

**Department of State Health Services  
Council Agenda Memo for State Health Services Council  
April 10, 2008**

**Agenda Item Title:** Amendment of Rules Concerning Charitable Drug Donations and the Licensing of Wholesale Distributors of Prescription Drugs, Including Good Manufacturing Practices

**Agenda Number:** 4d

**Recommended Council Action:**

For Discussion Only

For Discussion and Action by the Council

**Background:** The Environmental and Consumer Safety Section with the Regulatory Division of DSHS is responsible for the licensing and inspection of certain businesses including the manufacture and distribution of prescription and non-prescription drugs. During the 80th Legislative Session, 2007, two laws (Senate Bill (SB) 943 and SB 1896) were passed that impacted the function of this program. SB 1896 includes charitable pharmacies in the list of firms that may receive donations of drugs for charitable use. SB 943 amends the regulations governing wholesale distributors of prescription drugs. New controls were established to prevent the introduction of counterfeit or adulterated drugs into commerce, thus ensuring a more safe supply of prescription medication for the general population. License fees for wholesale drug distributors will be increased to cover the costs of the changes.

**Summary:**

SB 1896 requires changes to definitions for certain charitable drug donations. A new definition of charitable pharmacy was added in order to include those entities to receive and dispense donated prescription drugs under existing laws. SB 943 affects the regulatory oversight of and controls on the distribution of prescription drugs. The changes consist of new definitions and new language to bring the sections into compliance with the Federal Prescription Drug Marketing Act. New controls were established to prevent the introduction of counterfeit or adulterated drugs into commerce, thus ensuring a more safe supply of prescription medication for the general population. The amendments will impact licensing and inspection of these firms. Funding for the new provisions will be obtained through an increase in license fees for wholesale drug distributors.

Title 25, Texas Administrative Code (TAC), Chapter 229, §229.21 requires amendment of the definition of charitable medical clinic, and a new definition or community pharmaceutical access program added. These changes will allow certain pharmacies to participate in the drug donation process.

Title 25 TAC, Chapter 229, §§229.421, 229.423 - 229.425, and 229.427 - 229.429 will be amended to reflect legislative changes to the Texas Food Drug and Cosmetic Act. The affected sections pertain to the distribution of prescription drugs in the state. The changes consist of new definitions and new language to bring the sections into compliance with the Federal Prescription Drug Marketing Act. All distributors of prescription drugs will be impacted by these changes.

**Summary of Input from Stakeholder Groups:** Stakeholders approached for participation in the rules development process included: various individual drug manufacturers and drug distributors; Pharmaceutical Research and Manufacturing Association; Healthcare Distribution Management Association; specialty and niche market distributors; veterinary drug distributors; law firms representing licensed firms; other state agencies; pharmacy chains; grocery store chains; Consumer Healthcare Products Association; Texas Retailers Association; legislative aides; and individuals wishing to participate. Stakeholders provided constant feedback via e-mail, telephone, face-to-face meetings, and letters with suggestions for wording. Responses to specific questions were forwarded to all stakeholders via e-mail. Several changes, clarifying certain concepts, were made after consultation with the stakeholders.

The stakeholders with whom there were conversations included the following:

**Law Firms/Consultants** – Alston +Bird, PMP Health Services Inc, Hance Scarborough, LLP, Porzio, Bromberg & Newman, SRD Advisory Group, Arent Fox, Elaine Lust (Creighton Univ.), SBC Global, Hughes Luce, Capelo Law, BuzzeoPDMA, JM Arnold Assoc., Hillco Partners, Engel & Novitt, Fulbright & Jaworski, Williard Law

**Drug Manufacturers** – Johnson & Johnson, Pfizer, Lextron Animal Health, GlaxoSmithKline, Wyeth, Avid Medical, Schering-Plough, Merz Pharmaceuticals, Henry Schein, Genentech, Apotex, MedImmune

**Drug Distributors** – PSS World Medical Inc, Medical Express PSI, HD Smith, CVS, McKesson, Cardinal Health, UPS, Controlled Healthcare, Walgreens, Quality King Distributors, Stat Pharmaceuticals, Marine Medical, Atlantic Biologicals, TW Medical Vet Supply, AmeriSource Bergen, Physician Sales and Service, Rally Inc., Universal Medical Sales, Health Industry Distributors, SourceOne Healthcare Technologies

**Organizations** – Healthcare Distribution Management Association (HDMA), Texas Pharmacy Association (TPA), Pharmaceutical Research and Manufacturers of America (PhRMA), Healthcare Industry Distributors Association (HIDA), Texas Retailers Assoc

**Government** – Texas Board of Pharmacy, Patricia Becker (Senator Janek's office), Florida State Representatives Committee on Health Quality

**Other** – Christus Health, numerous individuals

The proposed rule language was amended numerous times over the last two years to attempt to address stakeholder concerns, meet the intent of the law, and stay within existing laws governing the regulations of drugs in Texas.

