



TEXAS DEPARTMENT OF STATE HEALTH SERVICES

DSHS Web Site: <http://www.tdh.state.tx.us/bfds/dmd/salvagerules.html>

LICENSING OF DRUG SALVAGE ESTABLISHMENTS AND BROKERS

(25 Texas Administrative Code, §§229.571 - 229.584)

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§229.571. Purpose

These sections provide for the licensing and regulation of drug salvage establishments and brokers in order to prevent the sale or distribution of adulterated or misbranded drugs to consumers.

§229.572. Applicable Laws and Regulations

(a) A salvage establishment or salvage broker who is subject to these sections and who is also involved in the reconditioning, sale, or distribution of distressed or salvaged medical devices, foods, or cosmetics must comply with the applicable requirements in Subchapter AA of this chapter (relating to Regulation of Food Salvage Establishments and Brokers), Subchapter CC of this chapter (relating to Regulation of Device Salvage Establishments and Brokers), and Subchapter DD of this chapter (relating to Regulation of Cosmetic Salvage Establishments and Brokers).

(b) The Department of State Health Services (department) adopts by reference the following federal laws and regulations:

(1) Federal Food, Drug, and Cosmetic Act, 21 U.S.C., §301 et seq. as amended;

(2) Fair Packaging and Labeling Act, 15 U.S.C., §1451 et seq. as amended;

(3) Section 501(c)(3), Internal Revenue Code of 1986, as amended;

(4) 21 Code of Federal Regulations (CFR), Part 205, §§205.1 - 205.50, titled "Guidelines for State Licensing of Wholesale Prescription Drug Distributors," as amended;

(5) 21 CFR Part 210, §§210.1 - 210.3, titled "Current Good Manufacturing, Processing, Packing, or Holding of Drugs" as amended, and §§211.1 - 211.208, titled "Current Good Manufacturing Practice for Finished Pharmaceuticals" as amended.

(c) Copies of these laws and regulations are indexed and filed at the department, located at 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>.

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

§229.573. Definitions

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

(1) Act--The Texas Food, Drug, Device, and Cosmetic Salvage Act, Health and Safety Code, Chapter 432.

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

(3) Authorized Agent--An employee of the department who is designated by the commissioner to enforce the provisions of this chapter.

(4) Change of ownership--A sole proprietor who transfers all or part of the salvage establishment or salvage broker business to another person or persons; the removal, addition, or substitution of a person or persons as a partner in a salvage establishment or salvage broker business owned by a partnership; a corporate sale, transfer; reorganization; or merger of the corporation which owns the salvage establishment or salvage broker business if the sale, transfer, reorganization, or merger causes a change in the salvage establishment's or salvage broker

business's ownership to another person or persons; or if any other type of association, the removal, addition, or substitution of a person or persons as a principal of such association.

(5) Commissioner--The Commissioner of Health, or his successor.

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

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

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

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

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

(8) Distressed drug--Any drug that is adulterated or misbranded within the meaning of the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, §§431.111 and 431.112. The term includes a drug that:

(A) has lost its labeling or is otherwise unidentified;

(B) has been subjected to prolonged or improper storage, including unsanitary conditions whereby the drug may have become contaminated with filth or whereby it may be rendered injurious to health;

(C) has been subjected for any reason to abnormal environmental condition, including temperature extremes, humidity, smoke, water, fumes, pressure, or radiation;

(D) has been subjected to conditions that result in either its strength, purity, or quality falling below that which it purports or is represented to possess; or

(E) has been rendered unsafe or unsuitable for human consumption or use for any other reason.

(9) Drug--

(A) an article or substance recognized in the official United States Pharmacopoeia, the official Homeopathic Pharmacopoeia of the United States, the official National Formulary, or any supplement of them;

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

(C) an article or substance, other than food, intended to affect the structure or any function of the body of man or other animals; or

(D) an article or substance intended for use as a component of any article or substance specified in this definition.

