inspection. The applicant shall cooperate with any pre-licensing inspection by the department of the charitable drug donor's facilities. The department may accept reports from authorities in other jurisdictions to determine the extent of compliance with the minimum standards in this chapter for applicants located out-of-state.

(h) Issuance of license. The department may license a charitable drug donor who meets the requirements of this section, and §229.251 of this title (relating to Minimum Standards for Licensure) for "Licensing of Wholesale Distributors of Nonprescription Drugs--Including Good Manufacturing Practices," and §229.429 of this title (relating to Minimum Standards for Licensure) for "Licensing of Wholesale Distributors of Prescription Drugs--Including Good Manufacturing Practices."

(i) The initial license shall be valid for two years from the date of issuance which becomes the anniversary date.

(j) The renewal license shall be valid for two years from the anniversary date.

(k) Renewal of license.

(1) Each year, the charitable drug donor shall renew its license following the requirements of this section, and §229.253 of this title.

(2) A person who holds a license issued by the department under the Health and Safety Code, Chapter 431 shall renew the license by submitting an application for renewal on a form prescribed by the department. A licensee must submit for renewal before the expiration date of the current license. A person who submits a renewal application after the expiration date must pay an additional \$100 as a delinquency fee.

(3) 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 §229.252 and §229.430 of this title (relating to Enforcement and Penalties), and/or the refusal, cancellation, suspension and revocation provisions in §229.250 and §229.428 of this title (relating to Refusal, Cancellation, Suspension or Revocation of License).

(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 required under the Health and Safety Code, §431.206 will require submission of a new application as required by this section.

(m) Notification of change of 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 ten days after the completion of the change of location, the licensee shall notify the department in writing to verify the change of location, the address of the new location, and the name and residence address of the individual in charge of the business at the new address. Notice will be deemed adequate if the licensee provides the intent and verification notices to the department by certified mail, return receipt requested, mailed to the department.

(n) Exemption from licensing. Persons who engage in the following charitable donations of prescription drugs for use in humans are exempt from the licensing requirements of this subchapter, to the extent that the donation does not violate the Health and Safety Code, Chapter 481, the Texas Controlled Substances Act, or Chapter 483, the Texas Dangerous Drug Act:

(1) intracompany donation;

(2) the donation of a drug by a charitable medical clinic to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(3) the donation of a drug or an offer to donate a drug among hospitals or other health care entities that is 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; and

(4) the donation of drug samples by manufacturers' representatives.

(o) Donation of drugs. The provisions of this section regarding the donation of drugs shall be considered to include the manufacture, production, processing, packaging, exposure, offer, possession, and holding of any such article for donation; and the donation, dispensing, and giving of any such article, and the supplying or applying of any such articles in the conduct of any drug place of business.

(p) Minimum standards. All charitable drug donors not engaged in manufacturing, processing, packing, or holding of drugs shall comply with the minimum standards specified in subsection (q) of this section as it applies to the firm's operations, and to the existing statutory standards contained in the Health and Safety Code, Chapter 431. All charitable drug donors engaged in manufacturing, processing, packing, or holding of drugs shall comply with subsections (q) and (r) of this section as it applies to the firm's operations, and to the existing statutory standards contained in the Health and Safety Code, Chapter 431. For the purpose of this section, the policies described in the United States Food and Drug Administration's Compliance Policy Guides as they apply to drugs shall be the policies of the department.

(q) Current good manufacturing practices in manufacturing, processing, packing, or holding of drugs by drug manufacturers.

(1) The department adopts by reference Title 21, CFR, Part 210, §§210.1 - 210.3, titled "Current Good Manufacturing Practices in Manufacturing, Processing, Packing, or Holding of Drugs"; and Part 211, §§211.1 - 211.208 entitled "Current Good Manufacturing Practice for Finished Pharmaceuticals," as those regulations apply to any building under the control of a drug manufacturer where drugs are manufactured, processed, packaged, or held.

(2) Copies are indexed and filed in the office of the Drugs and Medical Devices Group, Texas Department of State Health Services, 1100 West 49th Street, Austin, Texas 78756 and are available for inspection during normal working hours.

(r) Requirements for charitable drug donors.

(1) The department adopts by reference Title 21, CFR, Part 205, §§205.1 - 205.50, 1994, as amended, entitled "Guidelines for State Licensing of Wholesale Prescription Drug Distributors," for prescription drugs, and all charitable drug donors are subject to and must comply with these regulations.

