



Texas Department of State Health Services

DRUGS AND MEDICAL DEVICES GROUP WEB SITE:

<http://www.dshs.state.tx.us/dmd/>

DONATION OF UNUSED DRUGS

(25 Texas Administrative Code, §§229.21 – 229.26)

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

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

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

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

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

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

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

(7) Manufacture--The process of preparing, propagating, compounding, processing, packaging, repackaging, labeling, testing, or quality control of a drug or drug product, but does

not include compounding that is done within the practice of pharmacy and pursuant to a prescription from a practitioner for a patient.

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

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

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

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

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

(13) Wholesale distribution--Distribution to a person other than a consumer or patient including, but not limited to, distribution to any person by a manufacturer, repacker, own-label distributor, jobber, private label distributor, broker, manufacturer warehouse, distributor warehouse, or other warehouse, manufacturer's exclusive distributor, drug wholesaler or distributor, distributor, independent wholesale drug trader, specialty wholesale distributor, third party logistics provider, retail pharmacy that conducts wholesale distribution, and pharmacy warehouse that conducts wholesale distribution.

§229.22. Donation of Drugs to Charitable Medical Clinics.

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

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

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

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

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

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

(6) Previously dispensed drugs shall not be donated.

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

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

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

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

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

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

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

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

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

(D) the date of the donation; and

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

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

(A) the drug is out of date;

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

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

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

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

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

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

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

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

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

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

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

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

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

(2) Previously dispensed drugs shall not be donated.

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

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

(A) the drug is out of date;

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

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

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

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

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

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

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

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

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

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

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

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

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

(D) the date of the donation.

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

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

§229.24. Dispensing of Drugs from Charitable Medical Clinics.

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

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

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

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

(c) If the United States Food and Drug Administration (FDA) determines, with respect to a product that is a combination of a drug and a device that the primary mode of action of the product is as a drug, a person who engages in donation of the product is subject to licensing as described in this section.

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

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

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

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

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

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

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

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

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

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

Licensure) for "Licensing of Wholesale Distributors of Prescription Drugs--Including Good Manufacturing Practices."

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

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

(k) Renewal of license.

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

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

(3) A licensee who fails to submit a renewal application prior to the current licensure expiration date and continues operations may be subject to the enforcement and penalty provisions in §229.252 and §229.430 of this title (relating to Enforcement and Penalties), and/or the refusal, cancellation, suspension and revocation provisions in §229.250 and §229.428 of this title (relating to Refusal, Cancellation, Suspension or Revocation of License).

(l) Amendment of license. A license that is amended, including a change of name, ownership, or a notification of a change in the location of a licensed place of business required under the Health and Safety Code, §431.206 will require submission of a new application as required by this section.

(m) Notification of change of location of place of business. Not fewer than 30 days in advance of the change, the licensee shall notify the department in writing of the licensee's intent to change the location of a licensed place of business. The notice shall include the address of the new location, and the name and residence address of the individual in charge of the business at the new location. Not more than ten days after the completion of the change of location, the licensee shall notify the department in writing to verify the change of location, the address of the new location, and the name and residence address of the individual in charge of the business at the new address. Notice will be deemed adequate if the licensee provides the intent and verification notices to the department by certified mail, return receipt requested, mailed to the department.

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

(1) intracompany donation;

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

(3) the donation of a drug or an offer to donate a drug among hospitals or other health care entities that is under common control. For the purpose of this subsection, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, contract, or otherwise; and

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

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

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

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

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

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

(r) Requirements for charitable drug donors.

(1) The department adopts by reference Title 21, CFR, Part 205, §§205.1 - 205.50, 1994, as amended, entitled "Guidelines for State Licensing of Wholesale Prescription

Drug Distributors," for prescription drugs, and all charitable drug donors are subject to and must comply with these regulations.

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

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

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

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

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

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