(10) Drug Manufacturer--Includes a person who manufactures, prepares, propagates, compounds, processes, repackages, or changes the container, wrapper, or labeling of any drug.

(11) Food--

(A) any article of food or drink for man;

(B) chewing gum; or

(C) an article used for components of any such article.

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

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

(B) accompanying such article.

(13) Manufacture--The combining, preparing, propagation, compounding, purifying, processing, packing, repacking, wrapping, and labeling of drugs.

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

(15) Nonprofit organization--An organization that has received an exemption from federal taxation under 26 U.S.C., §501(c)(3).

(16) Nonsalvageable drug--Distressed drug, as defined in this section, which cannot be safely or practically reconditioned.

(17) Perishable--Capable of spoilage or deterioration due to improper refrigeration or handling.

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

(19) Personnel--Any person employed by a salvage establishment or salvage broker who does or may in any manner handle or come in contact with the handling, storing, transporting, or selling and distributing of salvageable or salvaged drugs.

(20) Place of business--Each location from which a salvage establishment or salvage broker operates.

(21) Practitioner--A person licensed by the Texas State Board of Medical Examiners, State Board of Dental Examiners, Texas State Board of Podiatric Medical Examiners, Texas Optometry Board, or State Board of Veterinary Medical Examiners to prescribe and administer prescription drugs.

(22) Reconditioning--Any appropriate process or procedure by which distressed drugs can be brought into compliance with the standards of the department for consumption or use by the public. In addition, all reconditioned drugs must be in compliance with the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431.

(23) Sale or distribution--The act of selling or distributing, whether for compensation or not, and includes delivery, holding, or offering for sale, transfer, auction, storage, or other means of handling or trafficking.

(24) Salvage broker--A person who engages in the business of selling, distributing, or otherwise trafficking in any distressed or salvaged food, drug, device, or cosmetic and who does not operate a salvage establishment.

(25) Salvage establishment--Any place of business engaged in reconditioning or by other means salvaging distressed food, drugs, devices, or cosmetics, or that sells, buys, or distributes for human use any salvaged food, drug, device, or cosmetic. For the purpose of licensing under these sections, a drug reclamation center is a salvage establishment.

(26) Salvage operator--A person who is engaged in the business of operating a salvage establishment.

(27) Salvage warehouse--A separate storage facility used by a salvage broker or salvage establishment for the purpose of holding distressed or salvaged drug.

(28) Salvageable drug--Any distressed drug, as defined in this section, which can be reconditioned to departmental standards.

(29) Salvaged drug--Any distressed drug that has been reconditioned.

(30) Sanitize--Adequate treatment of surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance and in substantially reducing numbers of other microorganisms. Such treatments shall not adversely affect the product and shall be safe to the consumer.

(31) Vehicles--Any truck, car, bus, or other means by which distressed, salvageable, or salvaged drugs is transported from one location to another.

§229.574. Exemptions and Applicability

(a) A person is exempt from licensing under these sections if the person is:

(1) a manufacturer, distributor, or processor of a drug who in the normal course of business engages in the activities of reconditioning the items manufactured, distributed, or processed by or for that person and not purchased by that person solely for the purpose of reconditioning and sale;

(2) a common carrier or a common carrier's agent who disposes of or otherwise transfers undamaged or distressed drugs to a person who is exempt under this section or to a currently licensed salvage broker or salvage operator; or

(3) a person who transfers distressed drugs to a licensed salvage broker or salvage operator.

(b) An exemption from the licensing requirements under these sections does not constitute an exemption from other applicable provisions of the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431, or the rules adopted to administer and enforce the Act.

(c) A salvage establishment or salvage broker who is engaging only within the scope of the license issued under §229.575 of this title (relating to Licensing Requirements and Procedures) is not required to be licensed under Health and Safety Code, Chapter 431. An exemption from licensing requirements under Health and Safety Code, Chapter 431, does not constitute an exemption from other applicable provisions of the Health and Safety Code, Chapter 431, or the rules adopted to administer and enforce the chapter.

