# TEXAS DEPARTMENT OF STATE HEALTH SERVICES

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## RULES FOR LICENSING OF DEVICE DISTRIBUTORS AND MANUFACTURERS

(25 Texas Administrative Code, §§229.431 - 229.444)

**Section**



### §229.431 Purpose

These sections provide for the minimum licensing standards necessary to ensure the safety and efficacy of devices distributed by device distributors and manufacturers.

### §229.432 Applicable Laws and Regulations

(a) The department adopts by reference the following laws and regulations:

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

(2) 21 Code of Federal Regulations (CFR), Part 801, Labeling, as amended;

(3) 21 CFR, Part 803, Medical Device Reporting, as amended;

(4) 21 CFR, Part 807, Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices, as amended;

(5) 21 CFR, Part 814, Premarket Approval of Medical Devices, as amended;

(6) 21 CFR, Part 820, Quality System Regulation, as amended; and

(7) 21 CFR, Subchapter J--Radiological Health, as amended.

(b) Copies of these laws and regulations are indexed and filed at the department, 1100 West 49th Street, Austin, Texas 78756, and are available for inspection during normal working hours. Electronic copies of these laws and regulations are available online at http://www.dshs.state.tx.us/license.shtm.

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

**§229.433 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, and Cosmetic Act, Health and Safety Code, Chapter 431.

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

(3) Advertising--All representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or that are likely to induce, directly or indirectly, the purchase of food, drugs, devices, or cosmetics.

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

(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) Distributor--A person who furthers the marketing of a finished domestic or imported device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user. The term includes an importer or an own-label distributor. The term does not include a person who repackages a finished device or who otherwise changes the container, wrapper, or labeling of the finished device or the finished device package.

(9) Electronic product radiation--Any ionizing or nonionizing electromagnetic or particulate radiation, or any sonic, infrasonic, or ultrasonic wave, which is emitted from an electronic product as the result of the operation of an electronic circuit in such product.

(10) Finished device--A device, or any accessory to a device, which is suitable for use, whether or not packaged or labeled for commercial distribution.

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

(12) Health authority--A physician designated to administer state and local laws relating to public health.

(13) Importer--Any person who initially distributes a device imported into the United States.

(14) Ionizing radiation--Any electromagnetic or particulate radiation capable of producing ions, directly or indirectly, in its passage through matter. Ionizing radiation includes gamma rays and x-rays, alpha and beta particles, high speed electrons, neutrons, and other nuclear particles.

(15) 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.

(16) Manufacture--The making by chemical, physical, biological, or other procedures of any article that meets the definition of device. The term includes the following activities:

(A) repackaging or otherwise changing the container, wrapper, or labeling of any device package in furtherance of the distribution of the device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer; or

(B) initiation of specifications for devices that are manufactured by a second party for subsequent commercial distribution by the person initiating specifications.

(17) Manufacturer--A person who manufactures, fabricates, assembles, or processes a finished device. The term includes a person who repackages or relabels a finished device. The term does not include a person who only distributes a finished device.

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

(19) Person--Includes individual, partnership, corporation, and association.

(20) Place of business--Each location at which a device is manufactured or held for distribution.

(21) Practitioner--Means 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 devices.

(22) Prescription device--A restricted device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and hence for which adequate directions for use cannot be prepared.

(23) Radiation machine--Any device capable of producing ionizing radiation except those devices with radioactive material as the only source of radiation.

(24) Radioactive material--Any material (solid, liquid, or gas) that emits radiation spontaneously.

(25) Reconditioning--Any appropriate process or procedure by which distressed merchandise can be brought into compliance with departmental standards as specified in the Texas Food, Drug, Device, and Cosmetic Salvage Act, Health and Safety Code, Chapter 432, §432.003, as interpreted in the rules in §229.192 of this title (relating to Definitions).

(26) Restricted device--A device subject to certain controls related to sale, distribution, or use as specified in the Federal Food, Drug, and Cosmetic Act, as amended, §520(e)(1).