**Proposed Motion:** Motion to recommend HHSC approval for publication of rules contained in agenda item #4d.

**Approved by Assistant Commissioner/Director:** Kathryn C. Perkins **Date:** 3/17/08

**Presenter:** Karen Tannert, RPH, **Program:** Drug and Medical Devices **Phone No.:** (512) 834-6755  
MPH Group / PSQA Unit / Division  
for Regulatory Services

**Approved by CCEA:** Rosamaria Murillo **Date:** March 17, 2008

Title 25. HEALTH SERVICES

Part 1. Department of State Health Services

Chapter 229. Food and Drug

Subchapter B. Donation of Unused Drugs

Amendment §229.21

Subchapter W. Licensing of Wholesale Distributors of Prescription Drugs - Including Good Manufacturing Practices

Amendments §§229.21, 229.421, 229.423 - 229.425, 229.427 - 229.429

Proposed Preamble

The Executive Commissioner of the Health and Human Services Commission, on behalf of the Department of State Health Services (department) proposes amendments to §§229.21, 229.421, 229.423 - 229.425, and 229.427 - 229.429 concerning charitable drug donations and the licensing of wholesale distributors of prescription drugs, including good manufacturing practices.

BACKGROUND AND PURPOSE

The amendments to §§229.21, 229.421, 229.423 - 229.425, and 229.427 - 229.429 are necessary to implement a legislative change to the Texas Health and Safety Code. The Texas Health and Safety Code, Chapter 431 was amended by Senate Bill (SB) 943 and SB 1896, 80th Legislature, 2007, to address charitable drug donations and new challenges to the integrity of the prescription drug distribution system as a result of the threat of counterfeit and adulterated drugs by requiring more stringent wholesaler and pedigree licensing. Current law requires wholesaler licensing and tracking drugs through commerce by means of “pedigree” documentation only in certain instances. Texas law requires further change to conform state law to newly clarified Food and Drug Administration (FDA) requirements in the Prescription Drug Marketing Regulations, 21 Code of Federal Regulations, Subchapters 203 and 205.

SECTION-BY-SECTION SUMMARY

The amendment to §229.21 changes the definition of charitable medical clinic, and adds a new definition for the community pharmaceutical access program. These changes will allow certain pharmacies to participate in the drug donation process. Also, the definition of wholesale distribution was amended to conform to the definition in Subchapter W of the rules.

Amendments to §229.421 add definitions of a broker, co-licensed product partner, drop shipment, manufacturer’s exclusive distributor, normal distribution channel, pharmacy warehouse, third-party logistics provider, and verification. Additional amendments to the definitions of a manufacturer and wholesale distribution are necessary to conform with the amendments to Texas Health and Safety Code, Chapter 431.

Amendments to §229.423 expand the exemptions from licensing to achieve compliance with Texas Health and Safety Code, Chapter 431, and with the new FDA requirements. Amendments to §229.424 clarify the licensing requirements for a designated representative, require a license renewal, including the payment of licensing fees within 30 days of receipt of a renewal notice,

and set out the requirements of providing a bond with the application. Licensing procedures were amended in §229.425 to conform to the provisions of Chapter 431 and to delete information no longer required in an application, and applicants will submit a bond to the department.

Licensing fees were amended in §229.427 to consolidate and simplify the categories of licensing, and to ensure that out-of-state licensees pay the same fee as in state licensees. Additionally, a new subsection of §229.427 was added to set out the fees to be paid by manufacturers of medical gases.

Amendments to §229.428 add reasons to refuse, suspend or revoke a license, the violation of the prohibited acts section of Texas Health and Safety Code, Chapter 431, as well as the furnishing of false or fraudulent information in an application. If a licensee no longer meets the qualifications for obtaining a license, the license may be suspended or revoked.

Amendments to §229.429 clarify the requirements of 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.