§229.575. Licensing Requirements and Procedures

(a) General. Except as provided by §229.574 of this title (relating to Exemptions and Applicability), it shall be unlawful for any person to operate a salvage establishment or operate as a salvage broker within the State of Texas, who does not possess a current and valid license issued by the department.

(b) Licensing of out-of-state salvage establishments and brokers. A person who operates a salvage establishment or acts as a salvage broker outside this state may not sell, distribute, or otherwise traffic in distressed or salvaged food, drugs, devices, or cosmetics within this state unless the person holds a license from the department.

(c) Reports from other jurisdictions. The department may accept reports from authorities in other jurisdictions to determine the extent of compliance with these sections and with the provisions of the Act.

(d) New place of business. Each person acquiring or establishing a place of business for the purpose of operating a salvage establishment or operating as a salvage broker shall apply for and obtain a license of such business prior to beginning operations.

(e) Two or more places of business. If the salvage establishment or salvage broker operates more than one place of business, the salvage establishment or salvage broker shall license each place of business separately.

(f) License application. 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>.

(g) Contents of license application. The salvage establishment or salvage broker license application shall be signed and verified, submitted on a license application form furnished by the department, and shall include the following information:

(1) the name of the legal entity to be licensed, including the name under which the business is conducted;

(2) the address of the place of business to be licensed and the mailing address if different;

(3) the address of any salvage warehouse used by a salvage establishment or salvage broker;

(4) if a sole proprietorship, the name of the proprietor; if a partnership, the names of all partners; if a corporation, the names and titles of all officers; in any other association, those in a managerial capacity; and

(5) a statement signed and verified by the sole proprietor, managing partner, corporate officer, or person in a managerial capacity for an association that acknowledges the applicant has read, understood, and agrees to abide by the provisions of these sections and those of the Act.

(h) 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 salvage establishment or salvage broker who meets the requirements of these sections and pays all fees in compliance with §229.276 of this title (Licensing Fees).

(i) Transfer of license. Licenses shall not be transferable from one person to another or from one place of business to another.

(j) Display of license. The license shall be displayed in an open public area at each place of business and each salvage operator shall have a copy of a valid license in each vehicle used by the salvage operator to transport distressed drugs.

(k) License term. Unless a license is amended as provided in subsection (o) of this section, or is revoked or suspended as provided in §229.584 of this title (relating to Enforcement and Penalties), the license is valid for one or two years as determined by the department.

(l) Renewal of license.

(1) The license application as outlined in subsection (g) of this section and nonrefundable licensing fees as outlined in §229.576 of this title (relating to Licensing Fees) for each place of business shall be submitted to the department prior to the expiration date of the current license. A person who files a renewal application after the expiration date shall pay an additional \$100 as a delinquency fee.

(2) The department shall renew the license for a one or two-year term as determined by the department if the licensee is in compliance with these sections and has paid all required fees, including any past due and delinquency fees.

(m) Completeness of license applications. Failure to complete the initial or renewal license application form may result in the denial of a license.

(n) Report of changes. The license holder shall notify the department in writing within ten days of any change, including change in location, name, or ownership of a salvage establishment or salvage broker, which would render the information contained in the initial license application no longer accurate. Failure to inform the department within ten days of a change in information required in the initial license application may result in enforcement action as described in §229.584 of this title.

(o) 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 fees as outlined in §229.576 of this title (relating to Licensing Fees).

(p) Return of license. A license issued under these sections shall be returned to the department if the place of business:

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

(2) relocates;

(3) changes the name of the business under which the salvage establishment or salvage broker operates; or

(4) changes ownership.

§229.576. Licensing Fees

(a) Licensing fees.

(1) All applicants for a license or a renewal license must pay a licensing fee. All fees are nonrefundable. The license fees are as follows:

(A) \$600 for a one-year license; or

(B) \$1,200 for a two-year license.