**§229.434 Exemptions**

(a) A person is exempt from licensing under these sections if the person engages only in the following types of device distribution:

(1) intracompany sales;

(2) distribution from a place of business located outside the State of Texas; or

(3) the sale, purchase, or trade of a distressed or reconditioned device by a salvage broker or a salvage operator licensed under §229.605 of this title (relating to Licensing Requirements and Procedures).

(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; the Texas Dangerous Drug Act, Health and Safety Code, Chapter 483; or the rules adopted to administer and enforce the Acts.

**§229.435 Licensure Requirements**

(a) General. Except as provided by §229.434 of this title (relating to Exemptions), a person may not engage in the distribution or manufacture of devices in Texas unless the person has a valid license from the Commissioner of the Department of State Health Services (commissioner) for each place of business.

(b) Display of license. The license shall be displayed in an open public area at each place of business.

(c) Existing place of business. Each person involved in the distribution or manufacture of devices in Texas on the effective date of these sections must apply for a device distributor manufacturer license no later than 60 days following the effective date of these sections.

(d) New place of business. Each person acquiring or establishing a place of business for the purpose of device distribution or manufacturing after the effective date of these sections shall apply to the Texas Department of State Health Services (department) for a license of such business prior to beginning operation.

(e) Two or more places of business. If the device distributor or manufacturer operates more than one place of business, the device distributor or manufacturer shall license each place of business separately.

(f) 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 distributor or manufacturer of devices who meets the requirements of these sections, and pays all fees in compliance with §229.439 of this title (relating to Licensing Fees).

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

(h) License term. Unless the license is amended as provided in subsection (j) of this section or revoked or suspended as provided in §229.440 of this title (relating to Refusal, Cancellation, Suspension, or Revocation of a License), the license is valid two years.

(i) Renewal of license.

(1) The license application as outlined in §229.436(b) of this title (relating to Licensing Procedures) and nonrefundable licensing fees as outlined in §229.439 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 must pay an additional $100 as a delinquency fee.

(2) A licensee who fails to submit a renewal application prior to the current licensure expiration date and continues operations may be subject to the enforcement and penalty provisions in §229.443 of this title (relating to Enforcement and Penalties), and/or the revocation and suspension provisions in §229.440 of this title.

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

(j) Amendment of license. A license that is amended, including a change of name, ownership, or a notification of a change in the location of a licensed place of business will require submission of an application as outlined in §229.436 of this title (relating to Licensing Procedures) and submission of fees as outlined in §229.439 of this title (relating to Licensing Fees).

(k) Notification of change of location of place of business. Not fewer than 30 days in advance of the change, the licensee shall notify the commissioner or the commissioner's designee 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 commissioner or the commissioner's designee in writing to verify the change of location, the specific date of change, the new 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 commissioner or the commissioner's designee by certified mail, return receipt requested, mailed to the department, 1100 West 49th Street, Austin, Texas.

(l) Combination products. If the United States Food and Drug Administration 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 device, a distributor or manufacturer of the product is subject to licensure as described in this section.

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

Authority, to recover costs associated with application and renewal application processing through Texas Online.

**§229.436 Licensing Procedures**

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

(b) Contents of license application. The application for licensure as a device distributor or manufacturer shall be signed and verified, submitted on a license application form furnished by the department, and contain 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 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 and corporation charter number; or if any other type of association, then the names of the principals of such association;

(4) the name, residence address, and valid driver license number for each individual 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;

(5) for each place of business, the residence address of the individual in charge thereof;

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

(7) 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) Renewal license application. The renewal application for licensure as a device distributor or manufacturer shall be made on a license application form furnished by the department.

**§229.437 Report of Changes**

The license holder shall notify the department in writing within ten days of any change which would render the information contained in the application for the license, reported pursuant to

§229.436 of this title (relating to Licensing Procedures), no longer accurate. Failure to inform the department no later than ten days of a change in the information required in the application for a license may result in a suspension or revocation of the license.

**§229.439 Licensure Fees**

(a) License fee.

(1) No person may operate or conduct business as a device distributor without first obtaining a license from the department. All applicants for a device distributor license or a renewal license shall pay a licensing fee. All fees are nonrefundable. Licenses are issued for two-year terms. A license shall only be issued when all past due fees and delinquency fees are paid. License fees are based on gross annual device sales.