#### FISCAL NOTE

Susan E. Tennyson, Section Director, Environmental and Consumer Safety Section, has determined that for each calendar year of the first five years §§229.421, 229.423 - 229.425, and 229.427 are in effect, there will be fiscal implications to the state as a result of enforcing or administering the sections as proposed. The effect on state government will be an increase in revenue to the state of \$720,370 in Fiscal Year 2008, \$928,240 in Fiscal Year 2009, \$928,240 in Fiscal Year 2010, \$1,205,400 in Fiscal Year 2011, and \$1,205,400 in Fiscal Year 2012. Regarding §§229.21 and 229.428, there will be no fiscal implications to the state or local governments as a result of enforcing or administering these sections as proposed.

Regarding §§229.424 and 229.425, there will be increasing costs for the review and pre-licensing inspection of applicants. The new information to be reviewed and verified and the addition of roughly 1300 pre-licensing inspections will require additional staff. Regarding §229.429, there will be an effect on state government which is expected to be an increase in inspection time for review of pedigrees, while there will be a corresponding decrease in the number of licensees who will be unable to obtain a pedigree. The effect on state government will be an increase in costs to the state of \$913,282 in Fiscal Year 2008, \$908,686 in Fiscal Year 2009, \$908,686 in Fiscal Year 2010, \$908,686 in Fiscal Year 2011, and \$908,686 in Fiscal Year 2012. The increased costs to the state will be recovered by increasing the licensing fees. Implementation of §229.421, 229.423 - 229.425, 229.427, and 229.429 will not result in any fiscal implications for local governments.

#### SMALL AND MICRO-BUSINESS IMPACT ANALYSIS

Ms. Tennyson has also determined that there are anticipated costs to small businesses or micro-businesses required to comply with the sections as proposed. There will be a 23% increase in

fees which will be from \$124 to \$403 for a two-year license, depending upon each firm's gross annual sales of all drugs. Additional requirements for a bond or equivalent security as required in §229.424 will add costs to small and micro-businesses. The cost of the bond or security cannot be determined, because various vehicles for providing the required security may be accepted. Pedigrees for prescription drugs in §229.429 must be provided and must be verified before sales can take place. The cost of meeting this requirement will vary, depending on the number and type of drugs distributed.

## ECONOMIC IMPACT STATEMENT

The new regulations in §229.429 require documentation (pedigree) of all purchases of prescription drug products back to the manufacturer of the drug. The regulations require each prior transaction to be verified by the purchaser before being passed along to the next purchaser. Firms interviewed have stated that they will have to hire additional staff to prepare and/or verify pedigrees. Employee salaries, labor costs, and sales figures are not available to department staff for evaluation. Firms will eventually be required to purchase electronic track and trace equipment (tags, readers, scanners) to facilitate the passing of electronic pedigrees, which are a pending requirement under federal law. Additional staff and equipment purchases will increase the cost of doing business. The cost of electronic track and trace technology has not been finalized since it is still in the development phase, but it is anticipated that such technology will be expensive to implement. There is no anticipated negative impact on local employment.

## REGULATORY FLEXIBILITY ANALYSIS

Government Code, §2006.002, requires the agency to consider using regulatory methods that accomplish the objectives of the rules while minimizing the adverse impacts on small business, if consistent with the health, safety, and environmental and economic welfare of the state. The proposal sets out statutory requirements for engaging in the wholesale distribution of drugs, and additionally follows the applicable requirements of the federal Prescription Drug Marketing Regulations found at 21 Code of Federal Regulations, Subchapters 203 and 205. Because the department is required to adopt as rules the specific standards and procedures mandated by SB 943, 80th Legislature, 2007, the mandated standards are *per se* consistent with the health, safety, or environmental and economic welfare of the state. Therefore, other methods to accomplish the objective of the rules would violate state and federal law.

## PUBLIC BENEFIT

Ms. Tennyson has also determined that for each year of the first five years the sections are in effect, the public will benefit from adoption of the sections. The public benefit anticipated as the result of administering and enforcing §§229.21, 229.421, 229.423 - 229.425, and 229.427 - 229.429 is to reduce the possibility of diversion of prescription drugs, and to reduce the likelihood that counterfeit drugs are introduced into commerce.