(2) Delinquency fee. A salvage establishment or salvage broker must pay a \$100 delinquency fee if:

(A) the renewal license application is submitted or the renewal license fee is paid after the expiration date of the current license; or

(B) the initial license application is submitted or the initial license fee is paid more than 30 days following the effective date of a change in location, name, or ownership of an existing salvage establishment or salvage broker as described in §229.575(o) of this title (relating to Licensing Requirements and Procedures).

(3) Reinspection fee. A salvage establishment or salvage broker who requests reinstatement of a license that has been denied, suspended, or revoked pursuant to §229.584 of this title (relating to Enforcement and Penalties), shall pay a nonrefundable inspection fee of \$600.

(b) Consolidation of license terms. The department may, upon receipt of a written request from a license holder, prorate a license fee for the purpose of consolidating the license renewal dates of multiple licenses issued in the name of the license holder.

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

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

§229.577. Personnel

(a) Employee health requirements. No person known to be or suspected of being affected with any communicable disease, or while a carrier of such disease, or while afflicted with boils, infected wounds, sores, or respiratory infection, shall work in an area of a salvage establishment or for a salvage broker in any capacity when there is any possibility of such person

contaminating salvageable or salvaged drugs with pathogenic organisms, or transmitting disease to other individuals.

(b) Personal cleanliness.

(1) All personnel while working in direct contact with salvageable drugs or while engaged in reconditioning, repacking, or otherwise handling any ingredients or components of salvageable drugs shall wear clean outer garments, maintain a high degree of personal cleanliness, and conform to hygienic practices while on duty.

(2) Personnel engaged in reconditioning salvageable drugs shall wash their hands thoroughly in a department approved hand-washing facility before starting work, and as often as may be necessary to remove soil and contamination.

(3) No person shall resume work after visiting the toilet room without first washing their hands.

§229.578. Construction and Maintenance of Physical Facilities

(a) Buildings. Buildings used by salvage establishments and salvage brokers shall be of suitable design and contain sufficient space to perform necessary operations, prevent mix-ups, and assure orderly handling.

(b) Floor construction.

(1) The floor surfaces in all rooms and areas in which salvageable or salvaged drugs are stored or processed and in which utensils are washed, and walk-in refrigerators, dressing or locker rooms, and toilet rooms, shall be constructed to be smooth and easily cleanable.

(2) Any floor that is exposed to water or liquids shall be nonabsorbent.

(3) All floors shall be kept clean and in good repair.

(4) Floor drains shall be provided in all rooms where floors are subjected to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.

(c) Walls and ceilings. Walls and ceilings of all rooms shall be clean, smooth, and in good repair.

(d) Lighting. Appropriate lighting shall be provided in hand washing areas, dressing and locker rooms, and toilet rooms and in areas where salvageable or salvaged devices are examined, processed, stored and where equipment or tools are cleaned.

(1) Where personnel are inspecting, sorting, or reconditioning distressed drug, at least 540 lux (50 foot candles) of light shall be provided at the work surface.

(2) At all other areas of the facility where light is required, at least 110 lux (ten foot candles) of light shall be provided when measured at a distance of 30 inches above the floor.

(e) Ventilation.

(1) All rooms, in which salvageable or salvaged drugs are reconditioned or utensils are washed, dressing or locker rooms, toilet rooms, and garbage and rubbish storage areas shall be well ventilated.

(2) Ventilation hoods and related equipment shall be designed to prevent condensation from dripping onto salvageable drugs or onto work surfaces.

(3) Filters shall be readily removable for cleaning or replacement.

(4) Ventilation systems shall comply with applicable federal, state, and local fire prevention and air pollution requirements.

(f) Locker area. Appropriate facilities shall be provided for the orderly storage of personnel clothing and personal belongings.

(g) Cleanliness of facilities.