(2) Copies are indexed and filed in the office of the Drugs and Medical Devices Group, Texas Department of State Health Services, 1100 West 49th Street, Austin, Texas 78756 and are available for inspection during normal working hours.

(3) Prescription drug means any drug, human, or veterinary, required by federal law or regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to the Federal Food, Drug, and Cosmetic Act, §503(b).

(4) Legend drugs. A charitable drug donor shall not possess, sell, or transfer drugs whose labels bear the legend "Caution: Federal law prohibits dispensing without prescription" or "Rx Only," unless that person is authorized to possess, sell, or transfer such drugs in compliance with the Health and Safety Code, Chapter 431, Texas Food, Drug, and Cosmetic Act, Subchapter I; and the Health and Safety Code, Chapter 483, Texas Dangerous Drug Act.

§229.26 Enforcement - Refusal, Revocation, or Suspension of License.

(a) The department may, after providing an opportunity for a hearing, refuse to license a charitable drug donor, or may revoke or suspend the license for violations of the requirements in §§229.21 - 229.25 of this title (relating to Donation of Unused Drugs), §229.251 and §229.429 of this title (relating to Minimum Standards for Licensure), and for violations of Health and Safety Code, Chapter 431, including §431.021 (prohibited acts).

(b) Hearing. Any hearing for the refusal, revocation, or suspension of a license is governed by the department's formal hearing procedures in Chapter 1 of this title (relating to Texas Board of Health) and the Government Code, Chapter 2001, Administrative Procedure Act.

SUBCHAPTER W. LICENSING OF WHOLESALE DISTRIBUTORS OF PRESCRIPTION DRUGS--INCLUDING GOOD MANUFACTURING PRACTICES.

§229.419 Purpose. This subchapter provides for 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 (U.S.C.), §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, 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;

- amended;
- (22) 21 CFR, Part 250, Special Requirements For Specific Human Drugs, as amended;
- (23) 21 CFR, Part 290, Controlled Drugs, as amended;
- 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;
- 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 500, General, as amended;
- (34) 21 CFR, Part 510, New Animal Drugs, as amended;
- (35) 21 CFR, Part 511, New Animal Drugs for Investigational Use, as amended;
- (36) 21 CFR, Part 514, New Animal Drug Applications, as amended;
- (37) 21 CFR, Part 515, Medicated Feed Mill License, as amended;
- (38) 21 CFR, Part 520, Oral Dosage Form New Animal Drugs, as amended;
- Drugs, as amended;
- (39) 21 CFR, Part 522, Implantation or Injectable Dosage Form New Animal
- as amended;
- (40) 21 CFR, Part 524, Ophthalmic and Topical Dosage Form New Animal Drugs,
- as amended;
- (41) 21 CFR, Part 526, Intramammary Dosage Forms, as amended;

- amended;
- (42) 21 CFR, Part 529, Certain Other Dosage Form New Animal Drugs, as amended;
- (43) 21 CFR, Part 530, Extralabel Drug Use in Animals, as amended;
- amended;
- (44) 21 CFR, Part 556, Tolerances for Residues of New Animal Drugs in Food, as amended;
- (45) 21 CFR, Part 558, New Animal Drugs for Use in Animal Feeds, as amended;
- as amended;
- (46) 21 CFR, Part 589, Substances Prohibited From Use in Animal Food or Feed, as amended;
- (47) 21 CFR, Part 600, Biological Products: General, as amended;
- (48) 21 CFR, Part 601, Licensing, as amended;
- (49) 21 CFR, Part 610, General Biological Products Standards, as amended;
- (50) 21 CFR, Part 660, Additional Standards for Diagnostic Substances for Laboratory Tests, as amended;
- amended;
- (51) 21 CFR, Part 680, Additional Standards for Miscellaneous Products, as amended;
- (52) 21 CFR, Part 1300, Definitions;
- (53) 21 CFR, Part 1301, Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances;
- (54) 21 CFR, Part 1302, Labeling and Packaging Requirements For Controlled Substances, as amended;
- (55) 21 CFR, Part 1304, Records and Reports of Registrants;
- (56) 21 CFR, Part 1305, Orders for Schedule I and Schedule II Controlled Substances;
- (57) 21 CFR, Part 1306, Prescriptions; and
- (58) 21 CFR, Part 1307, Miscellaneous.

(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 this subchapter shall relieve 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, must 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, §431.111.