## REGULATORY ANALYSIS

The department has determined that this proposal is not a “major environmental rule” as defined by Government Code, §2001.0225. “Major environmental rule” is defined to mean a rule the specific intent of which is to protect the environment or reduce the risk to human health from environmental exposure and that may adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment or public health and safety of a state or sector of the state.

#### TAKINGS IMPACT ASSESSMENT

The department has determined that the proposed amendments do not restrict or limit an owner’s right to his or her property that would otherwise exist in the absence of government action and, therefore, do not constitute a taking under Government Code, §2001.043.

#### PUBLIC COMMENT

Comments on the proposal may be submitted to Karen Tannert, R.Ph., M.P.H., Drugs and Medical Devices Group, Policy/Standards/Quality Assurance Unit, Environmental and Consumer Safety Section, Division for Regulatory Services, P.O. Box 149347, Mail Code 1875, Austin, Texas 78714-9347, 512-834-6770 extension 2350, or by email to Karen.Tannert@dshs.state.tx.us. Comments will be accepted for 30 days following publication of the proposal in the *Texas Register*.

#### LEGAL CERTIFICATION

The Department of State Health Services General Counsel, Lisa Hernandez, certifies that the proposed rules have been reviewed by legal counsel and found to be within the state agencies’ authority to adopt.

#### STATUTORY AUTHORITY

The proposed amendments are authorized by Health and Safety Code, §431.241, which provides the Executive Commissioner of the Health and Human Services Commission 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 authorize the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001.

The proposed amendments affect the Health and Safety Code, Chapters 431 and 1001; and Government Code, Chapter 531.

Legend: (Proposed Amendments)

Single Underline = Proposed language

**[Bold Print and Brackets]** = Current language proposed for deletion

Regular Print = Current language

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

§229.21. Definitions. The following words and terms, when used in these sections, shall have the following meanings, unless the context clearly indicates otherwise.

(1) (No change.)

(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 person to access prescription drugs at no charge or at a substantially reduced charge.

(4) [(3)] Department – The [Texas] Department of State Health Services.

(5) [(4)] 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) [(5)] 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) [(6)] 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) [(7)] Manufacturer – A person, other than a charitable drug donor, as defined in Civil Practice and Remedies Code, Chapter 82.

(9) [(8)] 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) [(9)] Person – An individual, partnership, corporation, or association.

(11) [(10)] Qualified program – Any program sponsored by a pharmaceutical manufacturer.

(12) [(11)] 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) [(12)] 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 [or] 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.

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

(1) - (3) (No change.)

(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) [(4)] Change of ownership – A sole proprietor who transfers all or part of the facility's ownership to another person or persons; the removal, addition, or substitution of a person or persons as a partner in a facility owned by a partnership; a corporate sale, transfer, reorganization, or merger of the corporation which owns the facility if sale, transfer, reorganization, or merger causes a change in the facility's ownership to another person or persons; or if any other type of association, the removal, addition, or substitution of a person or persons as a principal of such association.

(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) [(5)] Commissioner – Commissioner of the Department of State Health Services.

(8) [(6)] Department – The Department of State Health Services.

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

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

(B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man or other animals; or

(C) intended to affect the structure or any function of the body of man or other animals and that does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and is not dependent on 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) [(8)] Drug – Articles recognized in the official United States Pharmacopoeia National Formulary, or any supplement to it, articles designated or intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, articles, other than food, intended to affect the structure or any function of the body of man or other animals, and articles intended for use as a component of any such article. The term does not include devices or their components, parts, or accessories. A food for which a claim is made in accordance with the Federal Act, §403(r), and for which the claim is approved by the U.S. Food and Drug Administration, is not a drug solely because the label or labeling contains such a claim.

(12) [(9)] Emergency medical reasons – Includes transfers of a prescription drug between a wholesale distributor or pharmacy to alleviate a temporary shortage of a prescription drug arising from delays in or interruption of regular distribution schedules; sales to nearby emergency medical services, i.e., ambulance companies and firefighting organizations in the same state or same marketing or service area, or nearby licensed practitioners of drugs for use in the treatment of acutely ill or injured persons; provision of minimal emergency supplies of drugs to nearby nursing homes for use in emergencies or during hours of the day when necessary drugs

cannot be obtained; and transfers of prescription drugs by a retail pharmacy to alleviate a temporary shortage.

(13) ~~[(10)]~~ Federal Act – Federal Food, Drug, and Cosmetic Act, 21 United States Code, et seq., as amended.