(1) All parts of the salvage establishment or salvage warehouse and its premises shall be kept neat, clean, and free of litter and rubbish.

(2) Cleaning operations shall be conducted in such a manner as to prevent contamination of salvageable and salvaged drugs.

(3) None of the operations connected with a salvage establishment or salvage warehouse shall be conducted in any room used as an employee lounge or toilet facility, or living or sleeping quarters.

(4) Soiled coats and aprons shall be kept in suitable containers until removed for laundering.

(5) No birds or animals shall be allowed in any areas used for the conduct of salvage establishment operations or the storage of salvageable and salvaged drugs.

(h) Vehicles. Vehicles used to transport distressed, salvageable, or salvaged drugs shall be maintained in a clean and sanitary condition to protect the product from contamination.

§229.579. Sanitary Facilities and Controls

(a) Water supply. The water supply shall be adequate, of a safe and sanitary quality, and from a source constructed and operated in accordance with the Minimum Standards of Sanitation and

Health Protection, Health and Safety Code, Chapter 341, and rules promulgated under this chapter.

(b) Sewage. All sewage, including liquid waste, shall be disposed of in a public sewerage system or, in the absence thereof, in a manner applicable with the Minimum Standards of Sanitation and Health Protection, Health and Safety Code, Chapter 341, and rules promulgated under this chapter.

(c) Plumbing. Plumbing shall be sized, installed, and maintained in accordance with applicable state and local plumbing codes.

(d) Toilet facilities.

(1) Each salvage establishment shall provide its employees with adequate and conveniently located toilet facilities.

(2) Toilet facilities, including rooms and fixtures, shall be kept in a clean condition and in good repair at all times.

(3) All toilet room doors shall be self-closing.

(4) Toilet tissue shall be provided.

(5) Easily cleanable covered receptacles shall be provided for waste materials in all toilet rooms.

(6) Where the use of non-water-carried sewage disposal facilities are approved by the department they shall be located at least 100 linear feet from the salvage establishment and from any well or stream.

(e) Hand-washing facilities. Each salvage establishment shall be provided with adequate, conveniently located hand-washing facilities for its personnel, including a lavatory or lavatories, equipped with hot and cold or tempered running water, hand-cleansing soap or detergent, and approved sanitary towels or other approved hand-drying devices. Such facilities shall be kept clean and in good repair.

(f) Garbage and refuse.

(1) All organic or organic-containing refuse shall be kept in leak proof, non-absorbent containers which shall be kept covered with tight-fitting lids when filled or stored, or not in continuous use. Such containers shall be covered when stored and stored either in a vermin-proof room or enclosure or in a waste refrigerator.

(2) Paper, cardboard, unused equipment, and non organic refuse shall be stored in containers, rooms, or areas in such a manner to prevent it from becoming a source of contamination or pest harborage.

(3) Adequate cleaning facilities shall be provided, and each container, room, or area shall be thoroughly cleaned after the emptying or removal of refuse.

(4) All refuse shall be disposed of with sufficient frequency and in such a manner as to prevent contamination.

(5) All refuse shall be disposed of in accordance with all applicable state and local requirements, including requirements for solid waste disposal as referenced in Title 30, Texas Administrative Code, Chapters 330, 335, and 336.

(g) Insect and rodent control. Effective measures shall be taken to protect against the entrance, breeding or presence of rodents, insects, and other vermin within the salvage establishment or salvage warehouse.

§229.580. General Provisions for Handling and Movement of Distressed Drugs

(a) Notice to the department.

(1) When the source of distressed drugs is the result of a natural disaster, accident, power failure, or other emergency, the salvage establishment or salvage broker shall make contact with the department within 24 hours after their initial awareness of the emergency and prior to any removal of distressed drugs from the place at which it was located when it became distressed.