(A) For a distributor with gross annual device sales of $0 - $499,999.99, the fees are:

(i) $480 for a two-year license;

(ii) $480 for a two-year license that is amended due to a change of ownership; and

(iii) $240 for a license that is amended during the current licensure period due to minor changes.

(B) For a distributor with gross annual device sales of $500,000 - $9,999,999.99, the fees are:

(i) $1,080 for a two-year license;

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

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

(C) For a distributor with gross annual device sales greater than or equal to $10 million, the fees are:

(i) $1,680 for a two-year license;

(ii) $1,680 for a two-year license that is amended due to a change of ownership; and

(iii) $840 for a license that is amended during the current licensure period due to minor changes.

(2) A person who is required to be licensed as a device distributor under this section and who is also required to be licensed as a wholesale drug distributor under §229.252(a)(1) of this title (relating to Licensing Fee and Procedures) or as a wholesale food distributor under §229.182(a)(3) of this title (relating to Licensing Fee and Procedures) shall pay a combined licensure fee for each place of business. All fees are nonrefundable. Licenses are issued for two-year terms. A license shall only be issued when all past due fees and delinquency fees are paid. License fees are based on the combined gross annual sales of these regulated products (foods, drugs, and/or devices).

(A) For each place of business having combined gross annual sales of $0 - $199,999.99, the fees are:

(i) $520 for a two-year license;

(ii) $520 for a two-year license that is amended due to a change of ownership; and

(iii) $260 for a license that is amended during the current licensure period due to minor changes.

(B) For each place of business having combined gross annual sales of $200,000 - $499,999.99, the fees are:

(i) $780 for a two-year license;

(ii) $780 for a two-year license that is amended due to a change of ownership; and

(iii) $390 for a license that is amended during the current licensure period due to minor changes.

(C) For each place of business having combined gross annual sales of $500,000 - $999,999.99, the fees are:

(i) $1,040 for a two-year license;

(ii) $1040 for a two-year license that is amended due to a change of ownership; and

(iii) $520 for a license that is amended during the current licensure period due to minor changes.

(D) For each place of business having combined gross annual sales of $1 million - $9,999,999.99, the fees are:

(i) $1,300 for a two-year license;

(ii) $1,300 for a two-year license that is amended due to a change of ownership; and

(iii) $650 for a license that is amended during the current licensure period due to minor changes.

(E) For each place of business having combined gross annual sales greater than or equal to $10 million, the fees are:

(i) $1,950 for a two-year license;

(ii) $1,950 for a two-year license that is amended due to a change of ownership; and

(iii) $975 for a license that is amended during the current licensure period due to minor changes.

(3) No person may operate or conduct business as a device manufacturer in this state without first obtaining a license from the department. All applicants for a device manufacturer license or renewal license shall pay a licensing fee. All fees are nonrefundable. Licenses are issued for two-year terms. A license shall only be issued when all past due fees and delinquency fees are paid. License fees are based on the gross annual device sales.

(A) For a manufacturer with gross annual device sales of $0 - $499,999.99, the fees are:

(i) $480 for a two-year license;

(ii) $480 for a two-year license that is amended due to a change of ownership; and

(iii) $240 for a license that is amended during the current licensure period due to minor changes.

(B) For a manufacturer with gross annual device sales of $500,000 - $9,999,999.99, the fees are:

(i) $2,160 for a two-year license;

(ii) $2,160 for a two-year license that is amended due to a change of ownership; and

(iii) $1,080 for a license that is amended during the current licensure period due to minor changes.

(C) For a manufacturer with gross annual device sales greater than or equal to $10 million, the fees are:

(i) $3,600 for a two-year license;

(ii) $3,600 for a two-year license that is amended due to a change of ownership; and

(iii) $1,800 for a license that is amended during the current licensure period due to minor changes.

(b) 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.

(c) Exemption from licensing fees. A person is exempt from the licensing fees required by this section if the person is:

(1) licensed under §289.252 of this title (relating to Licensing of Radioactive Material) or registered under §289.226 of this title (relating to Registration of Radiation Machine Use and Services) and engages only in the following types of device distribution or manufacturing:

(A) the manufacture or distribution of radiation machines which are devices; or

(B) the manufacture or distribution of devices which contain radioactive materials; or

(2) a charitable organization, as described in the Internal Revenue Code of 1986, §501(c)(3), or a nonprofit affiliate of the organization, to the extent otherwise permitted by law.