(14) ~~[(11)]~~ Flea market – A location at which booths or similar spaces are rented or otherwise made available temporarily to two or more persons and at which the persons offer tangible personal property for sale.

(15) ~~[(12)]~~ Labeling – All labels and other written, printed, or graphic matter:

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

(B) accompanying such drug.

(16) ~~[(13)]~~ Manufacturer – A person who manufactures, prepares, propagates, compounds, processes, packages, or repackages prescription drugs, or a person who changes the container, wrapper, or labeling of any prescription drug package. 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) ~~[(14)]~~ Misbranded drug – Has the meaning specified in the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431, §431.112.

(19) ~~[(15)]~~ 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 pharmacy warehouse to the pharmacy warehouse's intracompany pharmacy;

(D) 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;

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

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

(21) [(16)] 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) [(17)] Place of business – Each location at which a prescription drug for wholesale distribution is located.

(24) [(18)] Prescription drug – Any drug (including any biological product, except for blood and blood components intended for transfusion or biological products that are also medical devices) required by Federal law (including Federal regulation) to be dispensed only by a prescription, including finished dosage forms and bulk drug substances subject to the Federal Act, §503(b).

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

(26) [(20)] Repackager – A person who engages in repackaging.

(27) 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.

(28) Verification – A person who is in possession of a pedigree for a prescription drug must, before distributing the prescription drug, authenticate and certify, in accordance with Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431, §§431.412 and 431.413, and §229.429(f)(3)(I) of this title, that each transaction listed on the pedigree has occurred.

(29) [(21)] Wholesale distribution – Distribution of prescription drugs to a person other than a consumer or patient [ , and includes distribution by a manufacturer, repackager, own label distributor, broker, jobber, warehouse, retail pharmacy that conducts wholesale distribution or wholesaler]. The term does not include:

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

(B) the sale, purchase, **[distribution,]** trade, or transfer of prescription drugs or the offer to sell, purchase, **[distribute,]** trade, or transfer a prescription drug for emergency medical reasons, 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, **[retail pharmacy, chain pharmacy warehouse,]** or charitable institution in accordance with 21 CFR, §203.23; **[or]**

(E) the sale of reasonable quantities [delivery] by a retail pharmacy of a prescription drug to **[a patient or a patient's agent under the lawful order of]** a licensed practitioner 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 section 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 section, 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.

(30) 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.

§229.423. Exemptions.

(a) (No change.)

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

(1) intracompany sales 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 (CFR), §203.23;

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

(6) the sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug under a prescription;

(7) the sale, transfer, merger, or consolidation of all or part of the business of a pharmacy from or with another pharmacy, whether accomplished as a purchase and sale of stock or business assets;

(8) the delivery of, or offer to deliver, a prescription drug by a common carrier solely in the common carrier's usual course of business of transporting prescription drugs, if the common carrier does not store, warehouse, or take legal ownership of the prescription drug; 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, CFR, §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 section, 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.

**[(1) intracompany sales]**

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

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

**[(4) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control. For the purpose of this subsection, “common control” means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, contract, or otherwise;]**

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

**[(6) the sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription;]**

**[(7) the distribution of drug samples by manufacturers' representatives or distributors' representatives; or]**

**[(8) the sale, purchase, or trade of blood and blood components intended for transfusion.]**

(c) (No change.)

(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: **[in]** §229.424(d) and (n) of this title (relating to License [Licensure] Requirements); §229.425**(b)(4)-(5)**, (c), **[and]** (d) and (g) of this title (relating to Licensing Procedures).

(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) and (n) of this title (relating to License Requirements); and §229.425(b)(4)-(5), (c), (d) and (g) of this title (relating to Licensing Procedures) .

§229.424. License 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(29)-(30) 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) - (c) (No change.)

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

(1) - (5) (No change.)

(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 §1504, Internal Revenue Code of 1986;

(7) - (8) (No change.)

(e) - (l) (No change.)

(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. [prior to the expiration date of the current license.] A person who files a renewal application after the expiration date must pay an additional \$100 as a delinquency fee.

(2) - (3) (No change.)

(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 shall 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) (No change.)

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

(3) [(2)] the address **[and]**, telephone number, and name of a contact person for each of the applicant's places of business; **[of each place of business that is licensed;]**

(4) [(3)] the type of business entity: **[and the name, residence address, and valid driver's license number of:]**

(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;

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

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

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

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

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

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

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

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

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

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

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

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

**(7) [(9)]** the name of the manager, if different from the designated representative, for each place of business;

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

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

(c) Designated representatives [**and managers**].