(2) If emergency removal of distressed drugs referenced in subsection (a)(1) of this section is required, notice to the department shall be made as soon thereafter as possible. It shall be the duty of the salvage establishment or salvage broker to make contact with the department within 48 hours whenever distressed drugs subject to the provisions of this subsection are obtained.

(3) Distressed drugs referenced in this subsection shall not be moved out of the State of Texas without prior approval of the department and the responsible state agency in the state to receive the drugs. Concurrence shall also be obtained from the U.S. Food and Drug Administration, or U.S. Department of Agriculture, Food Safety and Inspection Service, prior to interstate movement.

(b) Protection of Salvageable and Salvaged Drugs.

(1) All salvageable and salvaged drugs stored by salvage establishments or salvage brokers shall be held at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs.

(2) All salvageable and salvaged drugs, while being stored or processed at a salvage establishment, salvage warehouse, or during transportation, shall be protected from contamination.

(3) Poisonous and toxic materials shall be identified and handled under such conditions as will not contaminate other salvageable or salvaged drugs, or constitute a hazard to personnel.

(c) Segregation of drugs. All salvageable drugs shall be promptly sorted and segregated from nonsalvageable drugs to prevent further contamination of the distressed drugs to be salvaged or offered for sale or distribution.

(d) Nonsalvageable drugs.

(1) Containers, including metal and glass containers with press caps, screw caps, pull rings, or other types of openings which have been in contact with nonpotable water, liquid foam, or other deleterious substances, as a result of fire fighting efforts, flood, sewer backups, or similar mishaps, shall be deemed unfit for sale or distribution, i.e., nonsalvageable drugs as defined in §229.573(17) of this title (relating to Definitions).

(2) Nonsalvageable drugs shall be disposed of as in §229.579 of this title (relating to Sanitary Facilities and Controls).

(3) Distressed drugs which are deemed to be nonsalvageable by a duly authorized agent of the Texas Department of Health shall, at the request of the agent, be destroyed under the supervision of that agent at the expense of the owner.

(e) Transporting of distressed drugs.

(1) Distressed drugs shall be moved from the site of a fire, flood, sewer backup, wreck, or other cause as expeditiously as possible after compliance with subsection (a) of this section so as not to become putrid, rodent or insect defiled, or otherwise hazardous to public health.

(2) All distressed and salvageable drugs of a perishable nature shall be transported only in vehicles provided with adequate refrigeration, if necessary, for product maintenance prior to reconditioning.

(f) Handling of distressed articles other than drugs. If distressed articles other than drugs are also salvaged, they shall be handled separately so as to prevent contamination from poisonous and toxic materials or other contaminants.

(g) Cross-contamination protection. Sufficient precautions shall be taken to prevent cross-contamination among the various types of drugs that are salvageable or salvaged.

(h) Salvageable drugs. All salvageable drugs shall be reconditioned prior to sale or distribution except for such sale or distribution to a person holding a valid license to engage in a salvage operation.

(i) Reconditioned drugs. All reconditioned drugs must be in compliance with the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431.

(j) Labeling. All salvaged drugs must be labeled in accordance with the requirements of the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431; the Federal Food, Drug, and Cosmetic Act, 21 U.S.C., §301 et seq. as amended; the Fair Packaging and Labeling Act, 15 U.S.C., §1451 et seq. as amended; and the federal regulations promulgated under those Acts.

(k) Salvage warehouses. A person may not use a salvage warehouse to recondition drugs or sell to consumers.

§229.581. Handling Distressed Drugs

(a) Good manufacturing practices. A person must follow and comply with the requirements in 21 CFR, Parts 205, §§205.1 - 205.50, titled "Guidelines for State Licensing of Wholesale Prescription Drug Distributors," as amended, 21 CFR Part 210, §§210.1 - 210.3, titled "Current Good Manufacturing, Processing, Packing, or Holding of Drugs" as amended, and §§211.1 - 211.208, titled "Current Good Manufacturing Practice for Finished Pharmaceuticals" as amended, in the handling and reconditioning of all salvaged drugs.