(d) Sale of food, drugs, or devices. This section includes the manufacture, production, processing, packaging, exposure, offer, possession, and holding of any of the regulated articles for sale; the sale, dispensing, and giving of any regulated article; and supplying or applying of any regulated articles in the operation of any food, drug, or device place of business.

**§229.440 Refusal, Cancellation, Suspension, Revocation**

(a) The commissioner may refuse an application or may suspend or revoke a license if the applicant or licensee:

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

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

(3) has been convicted in a state or federal court of the illegal use, sale, or transportation of intoxicating liquors, narcotic drugs, barbiturates, amphetamines, desoxyephedrine, their compounds or derivatives, or any other dangerous or habit-forming drugs;

(4) is an association, partnership, or corporation and the managing officer has been convicted in state or federal court of the illegal use, sale, or transportation of intoxicating liquors, narcotic drugs, barbiturates, amphetamines, desoxyephedrine, their compounds or derivatives, or any other dangerous or habit-forming drugs;

(5) has violated any of the provisions of the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431 (Act) or these sections;

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

(7) has obtained or attempted to obtain a license by fraud or deception.

(b) The commissioner may refuse an application for a license or may suspend or revoke a license if the commissioner determines from evidence presented during a hearing that the applicant or licensee:

(1) has violated the Health and Safety Code, §431.021(l)(3), concerning the counterfeiting of a drug or the sale or holding for sale of a counterfeit drug;

(2) has violated the Health and Safety Code, Chapter 481 (Texas Controlled Substance Act), or the Health and Safety Code, Chapter 483 (Dangerous Drugs Act); or

(3) has violated the rules of the director of the Department of Public Safety, including being responsible for a significant discrepancy in the records that state law requires the applicant or licensee to maintain.

(c) The department may, after providing opportunity for hearing, refuse to license a distributor or manufacturer of devices, or may suspend or revoke a license for violations of the requirements in these sections or for any of the reasons described in the Act.

(d) Any hearings for the refusal, revocation or suspension of a license are governed by §§1.21, 1.23, 1.25, and 1.27 of this title (relating to Formal Hearing Procedures).

(e) A license issued under these sections shall be returned to the department if the device distributor's or manufacturer's place of business:

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

(2) relocates; or

(3) changes name or ownership. For a corporation, an ownership change is deemed to have occurred, resulting in the necessity to return the license to the department, when 5.0% or more of the share of stock of a corporation is transferred from one person to another.

**§229.441 Minimum Standards for Licensure**

(a) Minimum requirements. All distributors or manufacturers of devices engaged in the design, manufacture, packaging, labeling, storage, installation, and servicing of devices must comply with the minimum standards of this section in addition to the statutory requirements contained in the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431 (Act). For the purpose of this section, the policies described in the United States Food and Drug Administration's (FDA's) Compliance Policy Guides as they apply to devices shall be the policies of the Texas Department of Health (department).

(b) Federal establishment registration and device listing. All persons who operate as device distributors or manufacturers in Texas shall meet the applicable requirements in 21 Code of Federal Regulations (CFR), Part 807, titled "Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices." Devices distributed by device distributors or manufacturers shall have met, if applicable, the premarket notification requirements of 21 CFR, Part 807 or the premarket approval provisions of 21 CFR, Part 814, titled "Premarket Approval of Medical Devices."

(c) Good manufacturing practices. Device distributors or manufacturers engaged in the design, manufacture, packaging, labeling, storage, installation, and servicing of finished devices shall be in compliance with the applicable requirements of 21 CFR, Part 820, titled "Quality System Regulation." The requirements in this part govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use.

(d) Buildings and facilities.

(1) All manufacturing, assembling, packaging, packing, holding, testing, or labeling of devices by manufacturers shall take place in buildings and facilities described in 21 CFR, Part 820, Subpart L, titled "Handling, Storage, Distribution, and Installation."