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

(A) - (D) (No change.)

(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) (No change.)

(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) (No change.)

(J) a photograph of the person taken not earlier than 180 [30] days before the date the application was submitted.

(2) (No change.)

(d) (No change.)

(e) Renewal license application. The renewal application for licensure as a wholesale distributor of prescription drugs shall be made on a license application form furnished by the department. 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) (No change.)

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

#### §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 **[compressed]** medical gases **[with gross annual drug sales of \$0 - \$20,000]**, the fees are:

(i) \$830 **[\$675]** for a two-year license;

(ii) \$830 **[\$675]** for a two-year license that is **[amended]** due to a change of ownership; and

(iii) \$415 **[\$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 - \$1,999,999.99, **[\$199,999.99]** the fees are:

(i) \$1328 **[\$1,080]** for a two-year license;

(ii) \$1328 **[\$1,080]** for a two-year license that is **[amended]** due to a change of ownership; and

(iii) \$664 **[\$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 \$2,000,000 **[\$200,000]** - \$19,999,999.99, the fees are:

(i) \$2158 **[\$1,755]** for a two-year license;

(ii) \$2158 **[\$1,755]** for a two-year license that is **[amended]** due to a change of ownership; and

(iii) \$1079 **[\$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) \$2823 **[\$2,295]** for a two-year license;

(ii) \$2823 [**\$2,295**] for a two-year license that is **[amended]** due to a change of ownership; and

(iii) \$1412 [**\$1,147**] 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 **[only compressed]** medical gases who are not manufacturers and who also are required to be licensed as a device distributor under §229.439(a) of this title (relating to Licensure Fees), or as a wholesale food distributor under §229.182(a)(3) of this title (relating to Licensing/Registration Fee and Procedures) shall pay a combined two-year license fee for each place of business. License fees are based on the combined gross annual sales of these regulated products (medical gases, foods, drugs, and/or devices) as follows: [.]

(A) For **[a wholesale distributor with]** combined gross annual sales of \$0 - \$199,999.99, the fees are:

(i) \$664 [**\$540**] for a two-year license;

(ii) \$664 [**\$540**] for a two-year license that is **[amended]** due to a change of ownership; and

(iii) \$332 [**\$270**] for a license that is amended during the current licensure period due to minor changes.

(B) For **[a wholesale distributor with]** combined gross annual sales of \$200,000 - \$499,999.99, the fees are:

(i) \$996 [**\$810**] for a two-year license;

(ii) \$996 [**\$810**] for a two-year license that is **[amended]** due to a change of ownership; and

(iii) \$498 [**\$405**] for a license that is amended during the current licensure period due to minor changes.

(C) For **[a wholesale distributor with]** combined gross annual sales of \$500,000 - \$999,999.99, the fees are:

(i) \$1328 [**\$1,080**] for a two-year license;

(ii) \$1328 [**\$1,080**] for a two-year license that is **[amended]** due to a change of ownership; and

(iii) \$664 [**\$540**] for a license that is amended during the current licensure period due to minor changes.

(D) For **[a wholesale distributor with]** combined gross annual sales of \$1 million - \$9,999,999.99, the fees are:

(i) \$1661 **[\$1,350]** for a two-year license;

(ii) \$1661 **[\$1,350]** for a two-year license that is **[amended]** due to a change of ownership; and

(iii) \$831 **[\$675]** for a license that is amended during the current licensure period due to minor changes.

(E) For **[a wholesale distributor with]** combined gross annual sales greater than or equal to \$10 million, the fees are:

(i) \$2491 **[\$2,025]** for a two-year license;

(ii) \$2491 **[\$2,025]** for a two-year license that is **[amended]** due to a change of ownership; and

(iii) \$1246 **[\$1,012]** 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) for a two-year license;

(ii) \$1328 for a two-year license that is due to a change of ownership; and

(iii) \$664 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) \$2158 for a two-year license;

(ii) \$2158 for a two-year license that is due to a change of ownership; and

(iii) \$1079 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) \$2823 for a two-year license;

(ii) \$2823 for a two-year license that is due to a change of ownership; and

(iii) \$1412 for a license that is amended during the current licensure period due to minor changes.