(b) Distressed or nonsalvageable drugs. All distressed or nonsalvageable drugs shall be disposed of in accordance with §229.579(f) of this title (relating to Sanitary Facilities and Controls).

(c) Relabeling. All salvaged drugs in containers shall be provided with labels meeting the requirements in §229.580(i) of this title (relating to General Provisions for Handling and Movement of Distressed Drugs). Where original labels are removed from containers that are to be resold or redistributed, the replacement labels must show the name and address of the salvage establishment.

(d) Procedures. All salvage establishments shall have written procedure for identifying and retrieving over-the-counter and prescription drug products that are subject to recall.

§229.582. Records

(a) Inventory Records. A written record or receipt of distressed, salvageable, and salvaged drugs shall be maintained by the salvage establishment or salvage broker and shall include:

- (1) the common name and brand name or manufacturer and quantity of the drugs received;

(2) the source of the distressed, salvageable, and salvaged drugs;

(3) the date received;

(4) a brief description of the type or cause of damage (fire, flood, wreck, prolonged storage, warehouse damage, etc.); and

(5) the name of the individual or business that purchases any such drugs for the purpose of sale or distribution and the date of any such transaction.

(b) Retention of records. All records required in these sections shall be kept at the place of business of the salvage establishment or salvage broker for a period of two years following the completion of transactions involving a lot of drugs.

(c) Electronic records. Records required by these sections which are maintained by the salvage establishment or salvage broker on computer systems shall be regularly copied, at least monthly, and updated on storage media other than the hard drive of the computer. An electronic record must be retrievable as a printed copy.

§229.583. Inspection

(a) Inspection. To enforce these sections or the 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:

(1) enter at reasonable times the place of business of a salvage establishment or salvage broker;

(2) enter a salvage warehouse used to store or hold distressed or salvaged drug;

(3) enter a vehicle being used to transport or hold distressed or salvaged drug; or

(4) inspect at reasonable times, any place of business of a salvage establishment or salvage broker, salvage warehouse, or vehicle and all equipment, finished and unfinished materials, containers, and labeling of any item and obtain samples necessary for the enforcement of these sections or the Act.

(b) Access to records. A person who is required to maintain records referenced in these sections or under the 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 review, copy, and verify the records.

(c) Access to records showing movement in commerce. A person who is subject to licensing under §229.575 of this title (relating to Licensing Requirements and Procedures) or a person, including a common carrier or a common carrier's agent, who disposes of or otherwise transfers

distressed or salvaged drugs shall, at the request of the commissioner or an authorized agent, permit the commissioner or authorized agent at all reasonable times access to review, copy, and verify all records showing:

- (1) the movement in commerce of any distressed or salvaged drug;
- (2) the holding of any distressed or salvaged drug after movement in commerce; and
- (3) the quantity, shipper, and consignee of any distressed or salvaged drug.

(d) Receipt for samples. An authorized agent or health authority who makes an inspection of a place of business, including any vehicle or salvage 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.

§229.584. Enforcement and Penalties

(a) General license actions. The department may deny, suspend, or revoke the license of an applicant or licensee who fails to comply with any of the following:

- (1) failure to comply with the Act or these sections;
- (2) falsification of information provided in an application for a license;
- (3) refuses to allow the department to conduct an inspection or collect samples;
- (4) interferes with the department in the performance of its duties;
- (5) removes or disposes of a detained drugs in violation of the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, §431.021; or
- (6) fails to inform the department of any salvage warehouse(s) at the time of an inspection or when requested by the department.

(b) Emergency license suspensions.

(1) The department may suspend a license without notice when there is an imminent threat to the health or safety of the public.

(2) If an emergency suspension order is issued without a hearing, the department, not later than the 30th day after the date on which the emergency order was issued, shall determine a time and place for a hearing at which the emergency order will be affirmed, modified, or set aside. The hearing shall be held under departmental formal hearing rules governed by §§1.21, 1.23, 1.25 and 1.27 of this title (relating to Formal Hearing Procedures).