(2) No manufacturing, assembling, packaging, packing, holding, testing, or labeling operations of devices by manufacturers or distributors shall be conducted in any personal residence.

(3) Any place of business used by a distributor to store, warehouse, hold, offer, transport, or display devices shall:

(A) be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(B) have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, and space;

(C) have a quarantine area for storage of devices that are outdated, damaged, deteriorated, misbranded, or adulterated;

(D) be maintained in a clean and orderly condition; and

(E) be free from infestation by insects, rodents, birds, or vermin of any kind.

(e) Storage of devices. All devices stored by distributors shall be held at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such devices.

(f) Device labeling. Devices distributed by device distributors or manufacturers shall meet the labeling requirements of the Act and 21 CFR, Part 801, titled "Labeling."

(g) Device labeling exemptions. Device labeling or packaging exemptions adopted under the Federal Food, Drug, and Cosmetic Act, as amended, shall apply to devices in Texas except insofar as modified or rejected by rules of the Executive Commissioner of the Health and Human Services Commission.

(h) Reconditioned devices. Reconditioned devices must comply with the provisions of the Act and these sections and are subject to the provisions of the Texas Food, Drug, Device and Cosmetic Salvage Act, Health and Safety Code, Chapter 432.

(i) Medical device reporting. Device distributors or manufacturers shall meet the applicable medical device reporting requirements of 21 CFR, Part 803, titled "Medical Device Reporting".

(j) Radiation emitting devices. Devices which emit electronic product radiation and are distributed by device distributors or manufacturers shall meet the applicable requirements of the Act and 21 CFR, Subchapter J, titled "Radiological Health."

(k) Distribution of prescription devices.

(1) A prescription device in the possession of a device distributor or manufacturer licensed under these sections of this subchapter is exempt from Health and Safety Code, §431.112(f)(1), relating to labeling bearing adequate directions for use, providing it meets the requirements of 21 CFR, §801.109, titled "Prescription devices" and 801.110, titled "Retail exemption for prescription devices".

(2) Each device distributor or manufacturer who distributes prescription devices shall maintain a record for every prescription device, showing the identity and quantity received or manufactured and the disposition of each device.

(3) Each device distributor or manufacturer who delivers a prescription device to the ultimate user shall maintain a record of any prescription or other order lawfully issued by a practitioner in connection with the device.

(l) Sale of contact lenses at flea markets. Contact lenses may not be sold by persons at flea markets unless:

(1) the person selling the contact lenses has complied with the requirements of Business and Commerce Code, §35.55; and

(2) the person selling the contact lenses has complied with the requirements of the Texas Contact Lens Prescription Act, Texas Civil Statutes, Article 4552-A.

**§229.442 Advertising**

(a) An advertisement of a device shall be deemed to be false if it is false or misleading in any particular.

(b) An advertisement of a device is false if the advertisement represents that the device affects:

(1) infectious and parasitic diseases;

(2) neoplasms;

(3) endocrine, nutritional, and metabolic diseases and immunity disorders;

(4) diseases of blood and blood-forming organs;

(5) mental disorders;

(6) diseases of the nervous system and sense organs;

(7) diseases of the circulatory system;

(8) diseases of the respiratory system;

(9) diseases of the digestive system;

(10) diseases of the genitourinary system;

(11) complications of pregnancy, childbirth, and the puerperium;

(12) diseases of the skin and subcutaneous tissue;

(13) diseases of the musculoskeletal system and connective tissue;

(14) congenital anomalies;

(15) certain conditions originating in the perinatal period;

(16) symptoms, signs, and ill-defined conditions; or

(17) injury and poisoning.

(c) Subsection (b) of this section does not apply to an advertisement of a device if the advertisement does not violate the Act, §431.182(a), and is disseminated:

(1) to the public for self-medication and is consistent with the labeling claims permitted by the United States Food and Drug Administration (FDA);

(2) only to members of the medical, dental, and veterinary professions and appears only in the scientific periodicals of those professions; or

(3) only for the purpose of public health education by a person not commercially interested, directly or indirectly, in the sale of the device.

(d) This section does not indicate that self-medication for a disease, other than a disease listed under subsection (b) of this section, is safe and effective.