(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 and/or transfer of a prescription drug into, within, or out of Texas; and, who does not take 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 that have the right to engage in the manufacturing or marketing of a prescription drug consistent with the United States Food and Drug Administration's regulations and guidances implementing the Prescription Drug Marketing Act of 1987 (Pub. L. No. 100 - 293).

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

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

(9) 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 metabolism for the achievement of any of its principal intended purposes.

(10) 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.

(11) 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.

(12) 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.

(13) Federal Act--Federal Food, Drug, and Cosmetic Act, 21 United States Code (U.S.C.), §301, et seq., as amended.

(14) 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.

(15) 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.

(16) 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 United States Food and Drug Administration to engage in the manufacture of drugs or devices, consistent with the federal agency's definition of "manufacturer" under the agency's regulations and guidances implementing the Prescription Drug Marketing Act of 1987 (Pub. L. No. 100 - 293). The term does not include a pharmacist engaged in 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.

(17) 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.

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

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

(20) 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.

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

(22) Pharmacy warehouse--A location for which a person holds a wholesale drug distribution license under this subchapter, that serves 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.

(23) 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).

(24) 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.

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

(26) 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.

(27) 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 shall, before distributing the

prescription drug, authenticate and certify, in accordance with Texas Food, Drug, and Cosmetic Act, Health and Safety Code, §431.412 and §431.413 and §229.429(f)(3)(G) **§229.429(f)(3)(I)** of this title, that each transaction listed on the pedigree has occurred.

(28) 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 that is 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 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 Title 21, Code of Federal Regulations, §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 §501(c)(3) of the Internal Revenue Code of 1954 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 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, by contract, or otherwise; or

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

(29) Wholesale distributor--A person engaged in the wholesale distribution of prescription drugs, including, but not limited to, 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 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 this subchapter 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.

(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

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 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, 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, §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; or

(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 Title 21, Code of Federal Regulations, §203.23(a)(1) - (5);

(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 §501(c)(3) of the Internal Revenue Code of 1954 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, by 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 title (relating to Licensure Requirements), §229.425(b)(4) - (5), (c) and (d) of this title (relating to Licensing Procedures); and §229.424(n) and §229.425(h) of this title 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 title; and §229.424(n) and §229.425(h) of this title 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 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 title concerning bonds, and 229.429(f) of this title (relating to Minimum Standards of Licensure) concerning pedigree.

(4) The Executive Commissioner of the 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 that 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 title (relating to Exemptions), a person may not engage in the wholesale distribution of prescription drugs in Texas, as defined in §229.421(28) - (29) of this title (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 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 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 Internal Revenue Code of 1986, §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) 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 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 shall 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 §229.430 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.

(n) Bond.

(1) A wholesale distributor applying for or renewing a license shall 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 payable to this state.

(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, that are authorized under the laws of this state and that the license holder fails to pay 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 shall deposit the bonds and equivalent securities received under this section in a separate account.

(5) A pharmacy warehouse that is 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 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) 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 that acknowledges the applicant has read, understood, and agrees to abide by the provisions of this subchapter and those of the Texas Food, Drug, and Cosmetic Act, 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 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 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 shall 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 licensee shall request a replacement license from the department by submitting an application and non-refundable fee as outlined in §229.427 of this title (relating to Licensing Fees). A replacement license shall only be 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 by the Internet through texas.gov at www.texas.gov. The department is authorized to collect fees, in amounts determined by texas.gov, 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 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 must 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 subchapter will be deemed adequate if the licensee sends the notices by certified mail, return receipt requested, to the department at P. O. Box 149347, Austin, Texas 78714-9347, or submits them electronically through texas.gov at www.texas.gov.

§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 and out-of-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 medical gases, the fees are:

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

(ii) \$675 for a two-year license that is 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) \$1080 for a two-year license;

(ii) \$1080 for a two-year license that is 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) \$1755 for a two-year license;

(ii) \$1755 for a two-year license that is 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) \$2295 for a two-year license;

(ii) \$2295 for a two-year license that is due to a change of ownership; and

(iii) \$1147 for a license that is 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 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 (medical gases, foods, drugs, and/or 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 that is 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 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 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 combined gross annual sales of \$500,000 - \$999,999.99, the fees are:

(i) \$1080 for a two-year license;

(ii) \$1080 for a two-year license that is 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 combined gross annual sales of \$1 million - \$9,999,999.99, the fees are:

(i) \$1350 for a two-year license;

ownership; and (ii) \$1350 for a two-year license that is due to a change of

(iii) \$675 for a license that is amended 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) \$2025 for a two-year license;

ownership; and (ii) \$2025 for a two-year license that is due to a change of

(iii) \$1012 for a license that is amended during the current licensure period due to minor changes.