(c) Hearings.

(1) Any hearings for the denial, suspension, or revocation of a license are governed by §§1.21, 1.23, 1.25 and 1.27 of this title.

(2) Within 20 days after the postmark date of the department's written notice of proposed denial, suspension, or revocation, the applicant or licensee may request a hearing in writing from the department. If the applicant or licensee does not request a hearing during the required time period, then the applicant or licensee is deemed to have waived his/her right to a hearing.

(d) Reinstatement of license.

(1) A person whose application for a license has been denied or whose license has been placed under an emergency suspension may request a reinspection for the purpose of granting or reinstating a license not later than the 30th day after the denial or emergency suspension. Not later than the tenth day after the receipt of a written request from the applicant or licensee, the department shall make a reinspection.

(2) As regards a nonemergency suspension or a revocation, the licensee may request at any time, an inspection for reinstating the license or for issuing a new license.

(3) If, after inspection, the department determines that the applicant or licensee meets the requirements of the Act or these sections, the department shall reinstate the license or issue a new license, as appropriate.

(4) Reinspection fee. Except as provided for in §229.576(c) of this title (relating to Licensing Fees), a salvage establishment or salvage broker who requests reinstatement of a license that has been denied, suspended, or revoked pursuant to this section shall pay a nonrefundable inspection fee of \$600.

(e) Emergency order.

(1) General. The commissioner or the commissioner's designee may issue an emergency order, either mandatory or prohibitory, concerning the sale or distribution of distressed drugs in the department's jurisdiction if the commissioner or the commissioner's designee determines that:

(A) the sale or distribution of those drugs creates or poses an immediate and serious threat to human life or health; and

(B) other procedures available to the department to remedy or prevent the threat will result in unreasonable delay.

(2) Absence of notice and hearing. The commissioner or the commissioner's designee may issue the emergency order without notice and hearing if the commissioner or the commissioner's designee determines it is necessary under the circumstances.

(3) Hearings. If an emergency order is issued without a hearing, the department shall determine a time and place for a hearing at which the emergency order will be affirmed, modified, or set aside. The hearing shall be governed by §§1.21, 1.23, 1.25 and 1.27 of this title.

(f) Administrative penalty. If a person violates these sections, or an order adopted or license issued under the Act, the commissioner may assess an administrative penalty against the person.

(1) The penalty may not exceed \$25,000 for each violation. Each day a violation continues is a separate violation.

(2) In determining the amount of the penalty, the commissioner shall consider the following criteria:

- (A) the person's previous violations;
- (B) the seriousness of the violation;
- (C) any hazard to the health and safety of the public;
- (D) the person's demonstrated good faith; and
- (E) other matters as justice may require.

(3) Violations subject to this subsection shall be categorized into severity levels as determined in §229.261 of this title (relating to Assessment of Administrative Penalties).

(4) Hearings, appeals from, and judicial review of final administrative decisions under this subsection shall be conducted according to the contested case provisions of the Government Code, Chapter 2001, and §§1.21, 1.23, 1.25, and 1.27 of this title.

(5) An administrative penalty may be assessed only after a person charged with a violation is given an opportunity for a hearing.

(6) If a hearing is held, the commissioner shall make findings of fact and shall issue a written decision regarding the occurrence of the violation and the amount of the penalty.

(7) If the person charged with the violation does not request a hearing, the commissioner may assess a penalty after determining that a violation has occurred and the amount of the penalty.

(8) After making a determination under this subsection that a penalty is to be assessed, the commissioner shall issue an order requiring that the person pay the penalty.

(9) The commissioner may consolidate a hearing held under this subsection with another proceeding.

(10) Not later than the 30th day after the date of issuance of an order finding that a violation has occurred, the commissioner shall inform the person against whom the order is issued of the amount of the penalty.

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