**§229.443 Enforcement and Penalties**

(a) Inspection.

(1) To enforce these sections or the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431 (Act), the Commissioner of the Department of State Health Services (commissioner), an authorized agent, or a health authority may, on presenting appropriate credentials to the owner, operator, or agent in charge of a place of business:

(A) enter at reasonable times a place of business, including a factory or warehouse, in which a device is manufactured, assembled, packed, or held for introduction into commerce or held after the introduction;

(B) enter a vehicle being used to transport or hold a device in commerce; or

(C) inspect at reasonable times, within reasonable limits, and in a reasonable manner, the place of business or vehicle and all equipment, finished and unfinished materials, containers, and labeling of any item and obtain samples necessary for the enforcement of these sections or the Act.

(2) The inspection of a place of business, including a factory, warehouse, or consulting laboratory, in which a restricted device is manufactured, assembled, packed, or held for introduction into commerce extends to any place or thing, including a record, file, paper, process, control, or facility, in order to determine whether the device:

(A) is adulterated or misbranded;

(B) may not be manufactured, introduced into commerce, sold, or offered for sale under the Act; or

(C) is otherwise in violation of these sections or the Act.

(3) An inspection under paragraph (2) of this subsection may not extend to:

(A) financial data;

(B) sales data other than shipment data;

(C) pricing data;

(D) personnel data other than data relating to the qualifications of technical and professional personnel performing functions under the Act; or

(E) research data other than data:

(i) relating to devices; and

(ii) subject to reporting and inspection under regulations issued under §519 or §520(g) of the Federal Food, Drug, and Cosmetic Act, as amended.

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

(b) Receipt for samples. An authorized agent or health authority who makes an inspection of a place of business, including a factory or warehouse, and obtains a sample during or on completion of the inspection and before leaving the place of business, shall give to the owner, operator, or the owner's or operator's agent a receipt describing the sample.

(c) Access to records.

(1) A person who is required to maintain records referenced in these sections or under the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431 (Act) or §519 or §520(g) of the Federal Food, Drug, and Cosmetic Act or a person who is in charge or custody of those records shall, at the request of an authorized agent or health authority, permit the authorized agent or health authority at all reasonable times access to and to copy and verify the records.

(2) A person who is subject to licensure under these sections of this subchapter shall, at the request of an authorized agent or health authority, permit the authorized agent or health authority at all reasonable times access to and to copy and verify all records showing:

(A) the movement in commerce of any device;

(B) the holding of any device after movement in commerce; and

(C) the quantity, shipper, and consignee of any device.

(d) Retention of records. Records required by these sections of this subchapter shall be maintained at the place of business or other location that is reasonably accessible for a period of at least 2 years following disposition of the device unless a greater period of time is required by laws and regulations adopted in §229.432 of this title (relating to Applicable Laws and Regulations).

(e) Adulterated and misbranded device. If the Department of State Health Services (department) identifies an adulterated or misbranded device, the department may impose the applicable provisions of Subchapter C of the Act including, but not limited to: detention, emergency order, recall, condemnation, destruction, injunction, civil penalties, criminal penalties, and/or administrative penalties. Administrative and civil penalties will be assessed using the Severity Levels contained in §229.261 of this title (relating to Assessment of Administrative or Civil Penalties).

**§229.444 Device Distributors and Manufacturers Advisory Committee**

(a) The committee. An advisory committee shall be appointed under and governed by this section.

(1) The name of the committee shall be the Device Distributors and Manufacturers Advisory Committee (committee).

(2) The committee is required to be established by the Executive Commissioner of the Health and Human Services Commission by Health and Safety Code, §431.275 and is subject to the Health and Safety Code, §11.016.

(b) Applicable law. The committee is subject to the Government Code, Chapter 2110, concerning state agency advisory committees.

(c) Purpose. The purpose of the committee is to provide advice to the Executive Commissioner of the Health and Human Services Commission in the area of licensure of device distributors and manufacturers.

(d) Tasks.

(1) The committee shall advise the Executive Commissioner of the Health and Human Services Commission concerning rules relating to licensing of device distributors and manufacturers.