(3) In-state and out-of-state manufacturers of only medical gases shall 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) \$1080 for a two-year license;

ownership; and (ii) \$1080 for a two-year license that is due to a change of

(iii) \$540 for a license that is 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) \$1755 for a two-year license;

ownership; and (ii) \$1755 for a two-year license that is due to a change of

(iii) \$877 for a license that is 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) \$2295 for a two-year license;

(ii) \$2295 for a two-year license that is due to a change of ownership; and

(iii) \$1147 for a license that is amended during the current licensure period due to minor changes.

(4) In-state and out-of-state manufacturers of prescription drugs shall 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) \$1080 for a two-year license;

(ii) \$1080 for a two-year license that is 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 gross annual drug sales of \$200,000 - \$19,999,999.99, the fees are:

(i) \$1755 for a two-year license;

(ii) \$1755 for a two-year license that is 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 gross annual drug sales greater than or equal to \$20 million, the fees are:

(i) \$2295 for a two-year license;

(ii) \$2295 for a two-year license that is due to a change of ownership; and

(iii) \$1147 for a license that is 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 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.

(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, §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 this subchapter;

(5) has violated the Health and Safety Code, §431.021(1)(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, 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 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 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.

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

§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) 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 that is 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 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 U.S.C. §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 that Act; or

(iii) the interpretations of that Act set out in the compliance policy guide of the United States Food and Drug Administration.

(B) Each wholesale distributor and pharmacy shall administer the process of drug returns and exchanges to ensure that 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 that has not otherwise been 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 United States Food and Drug Administration's applicable guidances 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 Title 21, Code of Federal Regulations, §203.23(a)(1)-(5) [**§201.23(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 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 shall 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. Wholesale distributors physically located and conducting operations in another state shall verify, prior to purchasing or receiving product, that the suppliers of drugs are licensed under this subchapter and physically located in Texas; and, shall 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, shall provide a pedigree for each prescription drug for human consumption that leaves or at any time has left the normal distribution channel and is sold, traded, or transferred to any other person.

[(B) A pharmacy that sells a drug to a person other than the final consumer shall provide a pedigree to the person acquiring the prescription drug. The sale of a reasonable quantity of a drug to a practitioner for office use is not subject to this subsection.]

[(B) [(C)] 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.

[(D) The sale, trade, or transfer of a prescription drug between license holders with common ownership or for an emergency is not subject to this section.]

[(C) [(E)] 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 shall verify before distributing the prescription drug that each transaction listed on the pedigree has occurred.

[(D) [(F)] 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) ~~(G)~~ The pedigree must include, at a minimum, the:

(i) the name of the prescription drug;

(ii) the dosage form and strength of the prescription drug;

(iii) the size of the container;

(iv) the number of containers;

(v) the lot number of the prescription drug; and

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

(F) ~~(H)~~ 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 photocopying not later than the second business day after the date a request is submitted by the department or a peace officer in this state.

(G) ~~(I)~~ Verification procedures.

(i) Each transaction listed on the pedigree must be affirmatively authenticated prior to 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 shall certify, using the following methods, that 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 shall review the document received for signs of tampering, incompleteness, or inconsistency with other invoices or shipping documents from that manufacturer or wholesaler, and shall 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 shall establish policies and procedures for the random verification of the authenticity of the invoices or shipping documents according to statistically sound standards. Each wholesaler shall 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 [Electron] mail confirmation. Documentation requirements include a copy of the e-mail that identifies 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 that is secure from intentional or unintentional tampering or manipulation to conceal an accurate and complete history of the prescription drug transaction(s). 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 that confirms 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 that had been 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 shall review the document received for signs of tampering, incompleteness, or inconsistency, and shall randomly verify the authenticity of pedigrees using one of the methods in the this subparagraph. Each wholesaler shall 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 that requires that all prescription drugs distributed to the wholesale distributor by the authorized distributor of record must be purchased by the authorized distributor of record from the manufacturer. If this method is used to authenticate a pedigree, the wholesale distributor shall 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 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(a) of this title.

(h) Prescription drugs that are combination products. Any prescription drug that is a combination product as described in §229.424(c) of this title (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 this subchapter 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 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, 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 this subchapter 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 this subchapter 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 this subchapter 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.

(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 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 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.