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

(A) For [a wholesale distributor with] gross annual drug sales of \$0 - \$1,999,999.99, [\$199,999.99] the fees are:

(i) \$1328 [\$1,080] for a two-year license;

(ii) \$1328 [\$1,080] for a two-year license that is [amended] due to a change of ownership; and

(iii) \$664 [\$540] for a license that is amended during the current licensure period due to minor changes.

(B) For [a wholesale distributor with] gross annual drug sales of \$2,000,000 [\$200,000] - \$19,999,999.99, the fees are:

(i) \$2158 [\$1,755] for a two-year license;

(ii) \$2158 [\$1,755] for a two-year license that is [amended] due to a change of ownership; and

(iii) \$1079 [\$877] for a license that is amended during the current licensure period due to minor changes.

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

(i) \$2823 [\$2,295] for a two-year license;

(ii) \$2823 [\$2,295] for a two-year license that is [amended] due to a change of ownership; and

(iii) \$1412 [**\$1,147**] for a license that is amended during the current licensure period due to minor changes.

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

**[(A) For each wholesale distributor with gross annual drug sales of \$0 - \$19,999,999, the fees are:]**

**[(i) \$1,350 for a two-year license;]**

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

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

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

**[(i) \$2,025 for a two-year license;]**

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

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

(b) - (c) (No change.)

§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) - (4) (No change.)

(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) - (8) (No change.)

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

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

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

(b) - (f) (No change.)

(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) - (e) (No change.)

(f) Minimum restrictions on transactions.

(1) Returns.

(A) A wholesale distributor shall receive prescription drug returns or exchanges from a pharmacy or [chain] pharmacy warehouse in accordance with the terms and conditions of the agreement between the wholesale distributor and the pharmacy or [chain] pharmacy warehouse. 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 §431.412 of the Act if the returns or exchanges are exempt from pedigree under: [of the Act. In connection with the returned goods process, a wholesale distributor shall establish appropriate business practices and exercise due diligence designed to prevent the entry of adulterated or counterfeit drugs into the distribution channel.]

(i) Section 503, Prescription Drug Marketing Act of 1987 (21 U.S.C. §353(c)(3)(B));

(ii) the regulations adopted by the secretary 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 shall comply with the requirements of Title 21, Code of Federal Regulations, §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 must verify that the person is legally authorized by the department or the appropriate state licensing authority to receive the prescription drugs or authorized by federal law to receive the drugs.

(3) 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.

(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.

(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 must verify before distributing the prescription drug that each transaction listed on the pedigree has occurred.

(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 email address of each person who owns or possesses 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.

(G) The pedigree must include, at a minimum, the:

(i) name of the prescription drug;

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

(iii) size of the container;

(iv) number of containers;

(v) lot number of the prescription drug; and

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

(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.

(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 in possession of a pedigree for a prescription drug must 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 must review the document received for signs of tampering, incompleteness, or inconsistency with other invoices or shipping documents from that manufacturer or wholesaler, and must randomly verify the authenticity of the invoice or shipping document with the seller or shipping point reflected on that document using one of the methods in the subsections below. Each wholesaler 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 mail confirmation. Documentation requirements include a copy of the email 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 must review the document received for signs of tampering, incompleteness, or inconsistency, and must randomly verify the authenticity of pedigrees using one of the methods in the subsections above. 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 must establish policies and procedures for the random verification of the authenticity of the pedigrees that disclose the authorized distributor of record purchased the prescription drug from the manufacturer according to statistically sound standards.

(VII) Any other method approved by the department.

(4) [(3)] Premises. Prescription drugs distributed by a manufacturer or wholesale distributor may be delivered only to the premises listed on the license, except as listed in paragraph (5) [(4)] of this subsection. A manufacturer or wholesale distributor may distribute prescription drugs to an authorized person or agent of that person at the premises of the manufacturer or wholesale distributor if:

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

(B) delivery is made only to meet the immediate needs of a particular patient of the authorized person.

(5) [(4)] Delivery to hospital pharmacies. Prescription drugs may be distributed to a hospital pharmacy receiving area if a pharmacist or an authorized receiving person signs, at the time of delivery, a receipt showing the type and quantity of the prescription drug received. Any discrepancy between the receipt and the type and quantity of the prescription drug actually received shall be reported to the delivering manufacturer or wholesale distributor not later than the next business day after the date of delivery to the pharmacy receiving area.

(g) - (j) (No change.)