(2) The committee shall advise the Executive Commissioner of the Health and Human Services Commission in the development of standards and procedures relating to the licensing of device distributors and manufacturers; make recommendations to the Executive Commissioner of the Health and Human Services Commission relating to the content of the rules adopted to implement the licensing of device distributors and manufacturers; and perform any

other functions requested by the Executive Commissioner of the Health and Human Services Commission to implement and administer the rules regarding the licensing of device distributors and manufacturers.

(3) The committee shall carry out any other tasks given to the committee by the Executive Commissioner of the Health and Human Services Commission.

(e) Review and duration. By September 1, 2007, the Executive Commissioner of the Health and Human Services Commission will initiate and complete a review of the committee to determine whether the committee should be continued, consolidated with another committee, or abolished. If the committee is not continued or consolidated, the committee shall be abolished on that date.

(f) Composition. The committee shall be composed of five members appointed by the Executive Commissioner of the Health and Human Services Commission. The composition of the committee shall include:

(1) two consumer representatives;

(2) one person representing a distributor of devices; and

(3) two persons representing manufacturers of devices.

(g) Terms of office. The term of office of each member shall be three years. Members shall serve after expiration of their term until a replacement is appointed.

(1) Members shall be appointed for staggered terms so that the terms of a substantial equivalent number of members will expire on August 31st of each odd-numbered year.

(2) If a vacancy occurs, a person shall be appointed to serve the unexpired portion of that term.

(h) Officers. The committee shall elect a presiding officer and an assistant presiding officer at its first meeting after August 31st of each year.

(1) Each officer shall serve until the next regular election of officers.

(2) The presiding officer shall preside at all committee meetings at which he or she is in attendance, call meetings in accordance with this section, appoint subcommittees of the committee as necessary, and cause proper reports to be made to the Executive Commissioner of the Health and Human Services Commission. The presiding officer may serve as an ex-officio member of any subcommittee of the committee.

(3) The assistant presiding officer shall perform the duties of the presiding officer in case of the absence or disability of the presiding officer. In case the office of presiding officer becomes vacant, the assistant presiding officer will serve until a successor is elected to complete the unexpired portion of the term of the office of presiding officer.

(4) A vacancy which occurs in the offices of presiding officer or assistant presiding officer may be filled at the next committee meeting.

(5) A member shall serve no more than two consecutive terms as presiding officer and/or assistant presiding officer.

(6) The committee may reference its officers by other terms such as chairperson and vice-chairperson.

(i) Meetings. The committee shall meet only as necessary to conduct committee business.

(1) A meeting may be called by agreement of department staff and either the presiding officer or at least three members of the committee.

(2) Meeting arrangements shall be made by department staff. Department staff shall contact committee members to determine availability for a meeting date and place.

(3) The committee is not a "governmental body" as defined in the Open Meetings Act. However, in order to promote public participation, each meeting of the committee shall be announced and conducted in accordance with the Open Meetings Act, Texas Government Code, Chapter 551, with the exception that the provisions allowing executive sessions shall not apply.

(4) Each member of the committee shall be informed of a committee meeting at least five working days before the meeting.

(5) A simple majority of the members of the committee shall constitute a quorum for the purpose of transacting official business.

(6) The committee is authorized to transact official business only when in a legally constituted meeting with quorum present.

(7) The agenda for each committee meeting shall include an item entitled public comment under which any person will be allowed to address the committee on matters relating to committee business. The presiding officer may establish procedures for public comment, including a time limit on each comment.

(j) Attendance. Members shall attend committee meetings as scheduled. Members shall attend meetings of subcommittees to which the member is assigned.

(1) A member shall notify the presiding officer or appropriate department staff if he or she is unable to attend a scheduled meeting.

(2) It is grounds for removal from the committee if a member cannot discharge the member's duties for a substantial part of the term for which the member is appointed because of illness or disability, is absent from more than half of the committee and subcommittee meetings during a calendar year, or is absent from at least three consecutive committee meetings.

(3) The validity of an action of the committee is not affected by the fact that it is taken when a ground for removal of a member exists.

(k) Staff. Staff support for the committee shall be provided by the department.

(l) Procedures. Roberts Rules of Order, Newly Revised, shall be the basis of parliamentary decisions except where otherwise provided by law or rule.

(1) Any action taken by the committee must be approved by a majority vote of the members present once quorum is established.

(2) Each member shall have one vote.

(3) A member may not authorize another individual to represent the member by proxy.

(4) The committee shall make decisions in the discharge of its duties without discrimination based on any person's race, creed, gender, religion, national origin, age, physical condition, or economic status.

(5) Minutes of each committee meeting shall be taken by department staff.

(A) A draft of the minutes approved by the presiding officer shall be provided to the Executive Commissioner of the Health and Human Services Commission and each member of the committee within 30 days of each meeting.

(B) After approval by the committee, the minutes shall be signed by the presiding officer.

(m) Subcommittees. The committee may establish subcommittees as necessary to assist the committee in carrying out its duties.

(1) The presiding officer shall appoint members of the committee to serve on subcommittees and to act as subcommittee chairpersons. The presiding officer may also appoint nonmembers of the committee to serve on subcommittees.

(2) Subcommittees shall meet when called by the subcommittee chairperson or when so directed by the committee.

(3) A subcommittee chairperson shall make regular reports to the advisory committee at each committee meeting or in interim written reports as needed. The reports shall include an executive summary or minutes of each subcommittee meeting.

(n) Statement by members.

(1) The Executive Commissioner of the Health and Human Services Commission, the department, and the committee shall not be bound in any way by any statement or action on the part of any committee member except when a statement or action is in pursuit of specific instructions from the Executive Commissioner of the Health and Human Services Commission, department, or committee.

(2) The committee and its members may not participate in legislative activity in the name of the Executive Health and Human Services Commission, the department or the committee except with approval through the department's legislative process. Committee members are not prohibited from representing themselves or other entities in the legislative process.

(3) A committee member should not accept or solicit any benefit that might reasonably tend to influence the member in the discharge of the member's official duties.

(4) A committee member should not disclose confidential information acquired through his or her committee membership.

(5) A committee member should not knowingly solicit, accept, or agree to accept any benefit for having exercised the member's official powers or duties in favor of another person.

(6) A committee member who has a personal or private interest in a matter pending before the committee shall publicly disclose the fact in a committee meeting and may not vote or otherwise participate in the matter. The phrase "personal or private interest" means the committee member has a direct pecuniary interest in the matter but does not include the committee member's engagement in a profession, trade, or occupation when the member's interest is the same as all others similarly engaged in the profession, trade, or occupation.

(o) Reports to Executive Commissioner of the Health and Human Services Commission. The committee shall file an annual written report with the Executive Commissioner of the Health and Human Services Commission.

(1) The report shall list the meeting dates of the committee and any subcommittees, the attendance records of its members, a brief description of actions taken by the committee, a description of how the committee has accomplished the tasks given to the committee by the Executive Commissioner of the Health and Human Services Commission, the status of any rules which were recommended by the committee to the Executive Commissioner of the Health and Human Services Commission,, and anticipated activities of the committee for the next year.

(2) The report shall identify the costs related to the committee's existence, including the cost of department staff time spent in support of the committee's activities and the source of funds used to support the committee's activities.

(3) The report shall cover the meetings and activities in the immediate preceding 12 months and shall be filed with the Executive Commissioner of the Health and Human Services Commission each September. It shall be signed by the presiding officer and appropriate department staff.

(p) Reimbursement for expenses. In accordance with the requirements set forth in the Government Code, Chapter 2110, a committee member may receive reimbursement for the member's expenses incurred for each day the member engages in official committee business if authorized by the General Appropriations Act or budget execution process.

(1) No compensatory per diem shall be paid to committee members unless required by law.

(2) A committee member who is an employee of a state agency, other than the department, may not receive reimbursement for expenses from the department.

(3) A nonmember of the committee who is appointed to serve on a subcommittee may not receive reimbursement for expenses from the department.

(4) Each member who is to be reimbursed for expenses shall submit to staff the member's receipts for expenses and any required official forms no later than 14 days after each committee meeting.

(5) Requests for reimbursement of expenses shall be made on official state travel vouchers prepared by department staff.

(Revised 3/07/2007)